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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 year ended December 31, 2023

OR

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

For the transition period from to

Commission File Number 001-36464

Agile Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**23-2936302**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

500 College Road East, Suite 310
Princeton, New Jersey 08540
(Address including zip code of principal executive offices)

(609) 683-1880
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: **None**

Securities registered pursuant to Section 12(g) of the Act: **Common Stock, par value $0.0001 per share**

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 emerging growth company. See 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 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 checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant as of June 30, 2023 was approximately $4.8 million.

As of March 27, 2024, there were 6,856,229 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2024 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed within 120 days of the registrant's fiscal year ended December 31, 2023, are incorporated by reference in Part III of this Annual Report on Form 10-K. Except with respect to information specifically incorporated by reference in this Annual Report on Form 10-K, the Proxy Statement is not deemed to be filed as part of this Annual Report on Form 10-K.

Agile Therapeutics, Inc.
Annual Report on Form 10-K
For the Year Ended December 31, 2023

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K includes statements that are, or may be deemed, "forward-looking statements." In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "designed," "could," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Annual Report on Form 10-K and include statements regarding our current intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our results of operations, financial condition, liquidity, prospects, growth and strategies, including expense reduction strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the attractiveness of our business to potential investors or business partners, our ongoing and planned manufacturing and commercialization of Twirla®, the potential market acceptance and uptake of Twirla®, the development of our other potential product candidates, the strength and breadth of our intellectual property, our ongoing and planned clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our potential product candidates, the legal and regulatory landscape impacting our business, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report on Form 10-K, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Annual Report on Form 10-K. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Annual Report on Form 10-K, they may not be predictive of results or developments in future periods.

In addition, with respect to all our forward looking statements, we claim the protection of the safe harbor for forward looking statements contained in the Private Securities Litigation Reform Act of 1995.

Some of the factors that we believe could cause actual results to differ from those anticipated or predicted include:

- our available cash and our ability to obtain additional funding to fund our business plan without delay and to continue as a going concern;
- our ability to pay our obligations as they come due;
- we are now listed on the OTC markets, which could affect the liquidity in trading of our common stock and affect our ability to raise capital;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our ability to successfully maintain and enhance the commercialization of and increase the uptake for Twirla, our only approved product;
- the rate and degree of market acceptance of Twirla by physicians, patients, clinics, institutions, third-party payors and others in the healthcare community;

- our ability to obtain adequate coverage and reimbursement for Twirla in the United States from private and public third-party payors;
- the size and growth of the markets for Twirla and our ability to serve those markets;
- shortages of key materials in the supply chain implicating the manufacture and distribution of Twirla;
- regulatory and legislative developments in the United States and foreign countries, which could include, among other things, a government shutdown;
- the growth in demand for Twirla and our ability to manage the levels of Twirla inventory, which could result in our having to write off inventory and our inability to meet the minimum requirements under our supply agreement with Corium Innovations, Inc. ("Corium").
- our ability to timely obtain from our third-party manufacturer, Corium, sufficient quantities or quality of Twirla or other materials required for a clinical trial or other tests and studies;
- the ability of Corium to produce commercial supply in quantities and quality sufficient to satisfy market demand for Twirla;
- the performance and financial condition of Corium or any of the suppliers;
- our ability to design and successfully complete a post-marketing long-term, prospective observational safety study comparing risks for venous thromboembolism, or VTE, and arterial thromboembolism, or ATE, in new users of Twirla to new users of oral combined hormonal contraceptives, or CHCs, and new users of Xulane in U.S. women of reproductive age using CHCs and the outcomes of our discussions with the United States Food and Drug Administration, or FDA, regarding the results of our post-marketing commitment, or PMC, to assess the residual drug content of Twirla after use;
- our ability to maintain regulatory approval of Twirla and the labeling under any approval we obtain;
- our ability to obtain and maintain intellectual property protection for Twirla and our product candidates;
- the success and timing of our clinical trials or other studies, including post-marketing studies for Twirla;
- development of unexpected safety or efficacy concerns related to Twirla;
- our ability to continue to develop and maintain successful sales and marketing capabilities, including our ability to maintain an effective sales force or failure to build-out and implement an effective health care compliance program;
- our ability to retain key employees and recruit the additional personnel we will need to support our commercialization plan for Twirla; and
- our ability to successfully implement our strategy.

Risk Factor Summary

Our business is subject to numerous risks and uncertainties, including those described in Item 1A *"Risk Factors."* These risks include, but are not limited to, the following:

- We have incurred operating losses in each year since our inception, and we incurred losses every quarter in 2023. We may continue to incur substantial losses in the future if we are unable to generate positive cash flow from operations. Management has concluded that these factors raise substantial doubt about our ability to continue as a going concern.

- We will need to obtain additional financing to fund our operations and, if we are unable to obtain such financing, we may be unable to commercialize Twirla or resume the development of our pipeline;

- We have never been profitable. Currently, we have only one product available for commercial sale, Twirla, and we may never become profitable;

- Unstable global market and economic conditions may have serious adverse consequences on our business, financial condition and share price;

- We are significantly dependent on the commercial success of Twirla, our only approved product. If we are unable to successfully commercialize Twirla, our business, financial condition, revenue, results of operations, and prospects and value of our common stock will be materially adversely affected;

- It will be difficult for us to profitably sell Twirla if third-party coverage and reimbursement for such product is limited, and reimbursement and healthcare containment initiatives and treatment guidelines may constrain our future revenues;

- If we are unable to develop and maintain effective marketing and sales capabilities for Twirla or maintain our agreements with third parties to market and sell Twirla, we may be unable to generate product revenues;

- Twirla could develop unexpected safety, efficacy or quality concerns, which would likely have a material adverse effect on us;

- Sales of Twirla may be adversely affected by the consolidation among wholesale drug distributors and the growth of large retail drug store chains;

- Existing and future legislation may increase the difficulty and cost for us to commercialize Twirla and may affect the prices we may obtain;

- We remain subject to substantial ongoing legal and regulatory requirements related to Twirla, and failure to comply with these requirements could lead to penalties, including withdrawal from the market, suspension, or withdrawal of product approval;

- We have no manufacturing capacity and anticipate continued reliance on Corium, our third-party manufacturer, for the commercialization of Twirla and development of our potential product candidates, as a sole source provider. We may not have or be able to obtain sufficient quantities of Twirla or our potential product candidates to meet our required supply for commercialization or clinical trials. Alternatively, we may not realize the commercial demand for Twirla necessary to meet our obligations to Corium. Either of these events could materially harm our business;

- We rely on third parties to conduct aspects of our clinical trials and post marketing studies. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with applicable regulatory requirements, we may not be able to maintain regulatory approval for Twirla or develop our pipeline;

- We may rely on third parties to perform many essential services for any products that we commercialize, including, but not limited to, services related to government price reporting, customer service, accounts receivable management, cash collection, and pharmacovigilance and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize our potential product candidates will be significantly impacted and we may be subject to regulatory sanctions.

- We may not be able to protect our proprietary technology in the marketplace;

- We may infringe the intellectual property rights of others, which may prevent or delay our commercialization and product development efforts or increase the costs of commercializing Twirla or our potential product candidates, when and if approved;

- Any lawsuits relating to infringement of intellectual property rights brought by or against us will be costly and time consuming and may adversely impact the price of our common stock;

- If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of Twirla;

- We are now listed on the OTC markets, which could affect the liquidity in trading of our common stock and affect our ability to raise capital; and

- We expect that our stock price may fluctuate significantly.

Any forward-looking statements that we make in this Annual Report on Form 10-K speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Annual Report on Form 10-K. You should also read carefully the factors described in the "Risk Factors" section of this Annual Report on Form 10-K to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report on Form 10-K will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, any such inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard any of these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all.

This Annual Report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

Item 1. Business

Overview

We are a women's healthcare company dedicated to fulfilling the unmet health needs of today's women. We are committed to innovating in women's healthcare where there continues to be unmet needs – not only in contraception – but also in other meaningful women's health therapeutic areas. We are focused on our advancement as a commercial company and the growth of our first and only product, Twirla, a once-weekly prescriptions combination hormonal contraceptive patch.

Twirla exposes patients to an estrogen dose consistent with commonly prescribed combined hormonal contraceptives, or CHCs, and is lower than the estrogen dose found in other marketed contraceptive patches. We believe there is a market need for a contraceptive patch that is designed to deliver hormonal exposure equivalent to 30 mcg of estrogen and 120 mcg of progestin in a convenient once-weekly dosage form that may support compliance in a noninvasive fashion. Twirla leverages our proprietary transdermal patch technology called Skinfusion®. Skinfusion is designed to allow drug delivery through the skin while promoting patch adhesion and patient comfort and wearability, which may help support compliance.

We are focused on our advancement as a commercial company. Over the course of 2023, we continued to implement our commercialization plan for Twirla, with the goal of establishing a growing position in the hormonal contraceptive market. We believe we can achieve this goal by focusing our growth strategy in the states with the highest Twirla reimbursement potential, which we estimate will allow us to reach approximately 45% of U.S. women between the ages of 18-24. We also believe we can grow Twirla by leveraging our partnerships in the retail and non-retail channels. For example, we believe we can increase uptake of Twirla in the United States by growing our telemedicine presence through new partnerships as well as through our existing partnership with Nurx® and by driving growth in the non-retail channels through our collaboration with Afaxys, which provides us access to some of the largest Planned Parenthood organizations in the country. In addition to growing Twirla, we also plan to continue pursuing opportunities to broaden our portfolio to address areas of unmet medical need in women's health.

Our Strategy

Our near-term goal is to establish a growing franchise in the multi-billion-dollar U.S. hormonal contraceptive market built on approval of Twirla in the United States. Our resources are currently focused on the commercialization of Twirla. In 2024, we plan to explore additional partnerships that could potentially increase the sales reach for Twirla, supplement growth, and reduce operating expenses. We also expect to continue exploring possible expansion of our business more broadly through business development activities, such as acquiring access to new products through in-licensing, co-promotion or other collaborative and/or strategic arrangements.

Our current priorities are as follows:

- Continue to manage our available cash and obtain financing to fund our business plan without delay;
- Continue to implement our commercialization plans for Twirla to increase uptake of Twirla in the United States, through targeted digital direct to consumer advertising, growing our telemedicine presence through new partnerships and our existing partnership with Nurx, and driving growth in the non-retail channel through our collaboration with Afaxys, which provides us access to some of the largest Planned Parenthood organizations in the country;
- Continue to expand access to Twirla through multiple business channels including retail and specialty pharmacies, telemedicine, government contracting, and non-retail channels, including public health centers through our relationship with Afaxys;
- Expand coverage and reimbursement for Twirla in the United States from private and public third-party payors;
- Maintain and manage the supply chain for Twirla to support increased commercialization of Twirla across the United States and working through existing and future inventory prior to product becoming short-dated;
- Reduce our operating loss and continue to progress towards generating positive cash flows;
- Evaluate the advancement of our existing pipeline and its possible expansion through business development activities; and
- Continue to implement our obligations related to our post-marketing requirement study of Twirla.

Twirla

Twirla is our first and only approved product. Twirla received FDA approval on February 14, 2020, as a method of contraception for use in women of reproductive potential with a body mass index ("BMI") < 30 kg/m^2 for whom a combined hormonal contraceptive is appropriate, and was launched in December 2020. Based on the reduced efficacy seen with increasing BMI in a Phase 3 clinical trial, Twirla's limitation of use instructs healthcare providers to consider Twirla's reduced effectiveness in women with a BMI ≥ 25 to <30 kg/m^2 before prescribing. Twirla is contraindicated in women with a BMI ≥ 30 kg/m^2 because, compared to women with a lower BMI, women in this group had reduced effectiveness and may have a higher risk for VTEs. Twirla's label also includes the class-wide boxed warning, contraindications, and warnings and precautions applicable to all combined hormonal contraceptives, or CHCs.

Twirla is a prescription combined hormonal contraceptive patch that contains the active ingredients ethinyl estradiol, or EE, which is a synthetic estrogen, and levonorgestrel, or LNG, which is a type of progestin, both of which have an established history of efficacy and safety in currently marketed combination oral contraceptives. Twirla delivers 30 micrograms of EE per day, a dose of EE consistent with the dose delivered by many commonly prescribed oral contraceptives. Twirla is the only contraceptive patch that contains LNG, a widely prescribed progestin. Our Skinfusion technology allows Twirla to be the first approved patch capable of delivering a contraceptive dose of LNG across the skin. The patch is applied once weekly for three weeks, followed by a week without a patch. Twirla is packaged with three individually wrapped patches per carton to provide for one 28-day cycle of therapy.

Twirla's approval is primarily based on safety and efficacy data from the Phase 3 SECURE trial. The SECURE trial was a new approach to clinical trials and was intentionally designed to include broad enrollment criteria and a patient population of women likely to use hormonal contraceptives. In this purposefully inclusive trial, efficacy and safety were evaluated in a diverse study population, one that is more representative of the demographics of women across the US likely to use hormonal contraception.

The SECURE trial was a multi-center, single-arm, open-label, 13-cycle trial that evaluated the safety, efficacy and tolerability of Twirla in 2,031 healthy women, aged 18 and over, at 102 experienced investigative sites across the United States. The trial was designed in consultation with the FDA, and incorporated a number of stringent trial design elements, including exclusion of treatment cycles not only for use of backup contraception but also for lack of sexual activity. SECURE had broad entry criteria, placed no limitations on body mass index, or BMI, or other demographic factors during enrollment, and enrolled a large and diverse population from the United States in order to allow for efficacy to be assessed across different groups. These entry criteria resulted in the inclusion of a substantial number of women with high BMIs, who have frequently been underrepresented in prior contraceptive studies. The efficacy measure for SECURE was the Pearl Index in an intent-to-treat population of subjects 35 years of age and under. The FDA also requested the inclusion of prespecified efficacy analyses related to BMI and body weight.

As part of Twirla's approval, and consistent with requirements for another recently approved CHC, the FDA is requiring us to conduct a long-term prospective, observational post-marketing study, or PMR, comparing the risks for VTE and ATE in new users of Twirla to new users of CHCs. In January 2023, the FDA agreed with our proposal to address this PMR using electronic health records (EHR) and insurance claims from a large database from multiple healthcare systems. The FDA also agreed to extend the study milestones. Under these new milestones, interim safety data reporting to the FDA is due in November 2029, and the final PMR study report is scheduled to be submitted to the FDA in November 2035. As part of Twirla's approval, we also agreed to an FDA-requested post-marketing commitment, or PMC, study to assess the residual drug content and strength of Twirla in a minimum of 25 women. The PMC study is similar to residual drug studies requested of patch developers in the FDA's November 2019 draft guidance entitled *Transdermal and Topical Delivery Systems—Product Development and Quality Considerations.* The PMC study was completed in the fourth quarter of 2021, and the study report was submitted to the FDA in June 2022. The FDA notified us in August 2023 that the PMC requirement was fulfilled. We continue to discuss the results of the PMC study with the FDA.

Contraceptive Landscape and Market Opportunity

U.S. Hormonal Contraceptive Market Background

Contraceptive methods, other than sterilization, can be divided into non-hormonal and hormonal alternatives. Examples of non-hormonal products available in the United States include the diaphragm, male condom, female condom, and non-hormonal intrauterine device, or IUD. Hormonal contraceptives containing both estrogen and a progestin are referred to as CHCs, and contraceptives containing only progestin are referred to as P-only. There are several categories of hormonal contraception products available in the United States, including:

- transdermal patch
- oral contraceptive;
- vaginal ring;
- hormonal IUD;
- subcutaneous implant; and
- injectable.

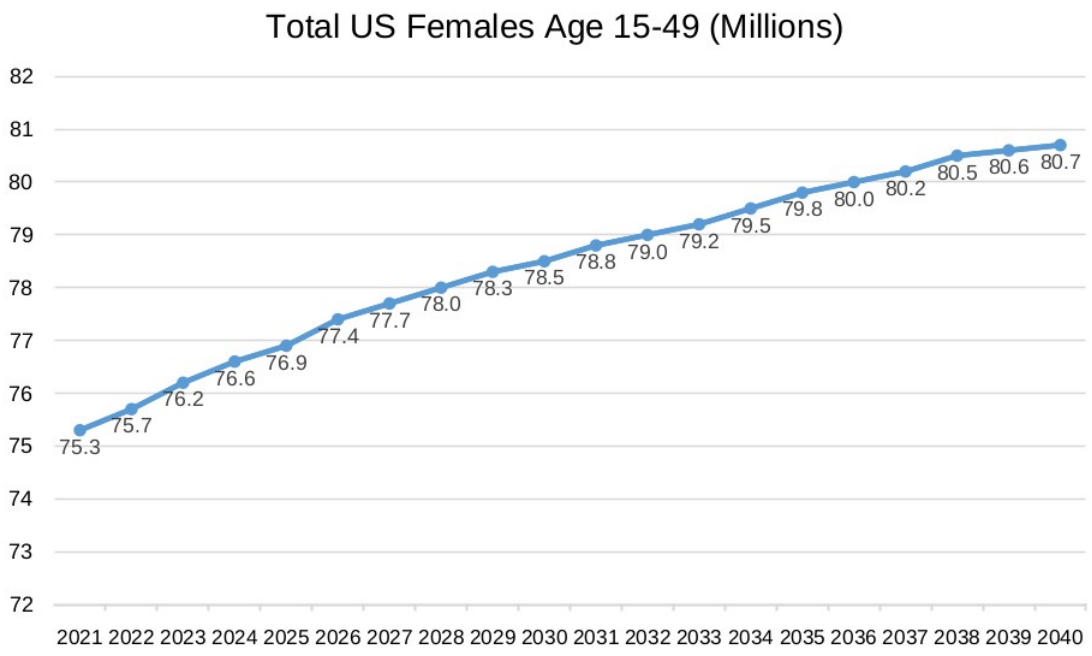
The U.S. hormonal contraceptive market is a multi-billion-dollar market. Data from 2017 to 2019 from the Centers for Disease Control, or CDC, indicate that approximately 28% of women aged 15 to 49 use some form of hormonal contraception, which amounts to approximately 20 million U.S. women. The CHC portion of the market, which includes pills, three transdermal patches, including Twirla, and two vaginal rings, generates significantly greater prescription volume and sales compared to the P-only portion of the market, consisting of hormonal IUDs, injectables, implants, and P-only pills.

The U.S. hormonal contraceptive market is a mature market, with many branded and generic products available. For the past 5 years, sales revenue in the CHC market has been essentially flat at approximately $6 billion per year using gross sales. Total prescription volume, or TRx, declined from 2019 to 2023 by 29.7%, from 72.3 million to 50.8 million; however the number of cycles dispensed (1 cycle = 1 month supply) declined by only 15% over the same time period, as the average TRx size (cycles/TRx) grew from 1.5 to 1.8 over the same time period. Therefore, the value of a TRx has grown significantly over the past 5 years, particularly for branded products, where the average gross revenue per TRx increased from $266 in 2019 to $413 in 2023.

Despite the availability of generic contraceptives for over 30 years, branded products have maintained a significant, though declining, share of CHC sales, with 18% of sales in 2023. In the five years ended December 2023, the average

annual price increase among the same branded products was 5.2%. The average price per cycle, referred to as the wholesale acquisition cost, or WAC, for a single 28-day cycle of these branded products was $162.83 in 2019 and rose to $182.10 in December 2023. The branded CHC transdermal patch (Ortho Evra) was discontinued in October 2014 and the branded generic CHC transdermal patches (Xulane and Zafemy) are both currently priced at $122.15 per cycle. Our current WAC price for Twirla is $204.57. The other non-oral form of CHC, the monthly vaginal ring, is currently priced at $162.63 per cycle for the branded version, Nuvaring, and $138.24, $140.52, and $103.82 for generic versions; Annovera®, another monthly vaginal ring, is currently priced at $2,305.28 per unit (each unit is intended for twelve months of use). We cannot predict how the manufacturers of branded or generic products will manage prices going forward.

The U.S. contraceptive population (defined by the Centers for Disease Control and Prevention as women aged 15-49) is currently approximately 76 million women and is estimated to grow to nearly 80 million by 2035.



Source: U.S. Census Bureau, 2020 National Dataset (2021 is base population estimate for projections).

Contraceptive Pills

Based on 2017 to 2019 data from the CDC, of women who choose to use a hormonal contraceptive, approximately 55% use a contraceptive pill, vaginal ring or patch, the majority of whom use the contraceptive pill. The remaining 45% of women using hormonal contraception are split between using injectables, implants, or IUDs. Based on this information, we believe that contraceptive pills are the most popular choice because:

- patients and physicians are familiar with pills;
- pills were the first to market and have been aggressively promoted for a long period of time;
- historically, pills have been a covered benefit with good reimbursement in private and public healthcare plans; and

- pills are a non-invasive option.

However, compliance remains a significant draw-back with pills. Published studies have shown that the average woman who uses oral contraceptives misses approximately two to four pills per month, which increases the potential for unintended pregnancies. We believe that a patch can offer greater convenience than a pill, as it does not require daily administration and, for certain women, could lead to greater compliance and ease of use.

Contraceptive Patch Market Experience

The Ortho Evra® contraceptive patch, or Evra, was introduced in early 2002 and was the first FDA-approved contraceptive patch. The initial approved labeling for Evra indicated that it delivered a daily EE dose of 20 micrograms. Evra had rapid uptake in the hormonal contraceptive market and achieved a 10% share of the CHC market by September 2003. Following FDA approval of Evra, users of Evra began to report thrombotic and thromboembolic events to the FDA. Johnson & Johnson, the manufacturer of Evra, revised the Evra labeling in November 2005 to include information that EE exposure with Evra is 60% higher than that of an oral contraceptive containing EE of 35 micrograms, based on area under the curve, a commonly-used metric for measuring EE exposure in contraceptives. This information was ultimately included in an addition to the boxed warning that was unique to the Evra label. In 2020, the Xulane label was revised to reflect a contraindication in women with a BMI $\geq$ 30 kg/m^2 because of the reduced efficacy and increased potential risk for VTEs in this population. In making this revision, the information about increased estrogen exposure was removed from the boxed warning but remains in the warnings and precautions and pharmacokinetics sections of the label. The Evra market share declined rapidly following the 2005 labeling changes, from a peak share of 11% in 2005, to 4% by the end of 2006, to 1.4% by the end of 2013, where it stabilized, with a 1.5% share of the market based on combined prescriptions for Evra and its generic equivalent (Xulane®) in 2014. In more recent years, the Xulane share of the CHC market TRx has grown, from a 2.4% share in 2019 to a 2.7% share in 2023. Zafemy, a second generic of Ortho Evra launched in 2021, had a market share of 1.0% in 2023.

The FDA has maintained, in spite of the wording in the labeling for Evra, which has been discontinued, and its approved branded generic, that none of the epidemiologic studies provides a definitive answer regarding the relative risk of VTE with Evra compared to combined oral contraceptive use or whether the increased risk that some studies demonstrated is directly attributable to Evra. In spite of the labeling changes, and Johnson & Johnson ceasing promotion of Evra in 2007, the generic equivalent of Evra (Xulane) generated estimated gross sales of $243 million in 2023. On February 26, 2021, Amneal Pharmaceuticals, Inc. announced that it had received approval by the FDA for Zafemy, a generic version of Ortho Evra. Zafemy generated estimated gross sales of $144 million in 2022.

Twirla is the only transdermal contraceptive option currently available to women that delivers a low dose of estrogen. We believe that the rapid uptake and acceptance of Evra upon its introduction and its (and Xulane's) continued sales over the past several years demonstrate a market opportunity for multiple choices in transdermal contraceptive patches.

Twirla Potential Market Share

Three of our market research studies have included an allocation exercise to estimate the potential uptake of Twirla and peak market share. In all of these studies, ObGyns and nurse practitioners, or NPs, indicated their allocation of contraceptive prescriptions before and after reviewing a product profile like Twirla that reflects the safety and efficacy results from our SECURE clinical trial. In the 2010 study, which was conducted prior to the implementation of the ACA, ObGyns estimated use of a product like Twirla in 17% of their CHC patients. A proprietary calibration model developed by the research firm was applied to the peak share estimate, to adjust for physician overstatement, resulting in an estimated peak market share of 9% of the CHC market. In the study completed in December 2016, ObGyns, NPs, and physicians' assistants, or PAs, estimated use of Twirla in 22% of their CHC patients, which was also calibrated to adjust for overstatement, resulting in an estimated peak market share of 14% of the CHC market. This estimate was confirmed in our most recent study completed in September of 2019, in which ObGyns and NPs/PAs estimated use of Twirla in 20% of their CHC patients, calibrated to 14% of the CHC market.

We continue to evaluate the commercial opportunity for Twirla. We believe that the potential new CHC users who are within Twirla's approved indication represent a significant population of women. Based on our market research, analysis of the current and expected future U.S. hormonal contraceptive market, and review of other product launches in the category, we estimate that Twirla can potentially achieve a peak market share of 5-8%. We believe that the ability of Twirla to achieve this potential peak market share will require a substantial level of investment in promotional activities supporting the marketing and sales of Twirla throughout the United States.

As we pursue the commercialization of Twirla, we will continue to analyze the CHC contraceptive market and update our market research for Twirla.

Twirla Commercialization Strategy

Our top priority is the successful commercialization of Twirla. Promptly after approval by the FDA in February 2020, we began implementation of our plan to market Twirla. Our plan is focused on promoting Twirla in the states with the highest Twirla reimbursement potential, which we estimate will allow us to reach approximately 45% of U.S. women between the ages of 18-24. During 2023 we concentrated our marketing efforts on increasing both patient awareness and access through digital advertising to consumers in our target market and strategic partnering, while at the same time reducing marketing activities during strategic timeframes to conserve cash. We also focused on increasing patient access to Twirla across different channels, including specialty pharmacy as well as through continuing our eVoucher programs at the pharmacy level, growing our relationship with Afaxys GPO, and growing our relationship with Nurx, a leader in female-focused telehealth. In 2024, we intend to continue implementation of our commercial strategy for Twirla with an emphasis on leveraging our strategic partners and expanding market access through multiple business channels, including third-party payor contracts, retail and specialty pharmacies, additional telemedicine presence, and government contracts. We also plan to continue to engage with third-party payors and insurers to seek expanded access and re-imbursement coverage of Twirla.

Twirla Promotion Strategy

We have a limited number of sales and marketing employees and primarily rely on third-party partners with experience in commercializing pharmaceutical products to advance the commercialization of Twirla. Our marketing efforts are primarily focused on ObGyns in the United States, and we plan to continue using a significant number of samples to gain patient trial and acceptance. We believe that we can continue to implement a national promotional strategy with a focused marketing and sales force presence in five key markets – California, New York, Texas, Florida, and Illinois – enabling us to address approximately 46% of our patient and prescriber targets. In areas of the country where it is not efficient to deploy a sales representative or where offices are closed to sales representatives, virtual promotion will be used to reach prescribers. We plan to complement these efforts by expanding the channels we utilize to drive awareness of Twirla and will focus on promotion with key prescribers and customer groups, including consumers and commercial managed care plans.

In 2024, we plan to further leverage cost-effective and focused promotion to reach our target demographic of females ages 18 to 24 years, who tend to engage in online activities to a high degree and are more likely to seek health information online and through social networks, subject to available funding. Marketing tactics aimed at today's female consumer need to be optimized for mobile technology because smartphones and text messaging are the preferred means of communication. We believe that a consumer promotion plan that uses digital media, social media advertising, video and other mass-market advertising vehicles will generate consumer awareness and demand for Twirla.

Twirla Coverage and Reimbursement Strategy

After approval of Twirla by the FDA, we began meeting with formulary decision makers as appropriate to secure positions for Twirla that minimize access barriers for prescribers and patients, and since then we estimate that we have been able to achieve access for approximately fifty-five to sixty percent (55-60%) of the estimated covered lives by commercial third-party payors. Third-party payors are increasingly challenging the prices charged for pharmaceutical products. The United States government and other third-party payors are increasingly limiting both coverage and level of reimbursement for new drugs, in addition to questioning their safety and efficacy. In this challenging environment, we

plan to continue our efforts to expand formulary access to Twirla through contracting strategies and engaging with formulary boards on the clinical profile of Twirla. We believe that it is important in this category for women to have equal access to all methods, dosing regimens and hormonal options so that they and their provider can select the choice that is the most appropriate to meet their lifestyle and family planning goals.

Our Pipeline: Twirla Line Extensions and Potential Product Candidates

Twirla is our first and only approved product, and, to date, substantially all of our resources have been committed to obtaining approval of Twirla and initiating our commercialization of Twirla. While seeking approval of Twirla and preparing for commercial launch, we paused all work on our pipeline. We have initiated a full evaluation of our pipeline to establish a plan to advance the development of Twirla line extensions and other potential product candidates.

Our potential product pipeline consists of two types of product candidates: a progestin-only (P-only) contraceptive patch and potential Twirla line extensions. These potential product candidates are designed to address market needs and offer additional non-daily contraceptive options. Though all product development activities have currently been put on hold, we expect that developing our P-only patch will be our first priority when we resume development activities.

Our primary potential product candidate is a progestin-only (P-only) contraceptive patch, or P-Patch, and is intended for use by women of reproductive potential to prevent pregnancy. The intended population for the P-Patch would be women who are unable or unwilling to take estrogen, including those who are breastfeeding or who are at greater risk of VTE, such as women who smoke, are over 35 years of age, or who have a BMI greater than 30 kg/m^2 (criteria for obesity). Currently, the P-only market consists of pills and several non-oral options, including intrauterine systems (IUS)/intrauterine devices (IUDs), implants, and injections. We believe there is a need for a P-only option in a convenient, non-daily, user-controlled method, especially as the population of women with obesity increases in the United States. We have completed formulation selection and conducted early pre-clinical work on our P-only patch. Additional formulation development work and dose selection is required, along with additional studies to optimize the formulation and determine the optimal dose to advance to Phase 3. We continue to explore our plan to develop this program and are considering all of our potential pathways, including a co-development and co-funding partnership to advance this program into the clinic.

In addition to our P-Patch, we have the ability to develop potential Twirla line extensions. The hormonal contraceptive market has a long history of manufacturers successfully using line extensions to extend the lifecycle of a brand, often by gaining additional exclusivity periods for the product extension under the provisions of the Hatch-Waxman Act and/or with additional patents. Our lifecycle strategy with Twirla may include introducing line extensions that will have exclusivity for some time period, either due to our intellectual property estate, or due to Hatch-Waxman exclusivity. These regimens are protected by patents issued to us in 2015 and include the following:

- AG200-15 Extended Regimen (ER) is an 84-day extended cycle regimen utilizing our approved Twirla TDS product designed to allow a woman to have four (4) episodes of withdrawal bleeding per year. In 2022, as part of the evaluation of AG200-15 ER we published an analysis with a simulated pharmacokinetic model that was used to predict the systemic LNG and EE exposure of Twirla if used for twelve (12) consecutive weeks. The simulation used data from a previously published clinical phase 1, open label, randomized clinical trial.
- AG200-15 SmP is a 28-day regimen designed to provide users with shorter, lighter withdrawal bleeds and potentially improve contraceptive efficacy. AG200-15 SmP may also provide benefit in patients with sensitivity to abrupt changes in hormone levels. AG200-15 SmP is designed to provide a simplified 28-day regimen through use of the same drug product as Twirla for the first three weeks of the cycle, and a smaller lower-dose patch, or SmP, in the fourth week, which will allow patients to continuously apply patches without interruption.
- AG200-15 ER SmP is a 91-day extended cycle regimen utilizing our approved Twirla TDS and the SmP that is designed to allow a woman to have four (4) shorter, lighter withdrawal bleeding episodes per year. By extending the length of the contraceptive cycle, AG200-15 ER SmP is designed to potentially minimize breakthrough bleeding and spotting, which are commonly reported events with patients using an extended regimen contraceptive product.

We do not expect to be required to conduct preclinical toxicology studies for any of these potential product candidates. Based upon a number of factors, including, but not limited to, our available capital resources and feedback

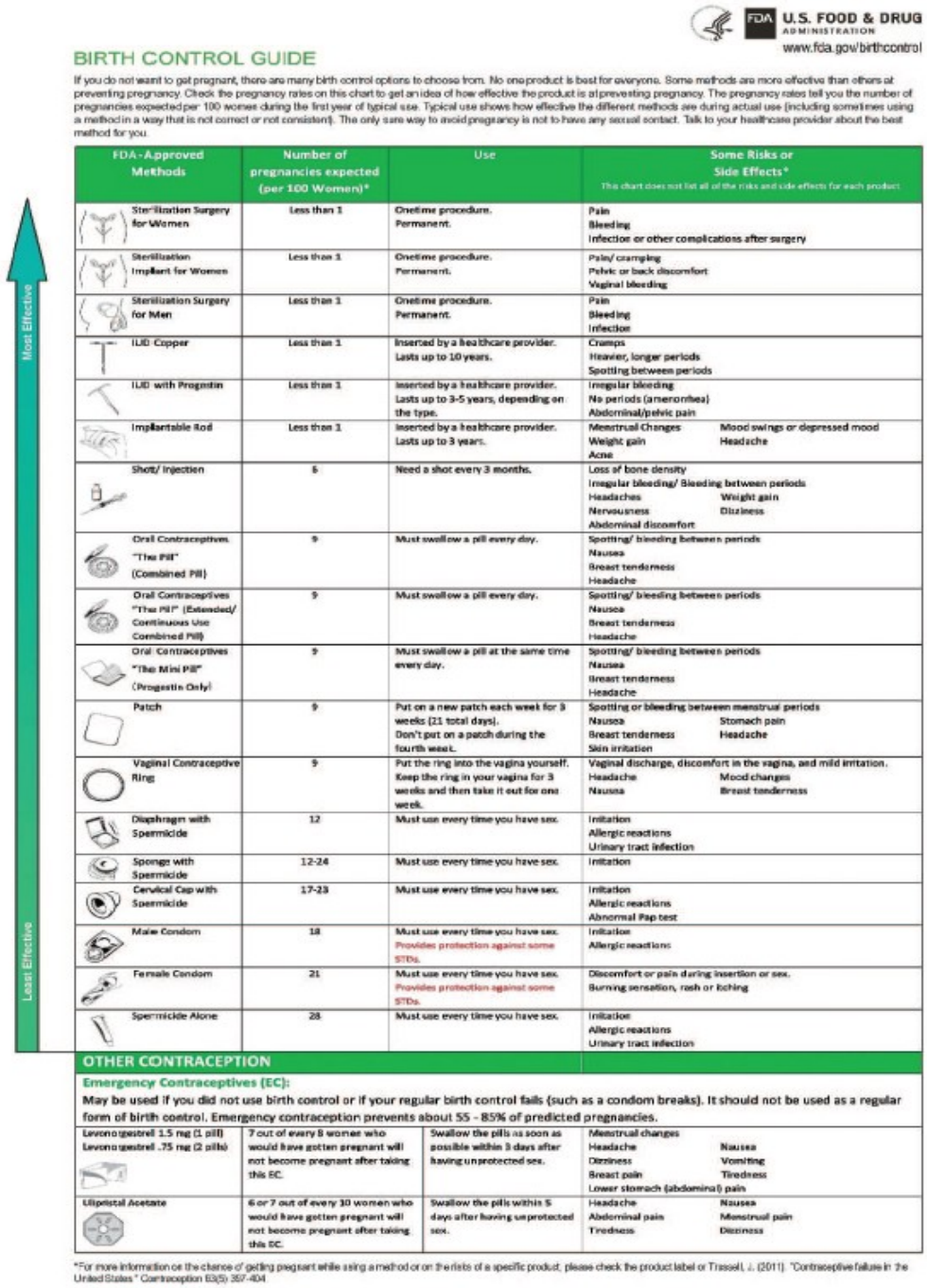
from the FDA, we continue to review the clinical path and the budgetary requirements for each of our potential product candidates.

Competition

The industry for contraceptive products is characterized by intense competition and strong promotion of proprietary products. We face potential competition from many different sources, including large pharmaceutical companies, specialty pharmaceutical and generic drug companies, and medical device companies. Any product candidates that we successfully develop and commercialize will compete with existing products and new products that may become available in the future.

We face competition from a variety of non-permanent birth control products across method categories. There are non-hormonal barrier methods, such as the contraceptive sponge, diaphragm, cervical cap or shield and condoms. Then, there are hormonal methods, which is the category for Twirla and our potential product candidates. Within the hormonal category, there are various methods of contraception, such as oral contraceptives, injections, implants, hormonal IUDs, vaginal rings, and transdermal contraceptive products. Each of the methods carries different efficacy and side effect profiles, which are important to providers and patients when making a contraceptive decision.

The following table is the FDA Birth Control Chart, which outlines the 18 unique forms of birth control and compares the effectiveness of each method.



U.S. FOOD & DRUG ADMINISTRATION
www.fda.gov/birthcontrol

BIRTH CONTROL GUIDE

If you do not want to get pregnant, there are many birth control options to choose from. No one product is best for everyone. Some methods are more effective than others at preventing pregnancy. Check the pregnancy rates on this chart to get an idea of how effective the product is at preventing pregnancy. The pregnancy rates tell you the number of pregnancies expected per 100 women during the first year of typical use. Typical use shows how effective the different methods are during actual use (including sometimes using a method in a way that is not correct or not consistent). The only sure way to avoid pregnancy is not to have any sexual contact. Talk to your healthcare provider about the best method for you.

Most Effective

Least Effective

FDA-Approved Methods	Number of pregnancies expected (per 100 Women)*	Use	Some Risks or Side Effects* The chart does not list all of the risks and side effects for each product.
Sterilization Surgery for Women	Less than 1	Onetime procedure. Permanent.	Pain Bleeding Infection or other complications after surgery
Sterilization Implant for Women	Less than 1	Onetime procedure. Permanent.	Pain/ cramping Pelvic or back discomfort Vaginal bleeding
Sterilization Surgery for Men	Less than 1	Onetime procedure. Permanent.	Pain Bleeding Infection
IUD Copper	Less than 1	Inserted by a healthcare provider. Lasts up to 10 years.	Cramps Heavier, longer periods Spotting between periods
IUD with Progestin	Less than 1	Inserted by a healthcare provider. Lasts up to 3-5 years, depending on the type.	Irregular bleeding No periods (amenorrhea) Abdominal/pelvic pain
Implantable Rod	Less than 1	Inserted by a healthcare provider. Lasts up to 3 years.	Menstrual Changes Weight gain Acne Mood swings or depressed mood Headache
Shot/ Injection	6	Need a shot every 3 months.	Loss of bone density Irregular bleeding/ Bleeding between periods Headaches Nervousness Abdominal discomfort Weight gain Dizziness
Oral Contraceptives "The Pill" (Combined Pill)	9	Must swallow a pill every day.	Spotting/ bleeding between periods Nausea Breast tenderness Headache
Oral Contraceptives "The Pill" (Extended/ Continuous Use Combined Pill)	9	Must swallow a pill every day.	Spotting/ bleeding between periods Nausea Breast tenderness Headache
Oral Contraceptives "The Mini Pill" (Progestin Only)	9	Must swallow a pill at the same time every day.	Spotting/ bleeding between periods Nausea Breast tenderness Headache
Patch	9	Put on a new patch each week for 3 weeks (21 total days). Don't put on a patch during the fourth week.	Spotting or bleeding between menstrual periods Nausea Breast tenderness Skin irritation Stomach pain Headache
Vaginal Contraceptive Ring	9	Put the ring into the vagina yourself. Keep the ring in your vagina for 3 weeks and then take it out for one week.	Vaginal discharge, discomfort in the vagina, and mild irritation. Headache Nausea Mood changes Breast tenderness
Diaphragm with Spermicide	12	Must use every time you have sex.	Irritation Allergic reactions Urinary tract infection
Sponge with Spermicide	12-24	Must use every time you have sex.	Irritation
Cervical Cap with Spermicide	17-23	Must use every time you have sex.	Irritation Allergic reactions Abnormal Pap test
Male Condom	18	Must use every time you have sex. Provides protection against some STDs.	Irritation Allergic reactions
Female Condom	21	Must use every time you have sex. Provides protection against some STDs.	Discomfort or pain during insertion or sex. Burning sensation, rash or itching
Spermicide Alone	28	Must use every time you have sex.	Irritation Allergic reactions Urinary tract infection

OTHER CONTRACEPTION

Emergency Contraceptives (EC):

May be used if you did not use birth control or if your regular birth control fails (such as a condom breaks). It should not be used as a regular form of birth control. Emergency contraception prevents about 55 - 85% of predicted pregnancies.

Levonorgestrel 1.5 mg (1 pill) Levonorgestrel .75 mg (2 pills)	7 out of every 8 women who would have gotten pregnant will not become pregnant after taking this EC.	Swallow the pills as soon as possible within 3 days after having unprotected sex.	Menstrual changes Headache Dizziness Breast pain Lower stomach (abdominal) pain Nausea Vomiting Tiredness
Ulipristal Acetate	6 or 7 out of every 10 women who would have gotten pregnant will not become pregnant after taking this EC.	Swallow the pills within 5 days after having unprotected sex.	Headache Abdominal pain Tiredness Nausea Menstrual pain Dizziness

*For more information on the chance of getting pregnant while using a method or on the risks of a specific product, please check the product label or Trussell, J. (2011). "Contraceptive failure in the United States." Contraception 83(5): 397-404

Our potential competitors include large, well-established pharmaceutical companies, and specialty pharmaceutical sales and marketing companies. The branded products with established market presence include Nuvaring®, marketed by Organon, and Annovera®, marketed in the U.S. by Mayne Pharmaceuticals, the Loestrin® franchise, marketed by Allergan (formerly known as Actavis), consisting of three oral contraceptives, Minastrin® 24, LoLoestrin® and Taytulla®, and Beyaz®, Yaz®, Yasmin® and Natazia® marketed by Bayer. Xulane®, a branded generic to Ortho Evra, generated an estimated $243 million in gross sales for Viatris in 2023. On February 26, 2021, Amneal Pharmaceuticals, Inc. announced that it had received approval by the FDA for Zafemy™, a second generic version of Ortho Evra. Zafemy had estimated gross sales of $144 million in 2023. Additionally, several generics manufacturers currently market and continue to introduce new generic contraceptives, including Sandoz, Glenmark, Lupin, Amneal, Mylan, Aurobindo, and Xiromed. Based on the market experience of other non-oral CHC dosage forms, including Evra and Nuvaring, we believe there is a continuing demand for an innovative transdermal contraceptive patch that can provide convenience in a low-dose transdermal format.

There are several other contraceptive products that are more recently approved and a limited number in development, which we are aware of that may compete with Twirla and our other potential product candidates. Phexxi®, a prescription non-hormonal vaginal gel approved for use as an on-demand contraceptive, was developed by Evofem and launched in August of 2020. Nextstellis®, a combined oral contraceptive containing drosperinone and a new form of estrogen, estetrol (E4), was developed by Mithra Pharmaceuticals and is licensed to Mayne Pharmaceuticals for marketing in the U.S. and Australia. Mayne fielded a women's health team in the U.S. and launched Nextstellis in June of 2021. The Population Council has a transdermal gel contraceptive and a vaginal ring contraceptive, both containing segesterone acetate (the same progestin contained in Annovera) and ethinyl estradiol in Phase 2 development. Bayer has an IUD containing both LNG and an NSAID (a non-steroidal anti-inflammatory), to reduce pain upon insertion in Phase 2. Bayer also signed a license agreement in January of 2020 with Dare Bioscience for U.S. commercial rights to Ovaprene, a hormone-free monthly contraceptive vaginal ring, which is in Phase 2 development.

We are aware of one other CHC transdermal patch in development in the United States. In October 2021, Mylan Technologies, Inc. started a Phase 3 clinical trial studying the contraceptive efficacy, cycle control, safety and tolerability of a CHC patch containing the same active ingredients as Xulane. The investigational patch contains the same amount of norelgestromin and a lower quantity of EE as Xulane. According to information posted on clinicaltrials.gov, the study is estimated to be completed in January 2025. After that time, the sponsor could submit a new drug application. If approved by the FDA, this transdermal contraceptive patch may directly compete with Twirla.

Manufacturing

We do not own any manufacturing facilities and rely on Corium for all aspects of the manufacturing of Twirla. In October 2022, Corium separated into two companies, Corium, Inc., a neurosciences commercialization company, and Corium Pharma Solutions, Inc., a contract development and manufacturing organization (the "Corium Reorganization"). In June 2023, Corium Pharma Solutions, Inc. changed its name to Corium Innovations, Inc., which we refer to as Corium. We, along with Corium, have made a significant investment in a proprietary process to manufacture Twirla. We believe we have a robust process to reliably manufacture Twirla on a commercial scale. We believe that the technical challenges and know how involved in manufacturing, including proprietary chemistry, production to scale and use of custom equipment, present significant barriers to entry for other pharmaceutical companies who might potentially want to replicate our Skinfusion technology.

Strategic Agreements

Agreement with Corium

In April 2020, we entered into a Manufacturing and Commercialization agreement with Corium, which we refer to as the Corium Agreement, and which replaced our previous development agreement. Corium continues to operate under the Corium Agreement after the Corium Reorganization. Pursuant to the Corium Agreement, Corium will manufacture and supply all of our product requirements for Twirla at certain specified rates. Under the terms of the Corium Agreement, Corium is to be the exclusive supplier of Twirla for ten years. The Corium Agreement included a quarterly minimum purchase commitment and a fixed price per unit for two years from December 2020, the date of the first

commercial batch purchase order invoice, depending on annual purchase volume. During 2021, we did not meet all of our minimum quantity purchases from Corium, and as a result, paid penalties as required by our agreement with Corium. On July 25, 2022, we, along with Corium, amended the Corium Agreement to restructure the minimums applicable to the purchase of manufactured Twirla and to extend the term of the Corium Agreement until December 31, 2033. Pursuant to the amended Corium Agreement, the parties agreed to transfer ownership of certain manufacturing equipment used in the manufacture of Twirla from us to Corium under a Bill of Sale dated July 25, 2022.

The Corium Agreement terminates automatically on December 31, 2033, but may be terminated for any reason upon the written mutual agreement of both parties; provided, however, that the parties must confer in good faith regarding possible mutual termination. In the event of such termination, we may still affect purchase orders after the notice of termination is given and until the time any such termination becomes effective. As of December 31, 2023, the minimum amount committed totals $225.0 million for the ten-year period from 2024 through 2033.

Agreement with Syneos Selling Solutions

In April 2020, we entered into a project agreement with inVentiv Commercial Services, LLC, or inVentiv, a Syneos Health Group Company, which we refer to as the Syneos Agreement, under our Master Services Agreement with inVentiv. Pursuant to the Syneos Agreement, inVentiv, through its affiliate Syneos Selling Solutions, will provide a field force of sales representatives to provide certain detailing services, sales operation services, compliance services and training services with respect to Twirla to us in exchange for an up-front implementation fee and a fixed monthly fee. Effective February 1, 2022, we entered into an amendment to the Syneos Agreement that extended the term until August 23, 2024. At that time, the Syneos Agreement will terminate automatically unless extended upon the mutual written agreement of the parties. We may terminate the Syneos Agreement for any reason upon timely written notice without incurring a termination fee. As of December 31, 2023, the minimum amount committed totals $2.4 million.

Pricing and Reimbursement

In the United States, decisions regarding the extent of coverage and the amount of reimbursement to be provided for pharmaceutical products are made on a payor-by-payor basis. The principal decisions about reimbursement for new medicines by the U.S. Government are typically made by the Centers for Medicare & Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services. As a result, coverage determinations often involve a time-consuming and costly process that require companies to provide scientific and clinical support for the use of approved products to multiple stakeholders which may include Group Purchasing Organizations (GPO's), Pharmacy Benefit Managers (PBM's), individual payer health plans, as well as government payors and federal purchasers including CMS, the Veterans Administration, Department of Defense and state Medicaid managed and Fee For Service plans, with no assurance on the level of coverage or that adequate reimbursement will be obtained. Third-party payors are increasingly challenging the prices charged for pharmaceutical products.

In the United States, third-party payors include federal health care programs, such as Medicare, Medicaid, TRICARE, and Veterans Health Administration programs, managed care providers, private health insurers and other organizations. Several of the U.S. federal health care programs require that drug manufacturers extend discounts or pay rebates to certain programs in order for their products to be covered and reimbursed. For example, the Medicaid Drug Rebate Program requires pharmaceutical manufacturers of covered outpatient drugs to enter into and have in effect a national rebate agreement with the federal government as a condition for coverage of the manufacturer's covered outpatient drug(s) by state Medicaid programs. The amount of the rebate for each product is based on a statutory formula and may be subject to an additional discount if certain pricing increases more than inflation. State Medicaid programs and Medicaid managed care plans can seek additional "supplemental" rebates from manufacturers in connection with states' establishment of preferred drug lists. A further requirement for Medicaid coverage is that the manufacturer enter into a Federal Supply Schedule, or FSS, agreement with the Secretary for Veterans Affairs to extend discounted pricing to the VA, DOD and other agencies.

Similarly, in order for a covered outpatient drug to receive federal reimbursement under the Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts on the covered outpatient drug to entities that are enrolled and participating in the 340B drug pricing program, which is a federal program that requires

manufacturers to provide discounts to certain statutorily-defined safety-net providers. The 340B discount for each product is calculated based on certain Medicaid Drug Rebate Program metrics that manufacturers are required to report to CMS.

There has been recent negative publicity and increasing legislative and public scrutiny around pharmaceutical drug pricing in the U.S. Moreover, U.S. government authorities and third-party payors are increasingly attempting to limit or regulate drug prices and reimbursement. These dynamics may give rise to heightened attention and potential negative reactions to pricing decisions for Twirla and products for which we may receive regulatory approval in the future, possibly limiting our ability to generate revenue and attain profitability.

The United States government and other third-party payors are increasingly limiting both coverage and level of reimbursement for new drugs, in addition to questioning their safety, efficacy and clinical value. Consolidation among managed care entities has increased the negotiating power of these entities. Third-party payors increasingly use closed formularies, which might not include all of the approved products for a particular indication, to control costs by negotiating discounted prices in exchange for formulary inclusion. Third-party payors have traditionally used differential co-pays to attempt to drive patients to use either generic products or products for which they have a contract with the manufacturer.

Reimbursement for female contraceptive products was changed by the enactment of the Patient Protection and Affordable Care Act (PPACA), which was signed into law on March 23, 2010, and further updated on March 30, 2010 to become the Affordable Care Act (ACA). On January 20, 2012, U.S. Department of Health and Human Services announced a final rule on health insurance coverage that provided for no cost sharing for FDA-approved contraceptives and contraceptive services for women of reproductive age if prescribed by health care providers, as part of women's preventive health services guidelines adopted by the Health Resources and Services Administration (HRSA) for the ACA. The final rule applied to all new health insurance plans in all states beginning August 1, 2012.

On May 11, 2015, The Departments of Labor and Health and Human Services and the Treasury (the "Departments") issued an FAQ ("2015 FAQ") clarifying that plans and issuers must cover without cost sharing at least one form of contraception in each of the methods (currently 18) identified for women by the FDA. The 2015 FAQ further clarified that to the extent plans and issuers use reasonable medical management techniques within a specified method of contraception, plans and issuers must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or provider (or other individual acting as a patient's authorized representative, including a provider) to ensure coverage without cost sharing of any service or FDA-approved item within the specified method of contraception. The 2015 FAQ also stated that if an individual's attending provider recommends a particular service or FDA-approved item based on a determination of medical necessity with respect to that individual, the plan or issuer must cover that service or item without cost sharing. The 2015 FAQ makes clear that a plan or issuer must defer to the determination of the attending provider. Medical necessity may include considerations such as severity of side effects, differences in permanence and reversibility of contraceptives, and ability to adhere to the appropriate use of the item or service, as determined by the attending provider.

On January 10th, 2022, the Departments released a set of "Frequently Asked Questions" ("2022 FAQ") which affirmed that under the ACA's women's preventives services, plans cannot limit their coverage of contraceptives. The Departments issued the 2022 FAQ in response to complaints and public reports of potential violations of the contraceptive coverage requirement. The 2022 FAQ makes clear that all FDA-approved cleared, or granted contraceptive products that are determined by an individual's medical provider to be medically appropriate for such individual must be covered without-cost sharing, whether or not specifically identified in the current FDA Birth Control Guide. Outlined under Coverage of Food and Drug Administration (FDA)-approved Contraceptives, the 2022 FAQ notes that on February 20, 2013, The Departments issued an FAQ stating that the HRSA Guidelines must ensure women's access to the full range of FDA-approved contraceptive methods including, but not limited to, barrier methods, hormonal methods, and implanted devices, as well as patient education and counseling, as prescribed by a health care provider. The FAQ further clarified that plans and issuers may use reasonable medical management techniques to control costs and promote efficient delivery of care, such as covering a generic drug without cost sharing and imposing cost sharing for equivalent branded drugs. However, in these instances, the FAQ stated that a plan or issuer must accommodate any individual for whom a particular drug (generic or brand name) would be medically inappropriate, as determined by the individual's

health care provider, by having a mechanism for waiving the otherwise applicable cost sharing for the brand or non-preferred brand version.

The 2022 FAQ noted that plans and issuers subject to these requirements are reminded of their responsibility to fully comply with the requirements under PHS Act section 2713 and the HRSA Guidelines, as interpreted in The Departments' implementing regulations and guidance, including the requirement that, if an individual and their attending provider determine that a particular service or FDA-approved, cleared or granted contraceptive product is medically appropriate for the individual (whether or not the item or service is identified in the current FDA Birth Control Guide), the plan or issuer must cover that service or product without cost sharing.

On June 3, 2023, President Biden issued an Executive Order directing the Secretaries of Health and Human Services, Labor and Treasury to consider actions, to the greatest extent permitted by law, to ensure coverage of comprehensive contraceptive care including all contraceptives approved, granted, or cleared by the Food and Drug Administration, without cost sharing for enrollees, participants, and beneficiaries.

The Departments published additional guidance on January 22, 2024, outlining a new pathway for plans and issuers to meet existing obligations under federal law by covering, at no cost, a broader range of FDA-approved contraceptive drugs and certain devices. The Departments described how plans may comply with the ACA requirement to cover contraception without cost sharing by covering all FDA-approved drugs and drug-led devices other than those for which there is a covered therapeutic equivalent as identified in the Orange Book. If a therapeutic equivalent exists, a plan may choose to cover only one therapeutically equivalent product, so long as it maintains an acceptable exceptions process in the case that a patient needs a specific product that is considered a therapeutic equivalent.

In conjunction with the release of the new guidance, the Secretary of Health and Human Services sent a letter to health plans and insurers highlighting the issuance of the updated guidance that ensures compliance with the ACA's requirement to cover contraception without cost-sharing. In his letter he noted, "In addition to this new guidance, and as we have previously made clear, we will continue to call on group health plan sponsors and issuers to remove impermissible barriers and ensure individuals in your plans have access to the contraceptive coverage they need, as required under the law."

It is difficult to determine the full effect of the ACA or any other healthcare reform efforts on our business. Presidential administrations can, and have, issued Executive Orders directing federal agencies on how to implement the ACA. Congress also could consider subsequent legislation to repeal and replace elements of the ACA. Additionally, in October 2017, the Department of Health and Human Services, jointly with the Department of Labor and the Treasury, issued two interim final rules outlining exemption processes for employers not wanting to offer contraceptive coverage based on their religious beliefs or sincerely held moral convictions. In January 2023, the Biden administration proposed rules that would remove the moral exemption and retain the existing religious exemption.

Before the ACA was passed, many states had enacted contraceptive equity laws that required plans to treat contraceptives in the same way they covered other services. In addition, since the ACA was passed, a number of states have enacted laws that basically codify in state legislation the ACA benefit rules (requiring all plans regulated by the state to cover, without cost-sharing, each of the 18 FDA-approved contraceptive methods and in some cases have gone further and required coverage of all FDA approved contraceptives). Federal law applies to all plans while state law applies to only individual plans and fully-insured group plans. Currently, 30 states and the District of Columbia require insurance plans to cover contraceptives, with a wide range of coverage and cost-sharing requirements, and exemptions among these mandates. We continue to monitor healthcare reform efforts and agency implementation as well as state contraceptive legislation.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, and import and export of pharmaceutical products. The

processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

FDA Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The FDA has also issued many guidance documents, which outline its interpretation of its governing laws and regulations. Over the last year, FDA has continued to issue new guidances, which are continually evolving, to assist companies navigating regulatory requirements affecting their products.

The process of obtaining regulatory approvals and subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold or termination of trials, issuance of Warning, Untitled, or Cyber Letters, requests for product recalls, product seizures or detention, operating restrictions such as the total or partial suspension or restriction of production, marketing or distribution, injunctions, fines, debarment, refusal to allow the import or export of product, adverse publicity, modification of promotional materials or labeling, refusals of government contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement, imprisonment, consent decrees and corporate integrity agreements, or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- Completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's Good Laboratory Practice, or GLP, regulations;
- Submission to the FDA of an Investigational New Drug Application, or IND, which must become effective before human clinical trials may begin;
- Approval by an independent Institutional Review Board, or IRB, for each clinical site before each trial may be initiated;
- Performance of human clinical trials, including adequate and well-controlled clinical trials, in accordance with Current Good Clinical Practices, or cGCPs to establish the safety and efficacy of the proposed drug product for each indication;
- Submission to the FDA of an NDA;
- Satisfactory completion of an FDA advisory committee review, if applicable;
- Satisfactory completion of an FDA inspection or remote regulatory assessment of the manufacturing facility or facilities at which the product is produced to assess compliance with FDA requirements for product manufacturing and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, as well as the potential for completion of an FDA inspection or remote regulatory assessment of selected clinical sites to determine cGCP compliance;
- FDA review and approval of the NDA; and
- Compliance with any post-approval commitments, including Risk Evaluation and Mitigation Strategies, or REMS, and post-approval studies required by the FDA.

Preclinical Studies and IND Submission

Preclinical studies include laboratory evaluations of drug substance chemistry, pharmacology, toxicity and drug product formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data, proposed clinical protocols, and any available clinical data or literature, among other things, to the FDA as part of an IND, unless the sponsor is relying on prior FDA findings of safety or efficacy of the drug product, in which case, some of the above information may be omitted. Some preclinical testing may continue even after the IND is submitted. 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 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.

Clinical Trials

Clinical trials involve the administration of an investigational new drug to human subjects under the supervision of qualified investigators in accordance with cGCP requirements, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, and the review and approval of the study by an IRB. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated and a statistical analysis plan. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Sponsors will also be required to provide FDA with diversity plans in order to improve clinical trial representation. In addition, an IRB for each clinical trial site participating in the clinical trial must review and approve the plan for any clinical trial before it commences, and the IRB must continue to oversee the clinical trial while it is being conducted, including any changes.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined. In Phase 1, the drug is initially introduced into healthy human subjects or subjects with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an initial indication of its effectiveness. In Phase 2, the drug typically is administered through controlled studies to a limited subject population with the target disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the drug for specific targeted diseases or conditions and to determine dosage tolerance and optimal dosage. In Phase 3, the drug is administered to an expanded subject population, generally at geographically dispersed clinical trial sites, in two adequate and well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product candidate for approval, to establish the overall risk-benefit profile of the product candidate and to provide adequate information for the labeling of the product candidate. In the case of a 505(b)(2) NDA, which is a marketing application in which sponsors may rely on investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted, some of the above-described studies and preclinical studies may not be required or may be abbreviated. Bridging studies may be needed, however, to demonstrate the applicability of the studies that were previously conducted by other sponsors to the drug that is the subject of the marketing application. In addition to the above traditional kinds of data required for the approval of an NDA, the 21st Century Cures Act and other statutes provides for FDA acceptance of additional kinds of data such as patient experience data, real world evidence for already approved products, and, for appropriate indications sought through supplemental marketing applications, data summaries.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA for a new active ingredient, indication, dosage form, dosage regimen or route of administration must contain data that are adequate to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to FDA product manufacturing requirements. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FDCA. Noncompliance with the applicable manufacturing requirements may also require costly corrective and preventative actions.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and the IRB and more frequently if serious adverse events occur. Information about certain clinical trials, including a description of the study and study results, must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their ClinicalTrials.gov website. Failure to submit the required information to ClinicalTrials.gov can result in monetary penalties. Marketing application applicants must also report certain investigator financial interests to the FDA.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to subjects. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of trial subjects, potential trial subjects, and the continuing validity and scientific merit of the clinical trial. We may also suspend or terminate a clinical trial based on evolving business objectives or competitive climate.

U.S. Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. These user fees must be filed at the time of the first submission of the application, even if the application is being submitted on a rolling basis. Under the Prescription Drug User Fee Act, or PDUFA guidelines that are currently in effect, the FDA has agreed to certain performance goals regarding the timing of its review of an application. The FDA's standard review goal is to act on 90% of all Non-New Molecular Entity applications within ten months of FDA receipt of the application. This time period may be extended by the FDA should an applicant submit new information to the agency during the course of the FDA's review of the marketing application. The time period is also only a goal and may not be met by the FDA.

The FDA conducts a preliminary review of all original NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be submitted again with the additional information and is also subject to review before the FDA accepts it for filing.

Once the submission is accepted for filing, the FDA begins an in-depth substantive review to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held, as well as the manufacturing processes and controls, meet standards designed to ensure the product's continued safety, quality and purity.

The FDA may refer a marketing application to an external advisory committee for questions pertaining to issues such as clinical trial design, safety and efficacy, and public health questions. 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 recommendations of an advisory committee, but it typically follows such recommendations and considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will inspect or conduct a remote regulatory assessment of the facility or facilities where the product is manufactured, referred to as a Pre-Approval Inspection. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with the FDA's requirements for product manufacturing and adequate to assure consistent production of the product within required specifications by the manufacturer and all of its subcontractors and contract manufacturers. Additionally, before approving an NDA, the FDA will typically inspect or conduct remote regulatory assessments for one or more clinical trial sites to assure compliance with cGCP. Also, as part of its regulatory review, the FDA verifies the data contained in the NDA.

The testing and approval process for a drug product requires substantial time, effort and financial resources, and may take several years to complete. Data obtained from preclinical and clinical testing are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval of a marketing application on a timely basis, or at all.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection or remote regulatory assessment reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a Complete Response Letter, or a CRL. A CRL indicates that the review cycle of the application is complete, and the application is not ready for approval. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the drug product and may require additional clinical or preclinical testing, or other information in order for the FDA to reconsider the application. If an application receives a CRL, the applicant may resubmit the application, addressing all of the FDA-cited deficiencies, withdraw the application, or request the opportunity for a hearing. Resubmitted applications may also be subject to FDA inspection or remote regulatory assessment of clinical and manufacturing sites, as well as review by FDA advisory committees. Following its review of a resubmitted NDA, the FDA may issue an approval letter or another CRL.

Even if an applicant resubmits with the required additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product candidate, it may limit the approved indications for use of the product candidate and require that contraindications, warnings or precautions be included in the product labeling, including a boxed warning. The FDA also may not approve the inclusion of labeling claims necessary for successful marketing. Moreover, the FDA may require that post-approval studies, including Phase 4 clinical trials, and trials to ensure that population representative data is collected, be conducted to further assess certain aspects of a drug's safety and efficacy after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms. For example, the FDA may require a REMS as a condition of approval or following approval to mitigate any identified or suspected serious risks and ensure safe use of the drug. The REMS plan could include a medication guide, a physician communication plan, an assessment plan, and elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. A REMS could materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. 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, submission of a supplemental application, and FDA review and approval. Further, should new safety information arise, additional testing, product labeling or FDA notification may be required. The FDA may also request – rather than require – change to a product's labeling based upon new information not implicating safety that arises after approval.

Hatch-Waxman Act

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy, but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of an approved drug product through the submission of an Abbreviated New Drug Application, or ANDA. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through *in vitro*, *in vivo*, or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's drug or a method of using the drug. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations publication, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA. In an effort to clarify which patents must be listed in the Orange Book, in January 2021, Congress passed the Orange Book Transparency Act of 2020, which largely codifies FDA's existing practices into the FDCA. Listing patents in the Orange Book that do not qualify for listing can be considered to be anticompetitive conduct and, in 2023, the Federal Trade Commission sent letters to a number of companies with respect to certain patents that agency asserted were improperly listed or inaccurate.

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA that: (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. The applicant may also elect to submit a statement certifying that its proposed label does not contain (or carves out) language regarding the patented method-of-use rather than certify a listed method-of-use patent. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a Paragraph IV certification. If the applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must send notice of the Paragraph IV certification to the NDA and patent holders within a specified timeframe. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. If the Paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the Paragraph IV certification, the FDA may not make an approval effective until the earlier of 30 months from the receipt of the notice of the Paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a Paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

The Hatch-Waxman Act establishes periods of regulatory exclusivity for certain approved drug products, during which the FDA cannot approve (or in some cases accept) an ANDA or 505(b)(2) application that relies on the branded reference drug. For example, the holder of an NDA, including a 505(b)(2) NDA, may obtain five years of exclusivity upon approval of a new drug containing new chemical entities, or NCEs, that have not been previously approved by the FDA. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The Hatch-Waxman Act also provides three years of marketing exclusivity to the holder of an NDA (including a 505(b)(2) NDA) for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. This three-year exclusivity period protects against the FDA making an ANDA and 505(b)(2) NDA approval effective for the condition of the new drug's approval. As a general matter, the three-year exclusivity does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full 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 efficacy.

Our NDA for Twirla was submitted under Section 505(b)(2), and we expect that some of our other drug candidates will utilize the Section 505(b)(2) regulatory pathway. Even though several of our drug products utilize active drug ingredients that are commercially marketed in the United States in other dosage forms, we need to establish the safety and efficacy of those active ingredients in the formulation and dosage forms that we are developing. All approved products, both innovator and generic, are listed in the FDA's Orange Book.

Recently, Congress, the executive branch, and FDA have taken certain measures to increase drug competition and thus, decrease drug prices. By example, measures have been proposed and implemented to facilitate drug importation, and Florida recently had its plan to import drugs from Canada approved by FDA. Moreover, the 2020 Further Consolidated Appropriations Act also required sponsors of NDA approved products to provide sufficient quantities of drug product on commercially reasonable market-based terms to entities developing generic and similar drug products. Failure to do so can subject the approved product sponsor to civil actions, penalties, and responsibility for attorneys' fees and costs of the civil action. This bill also included provisions on shared and individual REMS for generic drug products.

Combination Drug/Device Regulation

Twirla and our potential product candidates are considered to be drug-device combination products by the FDA. While our potential product candidates, as a whole, are subject to the NDA approval process, drug-device combination products require compliance with additional FDA regulations. For instance, drug-device combination products must comply with the drug cGMPs, as well as some of the device GMPs, as set forth in the FDA's Quality System Regulations, or QSRs. In January 2022, FDA issued its final guidance on premarket approval pathways for combination products to help facilitate development of safe and effective combination products. Specifically, in the guidance, FDA defines combination products and discusses how center assignments are determined; discusses the interaction between FDA and sponsors; and includes recommendations for discerning the appropriate premarket pathway for a combination product. These dual requirements for combination products will require additional effort, FDA reporting, and monetary expenditure to ensure that Twirla and our potential product candidates comply with all applicable regulatory requirements.

U.S. Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to manufacturing recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion, reporting of adverse experiences with the product and

drug shortages, and compliance with any post-approval requirements imposed as a condition of approval, such as Phase 4 clinical trials, REMS and surveillance to assess safety and efficacy after commercialization. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There are also continuing, annual prescription drug program user fee requirements for any approved products. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and list drugs manufactured at their facilities with the FDA.

Drug sponsors and manufacturers are subject to periodic announced and unannounced inspections and remote regulatory assessments by the FDA and state agencies for compliance with FDA and state requirements for product manufacturing and other requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented, or FDA notification. FDA regulations also require investigation and correction of any deviations from FDA requirements for product manufacturing and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain FDA product manufacturing compliance.

Once an 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 mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- Restrictions on the marketing, distribution or manufacturing of the product, complete withdrawal of the product from the market or requests for product recalls;
- Fines, or Untitled, Cyber or Warning Letters or holds on or termination of post-approval clinical trials;
- Refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- Product seizure or detention, or refusal to permit the import or export of products;
- Injunctions or the imposition of civil or criminal penalties including disgorgement, restitution, fines and imprisonment;
- Consent decrees, corporate integrity agreements or exclusion from federal healthcare programs;
- Debarment;
- Mandated modification of promotional materials and labeling and the issuance of corrective information; or
- The FDA or other regulatory authorities may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications, pharmaceutical companies and third parties engaged on their behalf to promote their drug products are prohibited from marketing or promoting their drug products for uses outside the approved label, a practice known as off-label promotion. Companies that market drug products must also provide adequate balancing information on a product's risk in its

advertising and promotional pieces. Communications about drug products is an evolving space. In 2023, FDA issued a final rule and a guidance on risk and efficacy disclosures in direct-to-consumer advertising, and a guidance on communication of off-label scientific information about approved products. The FDA and other agencies 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, including criminal fines and civil penalties under the FDCA and False Claims Act, exclusion from participation in federal healthcare programs, mandatory compliance programs under corporate integrity agreements, debarment and refusal of government contracts.

In addition, the distribution of prescription pharmaceutical samples is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drug samples at the federal level and reporting regarding drug samples. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Moreover, the Drug Quality and Security Act imposes obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, are required to label drug product with a product identifier and are required to keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers is also required to be done electronically and will be required to allow interoperable electronic product tracing at the package level by November 2023, though FDA does not intend to take action to enforce requirements for the interoperable, electronic, package level product tracing until November 27, 2024. Manufacturers must also verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this legislation, manufacturers have drug product verification responsibilities, as well as investigation, quarantine, disposition, and FDA and trading partner notification responsibilities related to counterfeit, diverted, stolen and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death. Other persons and entities within the drug supply chain are also subject to Drug Quality and Security Act requirements.

FDA's requirements with respect to drug manufacturing, marketing and distribution are continually evolving. FDA and Congress may pass new laws, regulations, and policies, as was done in March 2020 with the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act. The CARES Act included various provisions regarding FDA drug shortage reporting requirements, as well as provisions regarding supply chain security, such as risk management plan requirements, and the promotion of supply chain redundancy and domestic manufacturing. As part of the CARES Act implementation, the FDA issued a guidance on the reporting of the volume of drugs produced, which reporting will require additional administrative efforts by drug manufacturers. This and any future changes in law may require that we change our internal processes and procedures to ensure continued compliance.

U.S. Fraud and Abuse, Data Privacy and Security and Transparency Laws and Regulations

In addition to FDA restrictions on marketing of pharmaceutical products, federal and state fraud and abuse laws restrict business practices in the biopharmaceutical industry. These laws include, among other things, anti-kickback, healthcare professional payment transparency, drug price transparency, and false claims laws and regulations as well as data privacy and security laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any healthcare item or service, for which payment may be made in whole or in part under federally financed healthcare programs such as Medicare and Medicaid. The term "remuneration" has been interpreted broadly to include anything of value. Additionally, the intent standard under the Anti-Kickback Statute and criminal healthcare fraud statutes was amended by the Affordable Care Act, or ACA, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce or reward referrals or federal healthcare program business, including purchases of products paid by federal

healthcare programs, the statute has been violated. In addition, the ACA established that a claim for reimbursement involving items or services resulting from a violation of the federal Anti-Kickback Statute is grounds for the government or a whistleblower to assert that a claim for reimbursement submitted to a federal healthcare program for payment of items or services resulting from such a violation constitutes a per se false or fraudulent claim for purposes of the federal civil False Claims Act. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers, among others, on the other. The Beneficiary Inducement Civil Monetary Penalties Law imposes similar restrictions on interactions between pharmaceutical manufacturers and federal healthcare program beneficiaries. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. Practices that involve remuneration that may be alleged to be intended to induce or reward prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. On December 2, 2020, the U.S. Department of Health and Human Services (HHS) Office of Inspector General, or OIG, published further modifications to the federal Anti-Kickback Statute regulatory safe harbors. OIG promulgated two additional safe harbor regulations relative to pharmaceutical manufacturers under the final rule, the first of which excluded from the definition of "remuneration" limited categories of manufacturer rebates or other price reductions to a plan sponsor under Medicare Part D or a Medicaid Managed Care Organization plan reflected in point-of-sale reductions in price. The second safe harbor regulation excludes from the definition of "remuneration" PBM service fees paid by a manufacturer to a PBM. In addition, OIG revised the discount safe harbor regulation to exclude from the definition of "discount" a reduction in price by a manufacturer to plan sponsors under Medicare Part D, either directly to the plan sponsor or indirectly through a pharmacy benefit manager. The effective date of the two new safe harbors and the revision to the discount safe harbor was delayed by court order until January 1, 2023. Recent legislation further delayed implementation of the new safe harbors and the revision to the discount safe harbor until January 1, 2032. The final rule also added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others.

Many states have adopted laws similar to the federal Anti-Kickback Statute, which apply to healthcare items and services reimbursed under Medicaid and other state programs; furthermore, in several states, these statutes and regulations apply regardless of the payor, including commercial and other third-party payors. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer and its products from participation in federal healthcare programs, debarment from federal government procurement and non-procurement programs, criminal fines, and imprisonment.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal 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 federal government; or avoiding, decreasing, or concealing an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Claims under the federal civil False Claims Act may be initiated by whistleblowers, who receive substantial financial incentives to come forward, through qui tam actions. If the government decides to intervene in a qui tam action and prevails in the lawsuit, the whistleblower will share in the proceeds from any damages, penalties or settlement funds. If the government declines to intervene, the whistleblower may pursue the case alone. The civil False Claims Act provides for treble damages and a civil penalty for each false claim, such as an invoice or pharmacy claim for reimbursement, which can aggregate into tens and even hundreds of millions of dollars. For these reasons, False Claims Act lawsuits against pharmaceutical manufacturers have increased significantly in volume and breadth in recent years, leading to several substantial civil and criminal settlements, including for as much as $3.0 billion regarding certain sales practices and promoting off label uses. Intent to deceive and actual knowledge of falsity is not necessary to establish civil liability, which may be predicated on reckless disregard for or deliberate ignorance of the truth or falsity of the information provided. The federal government continues to use the False Claims Act, and the accompanying threat of significant liability, in investigations against pharmaceutical and health care companies. The False Claims Act has been used to assert liability on the basis of kickbacks and other improper relationships with referral sources, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper promotional activities, including off-label promotion of uses not expressly approved by the FDA in a drug's label, cGMP violations, and allegations as to misrepresentations with respect

to products, contract requirements, and services rendered. In addition, private payors have been filing follow-on lawsuits alleging fraudulent misrepresentation and other claims, although establishing liability and damages in these cases is more difficult than under the False Claims Act. The federal criminal False Claims Act imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false fictitious or fraudulent. Conviction or civil judgment for violation of the False Claims Act can also result in debarment from federal government procurement and non-procurement programs and exclusion from participation in federal healthcare programs. The majority of states also have statutes or regulations similar to the federal False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs. Additionally, the civil monetary penalties statute, among other things, imposes fines against any person who is determined to have presented, or caused to be presented, claims to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent.

The ACA authorized the imposition of civil monetary penalties on manufactures participating in the 340B program for failure to charge the statutory ceiling price and required HHS to promulgate regulations establishing the standards for implementing this Civil Monetary Penalty, or CMP, authority. The Centers for Medicare and Medicaid Services', or CMS, final CMP rule went into effect January 1, 2019.

The ACA also included a provision requiring certain providers and suppliers of items and services to federal healthcare programs to report and return overpayments, such as those caused by understated rebate amounts, within sixty days after they are "identified" (the "Overpayment Statute"), after which the recipient of the overpayment incurs federal civil False Claims Act liability. The law prohibits a recipient of a payment from the government from keeping an overpayment when the government mistakenly pays more than the amount to which the recipient is entitled even if the overpayment is not caused by any conduct of the recipient. The Overpayment Rule is not directly applicable to manufacturers, except if a manufacturer is a direct recipient of payment by an agency such as a research grant but may impact their customers and potential customers who are Medicare providers, suppliers, and plans.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, including private third party payors; knowingly and willfully embezzling or stealing from a healthcare benefit program; willfully obstructing a criminal investigation of a healthcare offense; and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services relating to healthcare matters. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, that apply regardless of the payor.

In addition, we may be subject to healthcare data privacy and security regulations promulgated by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, ("HITECH Act"), and their respective implementing regulations, impose certain requirements on covered entities relating to the privacy, security, and transmission of certain individually identifiable health information known as protected health information. The HIPAA privacy regulations impose certain requirements with respect to the disclosure of protected health information for research purposes, such as clinical trials. Among other things, the HITECH Act, and its implementing regulations, made HIPAA's security standards and certain privacy standards directly applicable to business associates, defined as persons or organizations, other than members of a covered entity's workforce, that create, receive, maintain or transmit protected health information on behalf of a covered entity for a function or activity regulated by HIPAA. The HITECH Act also strengthened the civil and criminal sanctions that may be imposed against covered entities, business associates, and individuals, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. Other federal and state laws, such as the California Consumer Privacy Act and Washington's My Health My Data Act, may govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and may not be preempted by HIPAA, thus complicating compliance efforts.

Additionally, the federal Physician Payment Sunshine Act created under Section 6002 of the ACA and its implementing regulations, require that manufacturers of prescription drugs for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, report annually to the CMS information related to certain payments or other "transfers of value" made or distributed to or at the request of covered recipients, namely US-licensed physicians (defined to include doctors of medicine or osteopathy, dentists, optometrists, podiatrists and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse-midwives and US teaching hospitals, as well as ownership and investment interests in an applicable drug manufacturer held by physicians and their immediate family. Payments made to physicians, other principal investigators, and certain research institutions for research, including clinical trials, are included within the ambit of this law. Disclosure of such information is made on a publicly available website. Failure to submit required information may result in civil monetary penalties, with increased penalties for "knowing failures," for each payment, transfer of value or ownership or investment interest not timely and accurately reported in an annual submission.

There are also an increasing number of analogous state laws and laws in local jurisdictions that regulate price increases, require manufacturers to file reports with states on pricing and price increases, prohibit, restrict and/or require tracking and reporting of gifts, compensation, other remuneration and items of value provided to healthcare professionals and healthcare entities, and require registration of and impose training requirements on sales representatives. Many of these laws contain ambiguities as to what is required in order to comply with such laws. The laws in some states also require pharmaceutical companies to establish and implement compliance programs that are consistent with voluntary industry guidelines and guidance published by the HHS-OIG. Certain state laws also regulate manufacturers' use of prescriber-identifiable data. These laws may affect our future sales, marketing and other promotional activities by imposing restrictions on those activities as well as administrative and compliance burdens. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities.

If our operations are found to be in violation of any of the laws or regulations described above or any other laws that apply to us, we may be subject to a variety of penalties, depending upon the law found to have been violated, potentially including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, corporate integrity agreements, non-prosecution agreements, refusal of government contracts, debarment from federal government procurement and non-procurement programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Notification Obligations and Potential Liability Around Data Security Incidents, Including Cyberattacks

If personal or other sensitive information about patients or employees is disclosed in an unauthorized manner, or if we or our service providers are subject to real or perceived cyberattacks, ransomware, data breaches, or other security incidents or compromises, or disruption of information technology systems or software, our customers may curtail use of our platform, we may be exposed to liability, our reputation may suffer and our operations may be materially harmed and disrupted.

We, and third parties acting on our behalf, receive, collect, access, generate, store, disclose, share, make accessible, protect, secure, transmit, transfer, dispose of, use, store and otherwise process (collectively, "Process" or "Processing") personal, confidential and proprietary information. The information technology networks and systems owned, operated, controlled or used by us or our service providers to Process information, including personal and other sensitive information, and to perform other business operations may be vulnerable to damage, disruptions or shutdowns, software or hardware vulnerabilities, data breaches, ransomware attacks, security incidents, supply-side attacks, failures during the process of upgrading or replacing software, databases or components, power outages, natural disasters, hardware failures, attacks by computer hackers, telecommunication failures, user errors, user malfeasance, computer viruses, unauthorized access, phishing or social engineering attacks, ransomware attacks, denial-of-service attacks and other real

or perceived cyberattacks or catastrophic events. Any of these incidents could lead to interruptions or shutdowns of our platform, loss or corruption of data, or unauthorized access to or disclosure of personal information or other sensitive information. Cyberattacks could also result in the theft of, or unauthorized access to or use or disclosure of, our intellectual property. We utilize security tools and controls, and we rely on our service providers to use sufficient security measures, including encryption and authentication technology, in an effort to protect personal and other sensitive information. However, advances in computer capabilities, increasingly sophisticated tools and methods used by hackers and cyber terrorists, new discoveries in the field of cryptography or other developments may result in our failure or inability, or the failure or inability of our vendors, to adequately protect personal information and there can be no assurance that we or our vendors will not suffer a data compromise, that hackers or other unauthorized parties will not gain access to personal information or other data, or that any such data compromise or unauthorized access will be discovered in a timely fashion.

Security incidents such as ransomware attacks, including those involving organized criminal threat actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe. We, and our service providers, have been subject to cyber, phishing and social engineering attacks and other security incidents in the past and may continue to be subject to such attacks in the future. Advances in computer capabilities, new technological discoveries or other developments may result in cyberattacks becoming more sophisticated and more difficult to detect. Techniques used to obtain unauthorized access to or to sabotage systems change frequently and generally are not known until launched against us or our service providers. We and our third-party vendors may not have the resources or technical sophistication to anticipate or prevent all such cyberattacks or our security measures, or those of our service providers, could fail or may be insufficient, resulting in security breaches, ransomware attacks, significant interruptions, delays, or outages in our operations, and/or the unauthorized disclosure, modification, misuse, unavailability, destruction or loss of personal or other sensitive information. Security breaches can also occur as a result of non-technical issues, including intentional or inadvertent actions by our employees, our service providers or their personnel or other parties.

If we or our service providers experience, or are believed to have experienced, a security breach or other security incident or compromise (or if there is a perception that we or a service provider has experienced such an event), it may result in: government enforcement actions, including by the Department of Health and Human Services, that could include investigations, fines, penalties, audits and inspections; class actions or other private litigation that could include penalties and injunctions, including in the form of a large settlement; increased regulatory scrutiny; additional reporting requirements and/or oversight; loss of income; significant extra expenses to restore data or systems or to otherwise remediate or mitigate the issue (including costs for credit monitoring, notification and other related costs); diversions of management's time and attention; temporary or permanent bans on all or some Processing of personal information; or orders to destroy, not use or to limit the Processing of personal information. Security incidents could also result in contractual breaches, indemnity obligations, negative publicity, damage to our reputation, and financial loss.

Security incidents and vulnerabilities may cause some of our customers to cease doing business with us and our failure, or perceived failure, to meet expectations or legal obligations with regard to the security, integrity, availability and confidentiality of our systems and the Processing of data could damage our reputation and affect our ability to retain customers, attract new customers and grow our business. Applicable data protection laws, privacy policies and data protection obligations (including contractual obligations) may require us to notify relevant stakeholders of a security incident, including affected individuals, customers, regulators and credit reporting agencies, and may also require us to provide other remedies, such as credit monitoring. Such notifications and other remedies are costly, and the notifications or the failure to comply with such requirements, could lead to material adverse impacts, including without limitation, negative publicity, a loss of customer confidence in our services or security measures or breach of contract claims. Furthermore, actual or perceived security breaches or attacks on our systems or those of our service providers may cause us to incur increasing operational costs, including costs to deploy additional personnel and protection technologies, train employees, and engage third-party experts and consultants.

There can be no assurance that the limitations of liability or other risk-mitigation provisions in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable data protection laws, privacy policies or data protection obligations (including contractual obligations) related to information security or security incidents. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from, or to adequately mitigate, liabilities or damages with respect to claims, costs, expenses, litigation,

fines, penalties, business loss, data loss, regulatory actions or material adverse impacts arising out of our privacy and security practices, Processing of data or security incidents we may experience, or that such coverage will continue to be available on commercially reasonable terms or at all.

Additionally, any material disruption of our systems, or the systems of our service providers, could disrupt our ability to track, record and analyze the products that we sell and could negatively impact our operations. If our information technology systems suffer damage, disruption or shutdown and we do not effectively resolve the issues in a timely manner, our business, financial condition and results of operations may be materially and adversely affected, and we could experience delays in reporting our financial results. Due to the criticality of our sites to our business and operations, we are vulnerable to website downtime and other technical failures. Our failure, or a failure on the part of one of our vendors, to successfully respond to these risks could reduce sales and damage our reputation.

Coverage and Reimbursement Generally

The commercial success of Twirla and our other potential product candidates and our ability to commercialize any approved product candidates successfully will depend in part on the extent to which governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payors provide coverage for and establish adequate coverage of and reimbursement levels for our potential product candidates. Government authorities, private health insurers and other organizations generally decide which drugs they will pay for and establish reimbursement levels for healthcare. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government provides reimbursement through the Medicare or Medicaid programs for such products and services. In the United States, the E.U. and other potentially significant markets for our potential product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the E.U. will put additional pressure on product pricing, reimbursement and utilization, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical coverage and reimbursement policies and pricing in general. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Sales of Twirla and our potential product candidates will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our products will be paid by health maintenance organizations, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, such as Medicare and Medicaid, private health insurers and other third-party payors.

Third-party payors are increasingly imposing additional requirements and restrictions on coverage and limiting access to and reimbursement levels for medical products, including pharmaceuticals. For example, federal and state governments reimburse covered prescription drugs at varying rates generally below average wholesale price. These restrictions and limitations influence the purchase of healthcare services and products. Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication. Certain third-party payors routinely impose additional requirements before approving reimbursement of a prescription, including prior authorization and the requirement to try another therapy first. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our potential product candidates may not be considered medically necessary or cost-effective. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development for a product candidate. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our potential product candidates, exclusion of our potential product candidates

from coverage or the requirement for payment of increased manufacturer rebates on units dispensed. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce our revenues from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our potential product candidates in whole or in part.

Healthcare Reform

Legislative proposals to reform healthcare or reduce costs under government healthcare programs may result in lower reimbursement for Twirla and our potential product candidates or exclusion of Twirla and our potential product candidates from coverage. There have been a number of legislative and regulatory changes to the healthcare system that could affect our ability to profitably sell Twirla and our potential product candidates, if approved. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

Specifically, there have been recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, penalize companies that do not agree to cap prices paid for certain drugs, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for drugs. For example, in 2016, CMS issued a final rule regarding the Medicaid drug rebate program, which among other things, revises the manner in which the "average manufacturer price" or AMP is to be calculated by manufacturers participating in the program and implements certain amendments to the Medicaid rebate statute created under the ACA. More recently, Congress amended the Medicaid statute, effective October 1, 2019, to exclude prices paid by secondary manufacturers for an authorized generic drug from the NDA holder's AMP for the brand, thereby increasing the rebate amount and the 340B price for the brand. This was implemented by CMS in a final rule issued December 31, 2021. The rule also expanded the definition of products identified as "line extensions" and, in certain circumstances, required inclusion of patient copay assistance in Medicaid best price (effective January 1, 2023), thereby potentially increasing Medicaid rebates paid by manufacturers for such drugs. 340B program guidance regulations on civil monetary penalties for statutory violations, which had been finalized in early 2017 but deferred, also recently went into effect. On November 27, 2020, CMS issued an interim final rule implementing a Most Favored Nation payment model under which reimbursement for certain Medicare Part B drugs would be based on a price that reflects the lowest per capita Gross Domestic Product-adjusted (GDP-adjusted) price of any non-U.S. member country of the Organisation for Economic Co-operation and Development (OECD) with a GDP per capita that is at least sixty percent of the U.S. GDP per capita. This rule now has been rescinded, but similar programs have been described in recent legislative proposals. While we do not currently have any products available through Medicare, these and any additional healthcare reform measures could further constrain our business or limit the amounts that federal and state governments will pay for healthcare products and services, which could result in additional pricing pressures.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. The law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Litigation and legislation related to the ACA are likely to continue, with unpredictable and uncertain results.

In addition, in August 2011, President Obama signed into law the Budget Control Act of 2011, as amended, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. In concert with subsequent legislation, this has resulted in aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2031 (with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, due to the COVID-19 pandemic) unless additional congressional action is taken. While we do not currently have any products available through Medicare, these and other healthcare reform initiatives may result in additional reductions in Medicare and other healthcare funding, which could have a material

adverse effect on our financial operations. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could further limit the prices we are able to charge, or the amounts of reimbursement available, for our potential product candidates if they are approved.

Congress has indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The effective date for these changes was delayed by court order until January 1, 2023. Recent legislation further delayed implementation until January 1, 2032. Although a number of these, and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative measures to control drug costs.

At the state level, legislatures 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.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, imposes certain recordkeeping requirements and prohibits various categories of entities – including those which are "issuers" of securities on a US based exchange – and individuals from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates those companies whose securities are listed in the United States to comply with accounting provisions requiring the company to: 1) maintain books and records that, in reasonable detail, accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and 2) devise and maintain an adequate system of internal accounting controls sufficient to assure management's control, authority, and responsibility over the company's assets. Activities that violate either the anti-bribery or accounting provisions of the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight and debarment from government contracts.

Foreign Regulation

We currently have no plans to seek approval for Twirla outside of the United States. In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Research and Development

Conducting research and development is central to our business model. We have invested and expect to continue to invest significant time and capital in our research and development operations. Our research and development expenses were $2.2 million, $3.3 million and $6.2 million for the years ended December 31, 2023, 2022, and 2021, respectively.

In 2024, we expect to continue to incur research and development expenses as we prepare to conduct our post marketing obligations to the FDA.

Intellectual Property

We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover our Skinfusion® technology, its methods of use, related technologies and other inventions that are important to our business. As more fully described below, our patents and patent applications are directed to our Skinfusion technology or aspects thereof including certain transdermal delivery systems having an active adhesive matrix and methods of using such transdermal delivery systems for controlling fertility. We also rely on manufacturing trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will depend significantly on our ability to obtain new patents and maintain existing patents and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable patents and other proprietary rights of third parties.

A third party may hold intellectual property, including patent rights, which are important or necessary to the development of our potential product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our potential product candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms. If we were not able to obtain a license on commercially reasonable terms, our business could be harmed, possibly materially.

We plan to continue to expand our intellectual property estate by filing patent applications directed to novel and nonobvious transdermal contraceptive products. The active pharmaceutical ingredients, or API, in our potential product candidates are generic and therefore our patents do not include claims directed solely to the API. We anticipate seeking additional patent protection in the United States and internationally for additional transdermal delivery systems and their methods of use.

The patent positions of pharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and the patent's scope can be modified after issuance. Consequently, we do not know whether any of our potential product candidates will remain protected by enforceable and valid patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

Because patent applications in the United States and certain other jurisdictions generally are maintained in secrecy for 18 months, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of our entitlement to patent rights in the inventions covered in our issued patents and pending patent applications. Moreover, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office, USPTO, to determine priority of invention, or in post-grant challenge proceedings in the USPTO or foreign patent offices such as oppositions, reexamination, inter-partes review, post grant review, or a derivation proceeding, that challenge our entitlement to an invention or the patentability of one or more claims in our patent applications or issued patents. Such proceedings could result in substantial cost, even if the eventual outcome is favorable to us.

More specifically, Twirla is a transdermal contraceptive hormone delivery system. The system is a patch for application to the skin and contains two API, the hormones LNG, which is a synthetic progestin, and EE, a synthetic estrogen. The API are formulated with a combination of skin penetration enhancers, which promote penetration through the dermis and into the bloodstream, such that effective blood levels of the active agents are achieved to suppress ovulation and thereby prevent pregnancy.

In our Twirla product candidate line the active adhesive system consists of the active ingredients in a polyacrylate adhesive polymer matrix comprising the permeation enhancers dimethylsulfoxide, ethyl lactate, capric acid and lauryl lactate. The active blend is coated onto a release liner, and a backing layer is added on top of the active blend. The peripheral adhesive system comprising three layers, also called the overlay, is added onto the backing layer. The overlay comprises a polyisobutylene adhesive layer, an acrylic adhesive layer, and an overlay covering. The overlay covering is a commercially available silk-like polyester fabric. The adhesive components of the overlay, in addition to their adhesive function, create an *in situ seal* with the disposable release liner, trapping evaporable solvents in the active blend, thereby extending the usable shelf life of the product candidate and contributing to the comfort and effectiveness of the transdermal system during use. Prior to use of any of our potential product candidates, the release liner is removed by the user and discarded. The patch is then applied to the skin.

Three U.S. patents are listed in the FDA's Orange Book. Five other previously listed U.S. patents have now expired. Of those expired U.S. Patents, foreign counterparts have been granted and remain in force in China, Hong Kong, India, Israel and Mexico. Those patents are directed to the dried final product formulation used in Twirla and to methods of administration.

U.S. Patent Nos. 8,246,978, 8,747,888, and 9,050,348, currently listed in the Orange Book, are directed to structural features of the transdermal delivery system used in Twirla patch design for transdermal delivery of hormones or of other drugs. As such, these patents protect a platform technology for delivery of LNG, EE, other hormones, and other drugs. These patents expire in July and August 2028. Foreign counterparts have been granted in Australia, Brazil, Canada, Eurasia, Switzerland, Germany, Spain, France, United Kingdom, Hong Kong, Ireland, India, Italy, Japan, Netherlands, New Zealand and Japan.

U.S. Patent Nos. 9,198,876, 9,192,614, 9,198,919, 9,198,920, 9,775,847 and 9,782,419 and related patents and patent applications are directed to various novel dosing regimens, each of which employs transdermal delivery of contraceptive doses of EE and LNG during a "treatment interval" and transdermal delivery of low dose EE and low dose LNG during a "withdrawal interval". Foreign counterparts are granted in Europe and Canada. We expect these patents will be relevant to two of the products in our pipeline, AG200-SP and AG200-ER, as well as other new potential regimens. These patents expire in October 2029.

U.S. Patent No. 9,364,487 is directed to a composition and device for transdermal delivery of LNG for P-only therapy. The composition contains an anti-oxidant to protect the progestin against oxidative degradation caused by other components of the composition. Foreign counterparts are granted in Canada, Europe, Hong Kong, India, Japan and Mexico. Though not relevant to any current pipeline products, these patents may be useful for protection of future products. These patents expire in November 2032.

We have patent applications pending in the United States directed to novel formulations and methods designed to improve efficacy and modulate side effects of administration, as well as to provide personalized dosing based on body weight or BMI. Counterparts of these patent applications are pending or granted in certain foreign jurisdictions. We also have a pending United States patent application directed to packaging for transdermal systems containing certain skin permeation enhancers.

Regulatory Exclusivity

Our NDA for Twirla was submitted under Section 505(b)(2) of the FDCA. Even though Twirla utilizes API that were previously approved in the United States, Twirla utilizes LNG in a new dosage form, specifically a transdermal patch, and we provided new clinical data essential to approval in our NDA to establish the safety and efficacy of Twirla. Therefore, we received three years of U.S. marketing exclusivity for Twirla under the Hatch Waxman Act. Twirla's marketing exclusivity, which prohibited the FDA from approving ANDAs and 505(b)(2) NDAs for the conditions of the Twirla approval, expired on February 13, 2023.

Employees

As of December 31, 2023, we had 19 full time employees, including three in research and development and sixteen in selling, general and administrative roles. On August 16, 2023, Scott M. Coiante became our Senior Vice President, Chief Financial Officer ("CFO"). In connection with his appointment as CFO, Mr. Coiante entered into an employment agreement that outlined his initial annual base salary and his eligibility to participate in the Company's benefit and compensation plans, including the Company's annual bonus plan and the 2023 Equity Incentive Compensation Plan. None of our employees are represented by a labor union or subject to a collective bargaining agreement. We have not experienced a work stoppage and consider our relations with our employees to be good.

Corporate Information

We were incorporated in Delaware in December 1997. Our offices are located at 500 College Road East, Suite 310, Princeton, New Jersey 08540, and our telephone number is (609) 683-1880.

Available Information

Our corporate website address is www.agiletherapeutics.com. Information contained on or accessible through our website is not a part of this Annual Report on Form 10-K, and the inclusion of our website address in this annual report is an inactive textual reference only. We make our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the Securities and Exchange Commission, or SEC.

Since the aggregate market value of our voting stock held by non-affiliates was less than $250 million on June 30, 2023, we are a "smaller reporting company," as defined in Rule 12b-2 of the Exchange Act. As a "smaller reporting company" with less than $100 million in annual revenues we are a non-accelerated filer under the rules of the SEC, and an auditor attestation report over Internal Controls over Financial Reporting does not need to be included in the 2023 Form 10-K.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risk factors set forth below as well as the other information contained in this Annual Report on Form 10-K and in our other public filings in evaluating our business. Any of the following risks could materially and adversely affect our business, financial condition or results of operations. The risks described below are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently view to be immaterial may also materially adversely affect our business, financial condition or results of operations. In these circumstances, the market price of our common stock would likely decline.

Risks Related to Our Financial Position and Need for Capital

We have incurred operating losses in each year since our inception and we incurred losses every quarter in 2023. We may continue to incur substantial losses in the future if we are unable to generate positive cash flow from operations. Management has concluded that these factors raise substantial doubt about our ability to continue as a going concern.

We have incurred losses in each year since our inception in December 1997. Our net loss was $14.5 million, $25.4 million and $71.1 million for the years ended December 31, 2023, 2022 and 2021, respectively. As of December 31, 2023, we had an accumulated deficit of approximately $423.2 million. Our cash and cash equivalents will not be sufficient to fund our current and planned operations through the 12 months following the date on which this Annual Report on Form 10-K is filed, which raises substantial doubt about our ability to continue as a going concern. Substantial doubt about our ability to continue as a going concern may create negative reactions to the price of our common stock and we may have a more difficult time obtaining financing in the future.

Specialty pharmaceutical product development is a speculative undertaking, involves a substantial degree of risk and is a capital-intensive business. We expect to incur expenses without corresponding revenues until we are able to sell Twirla in significant quantities, which may not happen. We have devoted most of our financial resources to research and development, including our non-clinical development activities and clinical trials. We will require additional capital to fund our operating needs beyond April 2024, including among other items, the commercialization of Twirla and advancing the development of our other potential product candidates. We may not be able to obtain sufficient additional funding to continue our operations at planned levels and be forced to reduce, or even terminate, our operations. To date, we have financed our operations primarily through sales of common stock, convertible preferred stock and convertible promissory notes and to a lesser extent, through term loans and government grants.

We expect that our expenses will increase as we continue to commercialize Twirla. As a result, we expect to continue to incur substantial losses for the foreseeable future. We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Any failure to become and remain profitable could impair our ability to sustain operations and adversely affect the price of our common stock and our ability to raise additional capital. We are significantly dependent on the success of Twirla, and if we do not achieve the commercial success of Twirla and/or are unable to obtain additional funding, we will need to reassess our operating capital needs and may be unable to continue our operations at planned levels and be forced to reduce, or even terminate, our operations.

We will need to obtain additional financing to fund our operations and, if we are unable to obtain such financing, we may be unable to commercialize Twirla or resume development of our pipeline.

Our operations have consumed substantial amounts of cash since our inception. From our inception to December 31, 2023, we have cumulative net cash flows used by operating activities of $385.3 million. We will need to obtain additional capital to fund our future operations, including the commercialization of Twirla. We will need to obtain additional financing to resume development of our pipeline. Moreover, our fixed expenses such as rent, interest expense and other contractual commitments are substantial and are expected to increase in the future.

Our future funding requirements will depend on many factors, including, but not limited to:

- Our ability to successfully commercialize Twirla;
- Our ability to have commercial product successfully manufactured in compliance with FDA regulations;
- Amount of sales and other revenues from Twirla, including the selling prices and the availability of adequate third-party coverage and reimbursement;
- Our ability to control our operating expenses and inventory levels in relation to the revenue growth of Twirla;
- Our ability to meet our minimum purchase requirements under our supply agreement with Corium, our third-party manufacturer;
- Sales and marketing costs associated with commercializing Twirla, including the cost and timing of expanding our marketing and sales capabilities and infrastructure;
- Time and cost necessary to obtain regulatory approvals for our other potential product candidates that may be required by regulatory authorities;
- Progress, timing, scope and costs of our clinical trials and studies, including the ability to timely meet our PMR milestones;
- Terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;

- Cash requirements of any future acquisitions or pipeline development;
- Time and cost necessary to respond to technological and market developments;
- Costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- Costs associated with any potential business or product acquisitions, strategic collaborations, licensing agreements or other arrangements that we may establish;
- Costs associated with the commercial manufacturing process for Twirla and/or the establishment of a backup supplier; and
- Costs associated with the hiring of new employees and maintaining our contract sales force.

Our ability to fund our operations through the period of time necessary to successfully commercialize Twirla could be adversely affected based on the risks impacting our ability to successfully commercialize Twirla discussed above. Until we can generate a sufficient amount of revenue, we may finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances and marketing or distribution arrangements, some of which may (1) risk dilution of our current stockholders and/or (2) require us to relinquish valuable rights to our technologies, future revenue streams or potential product candidates or grant licenses on terms that may not be favorable to us. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

We may not be able to obtain sufficient additional funding to continue our operations at planned levels and be forced to reduce, or even terminate, our operations. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital when needed or on attractive terms, or if we are unable to enter into strategic collaborations, we then may be unable to complete the commercialization of Twirla and may also be required to further cut operating costs, delay, reduce or eliminate our research and development programs or future commercialization efforts or even terminate our operations, which may involve seeking bankruptcy protection. Our forecast of the period of time through which our financial resources will be adequate to support our operating requirements is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section. We have based this estimate on a number of assumptions that may prove to be wrong and changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. If we choose to accelerate any elements of our commercial plan or we encounter any unforeseen events that affect our business plan, we may choose to raise additional funds to provide us with additional working capital. Our inability to obtain additional funding when we need it could seriously harm our business and we may be unable to continue our operations at planned levels and be forced to reduce, or even terminate, our operations.

We have never been profitable. Currently, we have only one product available for commercial sale, Twirla, and we may never become profitable.

We have never been profitable and do not expect to be profitable in the foreseeable future. Except for Twirla, we have no other products currently available for commercial sale. To date, we have generated very limited revenue from product sales. As we commercialize Twirla, there can be no assurance that we will generate significant revenues or ever achieve profitability. Our ability to generate product revenue depends on a number of factors, including the risks related to our ability to commercialize Twirla discussed herein.

In addition, because of the numerous risks and uncertainties associated with product commercialization and pipeline development, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond our current expectations and resources if we are required to provide increased rebates to managed care payors, need to increase our manufacturing capacity sooner than planned, experience disruptions in our manufacturing capabilities, or need to alter our marketing strategy.

We anticipate incurring significant costs associated with the commercialization of Twirla. Our ability to become and remain profitable depends on our ability to generate revenue in excess of our increasing costs. Even accounting for revenues from the sale of Twirla, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or obtain additional funding or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations. In the event we are not able to continue operations at planned levels, we may not be able to meet manufacturing minimums under the Corium Agreement, which may delay or prevent our becoming profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise additional capital, expand our business or continue our operations.

Unstable global market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates and uncertainty about economic stability. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. Similarly, the current conflict between Ukraine and Russia has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including with respect to global supply chain and energy concerns. Any such volatility may have adverse consequences for us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive.

Risks Related to the Commercialization of Twirla

We are significantly dependent on the commercial success of Twirla, our only approved product. If we are unable to successfully commercialize Twirla, our business, financial condition, revenue, results of operations, and prospects and value of our common stock will be materially adversely affected.

Twirla is the first and only product that we are commercializing. The rest of our potential product candidates are in earlier stages of clinical development and will require additional product development, clinical studies and funding in order to advance towards commercialization, which could take considerable time. Our ability to generate revenues and become profitable will depend in large part on the commercial success of Twirla.

The commercial success of Twirla will depend upon (1) the hormonal contraceptive market landscape and (2) acceptance and uptake of Twirla by prescribers, patients and third-party payors. Risks related to the hormonal contraceptive market landscape include:

- The prescription contraceptive market could experience a decrease in growth or negative growth if fewer women choose to use hormonal contraception;
- Price pressures and decisions to deny reimbursement coverage from third party payors, including managed care organizations and government-sponsored health systems, could limit our revenue;
- The proportion of the hormonal contraceptive market comprised of generic products could continue to increase, making the commercialization of a branded contraceptive difficult and expensive and increasing costs associated with marketing and market access;
- The perceived safety of hormonal contraceptives could be negatively affected by media reports of adverse effects and advertisements for mass tort lawsuits due to adverse effects;

- Competition in the hormonal contraceptive market from existing branded or generic contraceptives, or as a result of the introduction of new contraceptives, including the potential of a new generic or branded competitive contraceptive patch;

- Healthcare reform activities, including, without limitation, the repeal, reform or replacement of the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010 or, collectively, the Affordable Care Act, or ACA, and its effects on pharmaceutical coverage, reimbursement and pricing, could limit our revenue.

Secondly, if Twirla does not gain an adequate level of acceptance among prescribers, patients and third-party payors, we may not generate significant product revenues or become profitable. Market acceptance of Twirla by prescribers, patients and third-party payors and our resulting ability to commercialize Twirla will depend on a number of factors, some of which are beyond our control, including:

- Availability of adequate coverage or reimbursement of Twirla by third parties, such as insurance companies and other payors, and by government healthcare programs, including Medicare, Medicaid and state health insurance exchanges;

- Our limited resources, personal promotion in limited markets and reliance on non-personal promotion in many markets;

- Efficacy, safety and other potential advantages of Twirla in relation to alternative treatments;

- Relative convenience, acceptability of use, and ease of administration of Twirla;

- Prevalence and severity of adverse events associated with Twirla;

- Willingness of prescribers to prescribe a contraceptive patch based on the labeling and prior safety experience with the generic contraceptive patch already on the market. *For more information regarding the prior safety and market experience with the prior patch see Part 1, Item 1, Contraceptive Patch Market Experience;*

- Openness among Planned Parenthood and other non-retail healthcare providers to make Twirla available to the patients they serve;

- Cost of Twirla in relation to alternative treatments, including generic products;

- Access to the prescriber universe, particularly obstetrics and gynecology physicians, and pharmacists (in states where they are permitted to prescribe) could be limited, decreasing our ability to promote Twirla efficiently;

- Our reliance on data from external, unverifiable sources of data and market research to estimate the size of the CHC market, the potential market opportunity for Twirla, and to identify healthcare providers most likely to prescribe Twirla;

- Extent and strength of our third-party manufacturer and supplier support and ability to meet our market demand;

- Extent and strength of our marketing and distribution support; and

- Dose, limitations, warnings, or contraindications contained in Twirla's FDA approved labeling, including safety warnings and precautions, contraindications and limitations on the use of Twirla for women based on BMI, and any potential revisions thereto.

For example, prescribers and patients may not be immediately receptive to a transdermal contraceptive system, as opposed to a pill or any other method, and may be slow to adopt it as an accepted treatment for the prevention of

pregnancy. We also may face unexpected competition. Upon approval by the FDA, we received three years of FDA marketing exclusivity for Twirla under the FDCA. This three-year marketing exclusivity expired on February 14, 2023. Thus, Twirla's protection from competition is derived solely through the Twirla patent and trade secret portfolio, and we cannot guarantee that we will be able to protect our intellectual property rights in the marketplace. *See Risks Related to Intellectual Property Rights*. Competition that Twirla and our potential product candidates may face from generic or similar versions of the same or similar products could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in Twirla or our potential product candidates.

If Twirla does not achieve an adequate level of acceptance by prescribers, third-party payors and patients, we may not generate sufficient revenue, we may not be able to achieve or sustain profitability, and the value of our common stock may be adversely impacted. Our efforts to educate prescribers, patients and third-party payors on the benefits of Twirla may require significant resources and may never be successful. Even if we are able to demonstrate and maintain a competitive advantage over our competitors and become profitable, if the market for hormonal contraceptives fails to achieve expected future growth or decreases, we may not be able to generate sufficient revenue or sustain profitability. Our ability to generate sufficient revenue from Twirla will also be dependent on our ability to support the commercial demand for Twirla and we cannot assure that we and Corium will be able to manufacture sufficient quantities of Twirla in order to meet commercial demand.

It will be difficult for us to profitably sell Twirla if third-party coverage and reimbursement for such product is limited, and reimbursement and healthcare containment initiatives and treatment guidelines may constrain our future revenues.

Market acceptance and sales of Twirla will depend on coverage and reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels for approved medications. A primary trend in the U.S. healthcare industry is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, including branded innovator products. We cannot be sure that coverage or reimbursement will be available for Twirla and, if coverage is available, we cannot be sure of the level of reimbursement. Even when a payor determines that a product is eligible for reimbursement, the payor may set a reimbursement rate that is too low to support a profitable sales price for the product. Subsequent approvals of competitive products could result in a detrimental change to the reimbursement of our products. Reimbursement may impact the demand for, or the price of, Twirla. Numerous generic products may be available at lower prices than branded therapy products, such as Twirla, which may also reduce the likelihood and level of reimbursement for Twirla.

If we are unable to develop effective marketing and sales capabilities for Twirla or maintain our agreements with third parties to market and sell Twirla, we may be unable to generate product revenues.

At present, we have a limited number of marketing personnel and rely on a contract sales organization, or CSO, in the United States. In April 2020, we entered into an agreement with inVentiv Commercial Services, a Syneos Health group company, to provide a contract sales force and related sales services for Twirla, and they have been detailing Twirla to health care providers through both live and virtual meetings.

We cannot guarantee that we will be successful in marketing Twirla in the United States. We may not be able to continue to develop our own marketing capabilities or a contract sales force in a cost-effective manner or realize a positive return on this investment. In addition, we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize Twirla in the United States include:

- Our or our contractor's inability to recruit and retain adequate numbers of effective sales and marketing personnel;

- The ability of sales personnel to obtain access to or persuade adequate numbers of prescribers to prescribe Twirla, which has been and may continue to be influenced by the COVID-19 pandemic;

- The lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;

- The costs associated with training sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;

- Liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements;

- Unforeseen costs and expenses associated with creating an independent sales and marketing organization or partnering with our contract sales organization, including difficulty managing the growth that both of these activities would require; and

- Our ability to obtain the revenue or financing necessary to meet our contractual obligations to our CSO, with the potential result that our sales force could be recalled by the CSO.

If we are not successful in retaining sales and marketing personnel or in continuing to build and maintain a sales and marketing infrastructure, or if we do not successfully enter into appropriate collaboration arrangements, we could have difficulty commercializing Twirla, which could adversely affect our business, operating results, financial condition, and value of our common stock.

To the extent that we rely on, or partner with, third parties to commercialize Twirla, we may receive less revenue than if we commercialized these products ourselves. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts. We, however, will remain responsible for the conduct of any contract sales force, which could expose us to legal and regulatory enforcement actions and liability. In the event that we are unable to partner with a third-party marketing and sales organization, our ability to generate product revenues may be limited.

Twirla could develop unexpected safety, efficacy or quality concerns, which would likely have a material adverse effect on us.

Twirla was approved in the U.S. based on the SECURE clinical trial, in which patients were enrolled for 13 cycles of treatment. Twirla will now be used by larger numbers of patients, potentially for longer periods of time, and we and others (including regulatory agencies and private payors) will endeavor to collect extensive information on the efficacy and safety of Twirla by monitoring its use in the marketplace. In addition, we will endeavor to conduct the PMR. New safety, efficacy, or dosing data from both market surveillance and our post-marketing clinical trials may result in negative consequences including:

- Modification to product labeling or promotional statements, such as additional boxed or other warnings contraindications, or limitations, or the issuance of “Dear Doctor Letters” or similar communications to healthcare professionals or the public regarding safety, efficacy, or other concerns;

- Imposition of additional post-marketing clinical trial requirements, distribution restrictions or other risk management measures, such as a risk evaluation and mitigation strategy, REMS, which could include elements to assure safe use;

- Suspension or withdrawal of regulatory approval;

- Suspensions or termination of ongoing clinical trials or refusal by regulators to approve pending marketing applications or supplements to approved applications;

- Suspension of, or imposition of restrictions on, our operations, including costly new manufacturing requirements with respect to Twirla;
- Costly and time-consuming corrective actions; and
- Voluntary or mandatory product recalls or withdrawals from the market and costly product liability claims.

Furthermore, the discovery of significant problems with a product similar to Twirla that implicate (or are perceived to implicate) the entire class of products could have an adverse impact on our ability to commercialize Twirla. Any of these circumstances could reduce Twirla's market acceptance and could inhibit or delay our ability to commercialize Twirla or gain and/or sustain market share, any of which could adversely affect sales of Twirla.

Sales of Twirla may be adversely affected by the consolidation among wholesale drug distributors and the growth of large retail drug store chains.

The network through which we will sell Twirla and our potential product candidates, if and when approved, has undergone significant consolidation marked by mergers and acquisitions among wholesale distributors and the growth of large retail drugstore chains. As a result, a small number of large distributors control a significant share of the market. In 2021, three companies generated about 95% of all revenues from drug distribution in the United States, and the top five chain pharmacy companies owned about 54% of all retail pharmacy outlets. Consolidation of drug wholesalers and retailers, as well as any increased pricing pressure that those entities face from their customers, including the U.S. government, may increase pricing pressure and place other competitive pressures on drug manufacturers, including us.

Existing and future legislation may increase the difficulty and cost for us to commercialize Twirla and may affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could restrict or regulate post-approval activities and affect our ability to profitably sell Twirla. In addition, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA's regulations, guidance or interpretations will change, or what the impact of such changes on our ability to market Twirla may be.

In March 2010, President Obama signed into law the ACA. Of particular relevance to our business is the ACA requirement that all health plans, with limited exceptions, cover certain preventive services for women with no cost-sharing, which means no deductible, no co-insurance and no co-payments by the patient – including contraceptive methods, known as the contraceptive mandate. *For discussion on the ACA requirements for contraceptive coverage and applications to Twirla, see Part 1, Item 1, Pricing and Reimbursement and Part 1, Item 1, Government Regulation.* The ACA appears likely to continue to apply pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. There are several proposals to reform the federal healthcare laws being advocated and it is still unclear whether such reform efforts will succeed and if so, which proposals will ultimately be successful. Further, the Biden administration may choose to change or reverse regulatory decisions made by the previous administration. Therefore, it is difficult to determine the full effect of the ACA or any other healthcare reform efforts on our business. Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Litigation and legislation related to the ACA are likely to continue, with unpredictable and uncertain results.

Consistent with precedent, we expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of Twirla and our potential product candidates and reduce our profitability.

Other measures – such as provisions of the Medicare Modernization Act that would allow importation of drugs from Canada – have also been taken by Congress, the previous administration, and administrative agencies to increase drug competition and thus, decrease drug prices. At the state level, legislatures 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. New legislative and regulatory efforts could ultimately have an adverse impact on our business and results of operation.

Risks Relating to Maintaining Regulatory Compliance and Approval of Twirla

We remain subject to substantial ongoing regulatory requirements related to Twirla, and failure to comply with these requirements could lead to penalties, including withdrawal from the market, suspension, or withdrawal of product approval.

Twirla is subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, import, export, safety surveillance, advertising, marketing promotion, recordkeeping, reporting of adverse events and other post-market information, and further development, including ongoing requirements for costly post-marketing studies, including Phase 4 studies or post-market surveillance. For more information about the planned Phase 4 studies for Twirla, *see Part 1, Item 1, Twirla*. The results generated in these post-approval clinical trials and studies could result in loss of marketing approval, changes in product labeling, or new or increased concerns about side effects or efficacy of a product. Failure to comply with post-market study requirements can also result in different enforcement actions.

Post-approval requirements include registration with the FDA, listing of our drug products, payment of annual fees, as well as continued compliance with cGCPs for any clinical trials that we conduct post-approval. Application holders must notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product manufacturing changes. In addition, manufacturers of drug products and their facilities are subject to continual review and routine inspections by the FDA and other regulatory authorities for compliance with the FDA's manufacturing requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. If we are found to be noncompliant with applicable requirements, we may be subject to different enforcement actions.

In addition, our product labeling, advertising and promotional materials for Twirla will be subject to regulatory requirements and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. The FDA strictly regulates the promotional claims that may be made about prescription products, and the FDA has requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, a practice known as off-label promotion. Engaging in the impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes. If we or any third parties contracted to promote our product on our behalf are found to have promoted such off-label uses, we may become subject to significant liability, government fines, civil and criminal penalties, and other enforcement actions. The FDA and other agencies actively enforce 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 sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices promoting off-label drug uses involving fines that are as much as $3.0 billion.

If we or a regulatory agency discover previously unknown problems with Twirla, such as adverse events of unanticipated severity or frequency, data integrity issues with regulatory filings, advertising and promotion, problems with the facility where the product is manufactured or we or our manufacturers or others working on our behalf fail to comply with applicable regulatory requirements after marketing approval, we may be subject to reporting obligations as well as enforcement actions, such as Warning Letters, Cyber Letters, Untitled Letters, consent decrees, corporate integrity agreements, clinical holds or termination of clinical trials, criminal and civil penalties, including imprisonment, suspensions or impositions of restrictions on operations such as costly new manufacturing requirements or product seizures or detentions.

We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act and similar state laws, which impact, among other things, our proposed sales, marketing and scientific/educational efforts. Federal criminal statutes also prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. We are also subject to complex laws and regulations regarding reporting and payment obligations due to our participation in government drug programs. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and drug pricing; and state laws, such as the California Consumer Privacy Act, 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 federal law, thus complicating compliance efforts.

The occurrence of any event or penalty described herein may inhibit our ability to commercialize Twirla and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations are costly. Compliance with these and other federal and state laws applicable to the sale, marketing, and distribution of commercial drug products will require that we expend time and financial resources to maintain compliance, and it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations.

Risks Related to Manufacturing and Our Reliance on Third Parties

We have no manufacturing capacity and anticipate continued reliance on Corium, our third-party manufacturer, for the commercialization of Twirla and development of our potential product candidates, as a sole source provider. We may not have or be able to obtain sufficient quantities of Twirla or our potential product candidates to meet our required supply for commercialization or clinical trials. Alternatively, we may not realize the commercial demand for Twirla necessary to meet our obligations to Corium. Either of these events could materially harm our business.

We rely on Corium, our third-party manufacturer, to produce commercial supplies and samples of Twirla. We have no back-up or alternative manufacturer of Twirla. We do not own or operate, and have no plans to establish, any manufacturing facilities for Twirla. We lack the resources and the capabilities to manufacture Twirla or any of our potential product candidates on a commercial or clinical scale.

As a third-party manufacturer, Corium's business operations are completely beyond our control, and we have no influence over whether Corium changes its management or its business operations or discontinues them entirely. Furthermore, we do not control the manufacturing process of Twirla. Corium or other contract manufacturers that we may use are subject to routine inspection by regulatory authorities, including the FDA. If our contract manufacturer cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, they may receive adverse inspectional findings, may need to undertake costly and time-consuming corrective actions, and may not be able to maintain regulatory approval for their manufacturing facilities and may expose us to

enforcement actions. If the FDA withdraws its approval of Corium's facilities for the manufacture of Twirla, or if Corium experiences quality or other regulatory issues, we may need to find alternative manufacturing facilities that would also require FDA approval, which would significantly impact our ability to develop and sustain our market share of Twirla.

Corium may experience issues in the manufacturing process for Twirla. The custom machinery used to manufacture Twirla could malfunction at any time, creating a delay in manufacturing as Corium secures replacement parts, repairs and revalidates the equipment and manufacturing process, or, if the equipment cannot be repaired, we seek to secure alternative third-party manufacturers. Any such delays could limit our ability to meet commercial demand for Twirla, or to do so at an acceptable cost, either of which could delay, prevent, or impair the commercialization of Twirla.

Although we have manufacturing agreements with Corium for the commercial supply of Twirla, Corium and several of its suppliers of raw materials will likely be single source providers to us for a significant period of time. In particular, Corium manufactures Twirla using EE and LNG and components that it purchases from third parties, most of which are single source suppliers of the applicable material. We do not have any control over the process or timing of the acquisition of these raw materials by Corium or over whether any of these single-source supplies decide to suspend or cease production of raw materials. Corium's failure to timely obtain, or a disruption in the supply of, these raw materials could lead to an inability to adequately supply the commercial market with finished product of Twirla and in turn adversely affect our business.

Because we outsource all of our manufacturing processes, there is no guarantee that there will be sufficient supplies to fulfill our requirements or that we may obtain such supplies on acceptable terms. In addition, we are required to meet quantity minimums under our supply agreement with Corium. We may not realize sufficient commercial demand for Twirla to meet these obligations, which may result in periodic delays in the manufacturing process, penalty payments, or termination of the agreement. For example, during 2021, we did not meet all of our minimum quantity purchases from Corium, and as a result, paid penalties as defined in the contract. In July 2022, we amended the Corium Agreement to restructure the minimums applicable to the purchase of manufactured Twirla, defined as minimum revenue requirements. In the event we do not meet the guaranteed minimum revenue requirements in any given year, we will be required to make additional payments to Corium for the shortfall. If it becomes necessary to engage an additional third-party manufacturer to produce Twirla, we may need to license certain manufacturing know-how from Corium, and our commercial supply will be limited while the new third-party manufacturer develops the necessary know-how to manufacture Twirla and while we obtain regulatory approval for the addition of a new manufacturer and processes.

If Corium or any third-party manufacturer with whom we contract fails to perform its obligations or if our relationship is terminated for any reason, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different third-party manufacturer, which we may not be able to do on reasonable terms, if at all. In either scenario, our commercial supply of Twirla and clinical trials supply for other potential product candidates could be delayed significantly as we establish alternative supply sources in accordance with FDA regulations and requirements, which we may be unable to do expediently or without conducting additional studies, if at all. The delays associated with the verification of a new contract manufacturer could negatively affect our ability to commercialize our products, including Twirla, and to develop our other potential product candidates.

We rely on third parties to conduct aspects of our clinical trials and post marketing studies. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with applicable regulatory requirements, we may not be able to maintain regulatory approval for Twirla or develop our pipeline.

We currently rely and plan to continue to rely on CROs and clinical trial sites for most aspects of our post-marketing study and any other clinical trials of our potential product candidates, such as trial conduct, data management, statistical analysis and electronic compilation of our FDA submission. We may enter into agreements with additional CROs and clinical trial sites to obtain additional resources and expertise in an attempt to accelerate our progress with regard to new or ongoing clinical and preclinical programs, which involves substantial cost and requires extensive management time and focus. Delays may occur, which may materially impact our ability to meet our desired post-marketing and clinical development timelines and ultimately have a material adverse impact on the commercialization of Twirla, our ability to maintain our marketing authorization for Twirla, our operating results, financial condition or future prospects. For

example, we have engaged the services of a CRO to design, conduct, and complete the PMR database study, which will require substantial time and resources. If the CRO cannot obtain the necessary sample for the database and complete the study in a timely manner, we may be unable to meet study milestones and may fail to complete the study required by the FDA and subsequently may lose our marketing authorization for Twirla or be subject to other enforcement actions, and be forced to suspend commercial activities regarding the product.

As CROs and clinical investigators are not our employees, we cannot control whether or not they devote sufficient time and resources to our clinical trials for which they are engaged to perform, and whether they comply with the applicable regulatory requirements, including requirements related to the conduct of the study, subject informed consent, and IRB approval. If the CROs or clinical trial sites we engage do not successfully carry out their contractual duties or obligations, conduct the clinical trials in accordance with all regulatory requirements and the applicable protocols, or meet expected deadlines, or if they need to be replaced, or the quality or accuracy of the data they provide is compromised due to a failure to adhere to regulatory requirements or for other reasons, then our development programs may be extended, delayed or terminated, we may not be able to obtain marketing approval for or successfully commercialize our potential product candidates, or we may not be able to meet our post-market study requirements. Failure to comply with clinical trial regulatory requirements may further subject us to enforcement actions. As a result, our financial results and the commercial prospects for Twirla or our potential product candidates could be harmed, and our costs could increase.

We may rely on third parties to perform many essential services for any products that we commercialize, including, but not limited to, services related to government price reporting, customer service, accounts receivable management, cash collection, and pharmacovigilance and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize our potential product candidates will be significantly impacted and we may be subject to regulatory sanctions.

We may retain third-party service providers to perform a variety of functions related to Twirla, key aspects of which will be out of our direct control. These service providers may provide key services related to customer service, accounts receivable management, cash collection, pharmacovigilance and adverse event reporting, safety database management, and related services. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical or natural damage at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired and we may be subject to enforcement actions.

We may further contract with a third party to calculate and report pricing information mandated by various government programs. If a third party fails to timely report or adjust prices as required, or errors occur in calculating government pricing information from transactional data in our financial records, it could impact our discount and rebate liability, and potentially subject us to regulatory sanctions or False Claims Act lawsuits.

Risks Related to Intellectual Property Rights

We may not be able to protect our proprietary technology in the marketplace.

We depend on our ability to protect our proprietary technology. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability and any future licensee's ability to maintain our patents and to obtain additional patent protection in the United States and other countries with respect to our proprietary technology and products. If we are compelled to spend significant time and money protecting or enforcing our patents, designing around patents held by others or licensing or acquiring, potentially for large fees, patents or other proprietary rights held by others, our business and financial prospects may be harmed. If we are unable to effectively protect the intellectual property that we own, other companies may be able to offer for sale the same or similar products containing the generically available active pharmaceutical ingredients in Twirla and our potential product candidates, which could materially adversely affect our competitive business position and harm our business prospects.

Our patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing the same or similar products or limit the length of the term of patent protection that we may have for our potential product candidates. Even if our patents are unchallenged, they may not adequately protect our intellectual property, provide exclusivity for our potential product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The patent positions of pharmaceutical products are often complex and uncertain. The breadth of claims allowed in pharmaceutical patents in the United States and many jurisdictions outside of the United States is not consistent, and the breadth and strength of our patents may not be sufficient to prevent competition from similar or identical products. For example, in many jurisdictions the support standards for pharmaceutical patents are becoming increasingly strict. Some countries prohibit method of treatment claims in patents. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or create uncertainty. In addition, publication of information related to our current product and pipeline products may prevent us from obtaining or enforcing patents relating to this product and pipeline products, including without limitation transdermal delivery systems and methods of using such transdermal delivery systems. Our product and pipeline products contain generically available active pharmaceutical ingredients. As a result, new chemical entity patents directed to the active pharmaceutical ingredients in our product and pipeline products, which are generally believed to offer the strongest form of patent protection, are not available.

We may infringe the intellectual property rights of others, which may prevent or delay our commercialization and product development efforts or increase the costs of commercializing Twirla, or our potential product candidates, when and if approved.

Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. For example, there could be issued patents of which we are not aware that Twirla or our current or future potential product candidates infringe. There also could be patents that we believe we do not infringe, but that we may ultimately be found to infringe.

Third parties may assert that we are employing their proprietary technology without authorization and may sue us for patent or other intellectual property infringement or misappropriation. Third parties could similarly claim that our employees, consultants, or contractors have misappropriated their intellectual property, including know-how or trade secrets of a third party, in violation of nondisclosure agreements or noncompete agreements in place with the third party. These lawsuits are costly and could adversely affect our results of operations and divert the attention of managerial and scientific personnel. If we are sued for patent infringement, we would need to demonstrate that our product, potential product candidates or methods either do not infringe the claims of the relevant patent or that the patent claims are invalid or unenforceable, which is difficult and which we may not be able to do, and even if successful will result in substantial costs and time, which could have a material adverse effect on us. Successful third-party claims could block our ability to commercialize Twirla or potential product candidates, if approved, and could result in liability and monetary damages, any of which could materially harm our business.

Any lawsuits relating to infringement of intellectual property rights brought by or against us will be costly and time consuming and may adversely impact the price of our common stock.

We may be required to initiate litigation to enforce or defend our intellectual property rights. These lawsuits can be very time consuming and costly. There is a substantial amount of litigation involving patent and other intellectual property rights in the pharmaceutical industry generally. Such litigation or proceedings, if we have the time and/or resources to pursue them, could substantially increase our operating expenses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Any recovery may not be commercially valuable, and our confidential information and trade secrets may become publicly available during the course of litigation discovery.

In infringement litigation, any award of monetary damages we receive may not be commercially valuable. There can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims,

which typically last for years before they are resolved. Further, any claims we assert against a perceived infringer could provoke these parties to assert counterclaims against us alleging that we have infringed their patents. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the market price of our common stock.

Risks Related to Our Business Operations and Industry

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive pharmaceuticals industry depends in large part upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel. Competition for skilled personnel in our market is intense and competition for experienced personnel may limit our ability to hire and retain highly qualified personnel on acceptable terms. We are highly dependent on our management, scientific and medical personnel. In order to induce valuable employees to remain with us, we have provided these employees with stock options that vest over time. The value to employees of stock options that vest over time is significantly affected by movements in our stock price that we cannot control and may at any time be insufficient to counteract more lucrative offers from other companies. Additionally, at times, we have also implemented programs that included cash retention bonuses and/or restricted stock units as incentives to retain employees.

Despite our efforts to retain valuable employees, members of our management, scientific and medical teams may terminate their employment with us on short notice. We have employment agreements with our named executive officers which includes Alfred Altomari, our Chairman and Chief Executive Officer. The employment agreements provide for at-will employment, which means that Mr. Altomari or any of our other employees could leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results or financial condition. In particular, we believe that the loss of the services of Mr. Altomari may have a material adverse effect on our business. We do not currently carry “key person” insurance on the lives of members of executive management.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of Twirla.

We face potential risks of product liability as a result of the clinical testing and commercial availability of Twirla and the clinical testing of our other potential product candidates. For example, we may be sued if Twirla or any potential product candidate we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization or development of the product or potential product candidate subject to such claims. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in a decreased demand for Twirla or any future potential product candidates that we may develop, injury to our reputation, withdrawal of clinical trial participants, a diversion of management’s time and our resources, substantial monetary awards to trial participants or patients, product recalls or withdrawals, loss of revenue, the inability to

commercialize Twirla or our potential product candidates, if approved, or a decline in our stock price, among other negative impacts.

We have obtained limited product liability insurance coverage for Twirla and our clinical trials with a $10.0 million annual aggregate coverage limit. Although we maintain such insurance, 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.

Business interruptions, including those resulting from systems failures or cyber-attacks, could delay us in the process of developing our potential product candidates and could disrupt our sales.

Our headquarters are located in Princeton, New Jersey, and Corium, our contract manufacturer, is located in Grand Rapids, Michigan. We are vulnerable to natural disasters, such as severe storms and other events that could disrupt our or Corium's operations. We do not carry insurance for natural disasters, and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. In addition, despite the implementation of security measures, our internal computer systems, and those of other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, terrorism, war and telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. Any losses or damages we incur could have a material adverse effect on our business operations. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further commercialization of Twirla and/or development of our potential product candidates could be delayed.

See Part I, Item 1C, Cybersecurity, in this Annual Report on Form 10-K for more information regarding our cybersecurity risk management, strategy, and governance.

Our employees, independent contractors, principal investigators, CROs, manufacturers, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could significantly harm our business.

We are exposed to the risk that employees, independent contractors, principal investigators, CROs, manufacturers, consultants, commercial partners and vendors may engage in fraudulent or other illegal activity, fraud or other misconduct. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the law and regulations of the FDA and non-U.S. regulators, including those laws that require the reporting of true, complete and accurate information to the FDA and non-U.S. regulators, (ii) healthcare fraud and abuse laws and regulations in the United States and abroad and (iii) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations 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 in violation of these laws may also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter misconduct by our employees and other third 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 these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including enforcement actions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments may be limited by provisions of the Internal Revenue Code of 1986, as amended, and may be subject to further limitation as a result of our initial public offering.

Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, contain rules that limit the ability of a company that undergoes an ownership change, which is generally any change in ownership of more than 50% of its stock over a three-year period, to utilize its net operating loss and tax credit carryforwards and certain built-in losses recognized in years after the ownership change. These rules generally operate by focusing on ownership changes involving stockholders owning, directly or indirectly, 5% or more of the stock of a company and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change occurs, the yearly taxable income limitation on the use of net operating loss and tax credit carryforwards and certain built-in losses is equal to the product of the applicable long-term tax-exempt rate and the value of the company's stock immediately before the ownership change. We may be unable to offset future taxable income, if any, with losses, or our tax liability with credits, before such losses and credits expire and therefore would incur larger federal income tax liability. Our net operating loss carryforwards arising in taxable years ending on or prior to December 31, 2017 will expire between 2024 and 2037 if we have not used them. Net operating loss carryforwards arising in taxable years ending after December 31, 2017 are no longer subject to expiration under the Code.

In addition, it is possible that the transactions relating to our initial public offering or subsequent public offerings, either on a standalone basis or when combined with future transactions, have caused us to undergo one or more additional ownership changes. In that event, we generally would not be able to use our pre-change loss or credit carryovers or certain built-in losses prior to such ownership change to offset future taxable income in excess of the annual limitations imposed by Sections 382 and 383 of the Code. We have not completed a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since our inception.

Risks Related to Ownership of Our Common Stock

We are now listed on the OTC markets, which could affect our common stock's market price and liquidity and reduce our ability to raise capital.

On March 22, 2024, we received notice from The Nasdaq Stock Market LLC that the Nasdaq Hearings Panel has determined to delist our common stock. Suspension of trading in our common stock was effective at the open of trading on March 26, 2024. Following the delisting of our common stock from the Nasdaq Capital Market, we will continue to be a reporting company under the Securities Exchange Act of 1934. Our common stock commenced trading on the OTC Markets Group ("OTC") platform at the open of trading on March 26, 2024 under the symbol "AGRX." We have applied for trading on the OTC-QB market.

We have a period of 15 days from the date of the notice letter to submit a written request for a review of the Nasdaq Hearings Panel's delisting determination by the Nasdaq Listing and Hearing Review Council (the "Listing Council"). We do not plan to appeal the Nasdaq Hearings Panel's determination and expect that a Form 25-NSE will be filed with the Securities and Exchange Commission ("SEC"), which would remove our common stock from listing and registration on Nasdaq.

Trading of our common stock on the OTC could make it more difficult to buy or sell our securities and to obtain accurate quotations, and the price of our securities could suffer a material decline. Delisting from Nasdaq could also impair our ability to raise capital. Delisting by Nasdaq could negatively impact the Company as it would likely reduce the liquidity and market price of the Company's common stock, reduce the number of investors willing to hold or acquire the Company's common stock, negatively impact the Company's ability to access equity markets and obtain financing, and impair the Company's ability to provide equity incentives.

We expect that our stock price may fluctuate significantly.

The trading price of our common stock is highly volatile and is subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this annual report, these factors include:

- Actual or anticipated fluctuations in our financial condition and operating results;
- Actual or anticipated changes in our growth rate relative to our competitors;
- Announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- Failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- Issuance of new or updated research or reports by securities analysts, including reports that downgrade our common stock, issue unfavorable commentary, or analyst decisions to stop reporting on us or our business;
- Fluctuations in the valuation of companies perceived by investors to be comparable to us;
- Share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- Announcement or expectation of additional debt or equity financing efforts;
- Sales of our common stock by us, our insiders or our other stockholders; and
- General economic and market conditions.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and the OTC and the stock prices of pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Raising additional capital may cause dilution to our existing stockholders or restrict our operations.

We will need to seek additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations. The sale of additional equity or convertible debt securities could result in the issuance of additional shares of our capital stock and could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing research and development efforts and could be forced to limit funding of our efforts to commercialize Twirla. This could harm our business, operating results and financial condition and cause the price of our common stock to fall.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation, which could result in substantial costs and diversion of management's attention and resources, which could adversely impact our business. Any adverse determination in litigation could also subject us to significant liabilities.

We have never paid monetary dividends on our common stock, and we do not anticipate paying any dividends in the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases.

We have not paid monetary dividends on our common stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions:

- Authorize the issuance of preferred stock which can be created and issued by the board of directors without prior stockholder approval, with rights senior to those of our common stock;
- Provide for a classified board of directors, with each director serving a staggered three-year term;
- Prohibit our stockholders from filling board vacancies, calling special stockholder meetings or taking action by written consent;
- Provide for the removal of a director only with cause and by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of our directors;
- Define the number of holders of the shares outstanding of our capital stock needed to constitute a quorum for the transaction of business at the meeting of stockholders as one-third;
- Require advance written notice of stockholder proposals and director nominations; and
- Require any action instituted against our officers or directors in connection with their service to the Company to be brought in the state of Delaware.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including a merger, tender offer or proxy contest involving our company. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

We incorporate assessment of our cybersecurity risk management and strategy into our overall management of enterprise risk. The Company evaluates cybersecurity threat risk areas across its business including, but not limited to, operational risk, fraud, harm to employees or third parties, patient safety and violation of privacy or security-related laws or regulations. The Company has a Compliance Committee that is responsible for overseeing the enterprise risk management process. As part of our efforts to mitigate cybersecurity threats, we have implemented cybersecurity

processes, technologies, and controls designed to effectively identify and manage potential material cybersecurity threats.

Assessment, Identification and Risk Management of Cybersecurity Threats

We employ a range of tools and services, including regular network and endpoint monitoring, managed detection and response, system patching, managed security services, server and endpoint scheduled backups, awareness training and testing, periodic vulnerability assessment and penetration testing, to update our ongoing risk management and strategy. Furthermore, we have a cybersecurity assessment process that is conducted regularly with our current information technology (IT) services provider. -We proactively engage with our IT services provider as part of our continuing efforts to evaluate and enhance the effectiveness of our information security policies and procedures. We also have used an additional third-party services provider to perform internal and external penetration testing and social engineering employee challenge testing.

Governance and Oversight of Cybersecurity Threats

Our information security program is managed by our Chief Corporate Planning and Supply Chain Officer (CCPO), who has more than ten years' experience managing IT services for Agile and possesses the required subject matter expertise, skills, and experience expected of an individual assigned to these duties. Our information security team, which includes the CCPO as well as additional professionals from our IT services provider, is responsible for leading enterprise-wide cybersecurity threat strategy, policy, standards, and processes. Our CCPO provides regular updates to our Chief Executive Officer and other members of management regarding cybersecurity threats and participates in the quarterly Compliance Committee meetings.

The Audit Committee is responsible for oversight of the Company's cybersecurity risk exposure. The CCPO provides reports to the Audit Committee and Board at least annually, which include updates on the Company's cybersecurity risks and threats, the status of projects to strengthen our information security systems, assessments of the information security program, and the emerging cybersecurity threat landscape.

Incident Response and Reporting

The Company has a cybersecurity policy that governs the corporate response to and communication of security incidents affecting the Company's information technology system and stresses the need for fast response times and continuous improvement in security measures. The policy requires immediate reporting of any observed security incident to the CCPO, the Company's third-party IT services provider, Chief Financial Officer, and Chief Executive Officer. The CCPO, working with our IT services provider and any other third parties required, is responsible for taking steps to minimize loss and destruction, identify and correct any weakness that was exploited, restoring IT services and continuing to communicate to senior management and the Board on the event. The CCPO is authorized to employ any third-party service providers as necessary. The policy also requires the conduct of post-incident analyses, reporting on the incident, identification of lessons learned and a close-out report.

Oversight of Third-Party Providers

Prior to doing business with third-party providers or suppliers with access to our network, systems or data or a third party providing cybersecurity support or infrastructure, we assess and evaluate their cybersecurity preparedness. Our assessment of cybersecurity threats associated with our third-party providers is part of our overall cybersecurity risk management framework.

Impact of Cybersecurity Threats on our Business

Although risks from cybersecurity threats did not, to our knowledge, materially affect our business strategy, results of operations, or financial condition for the fiscal year ended December 31, 2023, we may not be successful in preventing or mitigating a cybersecurity incident that could have a material adverse effect on us. See Part I, Item 1, Business, in this Annual Report for a discussion of notification obligations and potential liability around data security incidents, including cyberattacks.

Item 2. Properties

Our principal offices occupy approximately 13,775 square feet of leased office space in Princeton, New Jersey pursuant to a lease agreement that expires in March 2025. We believe that our current facilities are suitable and adequate to meet our current needs.

Item 3. Legal Proceedings

None.

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 and Holders of Record

Our common stock was listed on the Nasdaq Global Market under the symbol "AGRX" from May 23, 2014 through January 2, 2019. From January 3, 2019 to March 25, 2024, our common stock was listed on the Nasdaq Capital Market under the symbol "AGRX". Beginning on March 26, 2024, our common stock is trading on the "over-the-counter" market operated by the OTC Markets Group under our existing "AGRX" trading symbol. We have applied for trading on the OTC-QB market.

As of March 27, 2024, we had 13 holders of record of our common stock. The actual number of shareholders is greater than this number of record holders and includes shareholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. The number of holders of record also does not include shareholders whose shares may be held in trust by other entities. The closing price of our common stock on March 27, 2024 was $0.37.

Dividends

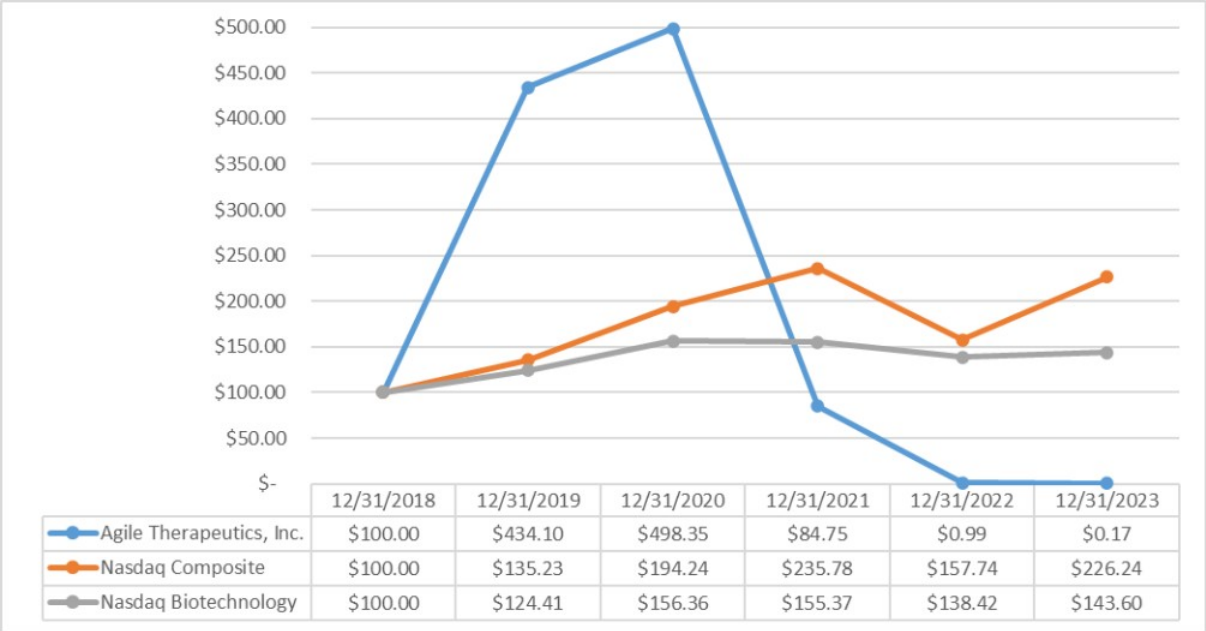
We have never declared or paid a cash dividend on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. Subject to such restrictions, any future determinations to pay cash dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend on a number of factors, including our financial condition, results of operations, capital requirements, contractual restrictions, general business conditions, and any other factors that our board may deem relevant.

Stock Performance Graph

This performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Exchange Act or the Securities Act of 1933, as amended.

The following graph shows a comparison from December 31, 2018 through December 31, 2023 of the cumulative total return for our common stock, and the Nasdaq Composite Index and The Nasdaq Biotechnology Index. The graph assumes that $100 was invested at the market close on December 31, 2018 in the common stock of Agile Therapeutics, Inc., the Nasdaq Composite Index and The Nasdaq Biotechnology Index and assumes reinvestments of dividends. The stock price performance of the following graph is not necessarily indicative of future stock price performance.

Comparison of Cumulative Total Return
December 31, 2023



	12/31/2018	12/31/2019	12/31/2020	12/31/2021	12/31/2022	12/31/2023
Agile Therapeutics, Inc.	$100.00	$434.10	$498.35	$84.75	$0.99	$0.17
Nasdaq Composite	$100.00	$135.23	$194.24	$235.78	$157.74	$226.24
Nasdaq Biotechnology	$100.00	$124.41	$156.36	$155.37	$138.42	$143.60

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of financial condition and results of operations is provided to enhance the understanding of, and should be read in conjunction with, Part I, Item 1, "Business" and Item 8, "Financial Statements and Supplementary Data." For information on risks and uncertainties related to our business that may make past performance not indicative of future results or cause actual results to differ materially from any forward-looking statements, see "Special Note Regarding Forward-Looking Statements," and Part I, Item 1A, "Risk Factors." Dollars in tabular format are presented in thousands, except per share data, or as otherwise indicated.

Overview

We are a women's healthcare company dedicated to fulfilling the unmet health needs of today's women. We are committed to innovating in women's healthcare where there continues to be unmet needs – not only in contraception – but also in other meaningful women's health therapeutic areas. We are focused on our advancement as a commercial company and the growth of our first and only product, Twirla, a once-weekly prescription combination hormonal contraceptive patch. For a summary of our ongoing commercial plan and programs for Twirla, *see Part I, Item 1, "Business."*

Financial Overview

Since our inception in 1997 through 2022, we generated minimal revenue and have never been profitable. Through December 31, 2023, we had an accumulated deficit of $423.2 million, and our net loss was $14.5 million, $25.4 million

and $71.1 million for the years ended December 31, 2023, 2022 and 2021, respectively. We expect to continue to incur operating losses for the foreseeable future as we commercialize Twirla. We have financed our operations primarily through the public offerings of equity securities, convertible preferred stock, term loans and sale of our New Jersey net operating losses. As of December 31, 2023 and 2022, we had $2.5 million and $5.2 million in cash and cash equivalents, respectively.

We plan to continue to monitor our cash and cash equivalents balances, in an effort to ensure we have adequate liquidity to fund our operations. If we encounter unforeseen factors that impact our current business plan or our ability to generate revenue from the commercialization of Twirla, we believe we have the ability to revise our commercial plans, including curtailing sales and marketing spending, to allow us to continue to fund our operations using existing cash and cash equivalents.

As we continue to develop as a commercial company, we anticipate that our operating expenses will be primarily focused on commercialization activities for Twirla. We also expect a portion of our operating expenses in the future will be related to research and development as we design and conduct our long-term, prospective observational safety study for Twirla, which is a post marketing requirement from the FDA and evaluate the development of our pipeline. As of December 31, 2023, we have significantly reduced our operating expenses through several measures, including optimizing our sales force, reorganizing our internal operations, reducing our advertising spend, and reorganizing our executive leadership team and general personnel. We are committed to continuing to explore ways to reduce expenses in a manner that allows us to simultaneously focus efforts and available resources on the commercialization, uptake and growth of Twirla. Our ability to reduce our operating loss and begin to generate positive cash flow from operations depends on the continued success in commercializing Twirla and maintaining discipline over our operating expenses. We continue to explore business development opportunities to commercialize a second product, and to do so in a way that we believe would contribute to our ability to reduce our operating losses and reduce our time to achieving positive cash flow from operations.

Going Concern

As of December 31, 2023, we had cash and cash equivalents of $2.5 million. We believe our current cash and cash equivalents will support operations through April 2024**.**

We have generated losses since inception, used substantial cash in operations, and anticipate we will continue to incur net losses for the foreseeable future. Our future success depends on our ability to obtain additional capital and/or implement various strategic alternatives, and there can be no assurance that any financing can be realized by us, or if realized, what the terms of any such financing may be, or that any amount that we are able to raise will be adequate. If we are unable to raise capital when needed or on acceptable terms, we then will be unable to continue the commercialization of Twirla, be required to cut operating costs, and forego future development and other opportunities. Based upon the foregoing, management has concluded that there is substantial doubt about our ability to continue as a going concern through the 12 months following the date on which this Annual Report on Form 10-K is filed.

We continue to analyze various alternatives, including refinancing alternatives, potential asset sales and mergers and acquisitions. We cannot be certain that these initiatives or raising additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to us or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, whether through the issuance of equity or convertible debt securities, or any combination thereof, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current stockholders will experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, including Twirla, or grant licenses on terms that may not be favorable to us. If we are unable to obtain funds when needed or on acceptable terms, we then may be unable to continue the commercialization of Twirla and may also be required to further cut operating costs, forego future development and other opportunities and may need to seek bankruptcy protection.

The financial statements as of December 31, 2023 have been prepared under the assumption that we will continue as a going concern for the next 12 months. Our ability to continue as a going concern is dependent upon our uncertain ability to obtain additional capital, reduce expenditures and/or execute our business plan and continue the commercial growth of Twirla. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We do not own any manufacturing facilities and rely on our contract manufacturer, Corium, for all aspects of the manufacturing of Twirla. We will need to continue to invest in the manufacturing process for Twirla, and incur significant expenses, in order to be capable of supplying projected commercial quantities of Twirla. We have incurred significant expenses in order to create an infrastructure to support the commercialization of Twirla, including sales, marketing, distribution, medical affairs and compliance functions. We will need to generate significant revenue to achieve profitability, and we may never do so.

Financial Operations Overview

Revenue

To date, we have generated minimal revenue from product sales. In the future, in addition to revenue from product sales, we may generate revenue from license fees, milestone payments or royalties from the sale of products developed using our intellectual property. Our ability to generate revenue and become profitable depends on our ability to successfully commercialize Twirla and any product candidates that we may advance in the future. If we fail to successfully commercialize Twirla, or any other product candidates we advance in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, could be adversely affected.

For the years ended December 31, 2023 and 2022, net sales totaled $19.6 million and $10.9 million, respectively, representing the sale of 248,220 units and 114,546 units, respectively. The increase in net sales was driven by increased sales in both the retail and non-retail channels.

Cost of Product Revenues

Cost of product revenues include direct and indirect costs related to the manufacturing of Twirla sold, including packaging services, freight, obsolescence, and allocation of overhead costs that are primarily fixed such as depreciation, salaries and benefits, and insurance. We expect these relatively fixed costs to become less significant as a percentage of sales with anticipated volume increases. There was no direct cost of product revenue on approximately 3,000 units sold in the year ended December 31, 2021, as those units were validation inventory which was previously expensed as research and development expense in the fourth quarter of 2020.

For the years ended December 31, 2023 and 2022, cost of product revenues totaled $9.0 million and $6.8 million, respectively.

Research and Development Expenses

Since our inception and through approval of Twirla by the FDA in February 2020, we focused our resources on our research and development activities. Research and development expenses consist primarily of costs incurred for the development of Twirla and other current and future potential product candidates, and include:

- expenses incurred under agreements with contract research organizations, or CROs, and investigative sites that conduct our clinical trials and preclinical studies;
- employee-related expenses, including salaries, benefits, travel and stock-based compensation expenses;
- the cost of acquiring, developing and manufacturing clinical trial materials, including the supply of our potential product candidates; and

- costs associated with research, development and regulatory activities.

Research and development costs are expensed as incurred. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information provided to us by our third-party vendors.

Historically, research and development activities were central to our business model and to date, our research and development expenses have been related primarily to the development of Twirla. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We do not currently utilize a formal time allocation system to capture expenses on a project-by-project basis, as the majority of our past and planned expenses have been and will be in support of Twirla. Our research and development expenses have decreased significantly over the past three years.

For the years ended December 31, 2023, 2022 and 2021, our research and development expenses were approximately $2.2 million, $3.3 million and $6.2 million, respectively. The following table summarizes our research and development expenses by functional area.

	Year ended December 31,		
	2023	2022	2021
		(In thousands)	
Clinical development	$ 137	$ 977	$ 3,394
Regulatory	540	480	282
Personnel related	1,190	1,426	2,115
Manufacturing -- commercialization	—	—	(35)
Stock-based compensation	358	370	490
Total research and development expenses	$ 2,225	$ 3,253	$ 6,246

It is difficult to determine with any certainty the exact duration and completion costs of any of our future clinical trials of Twirla or our current and future potential product candidates we may advance. It is also difficult to determine if, when or to what extent we will generate revenue from the commercialization and sale of our potential product candidates that obtain regulatory approval.

Future research and development costs incurred for our potential product candidates and required post-marketing studies will depend on a variety of factors, including the uncertainties of future clinical trials and preclinical studies, the rate of subject enrollment, access to additional capital, and significant and changing government regulation. For the foreseeable future, we expect the current public health crisis to have a negative effect on the conduct of clinical trials. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the U.S. Food and Drug Administration (“FDA”) or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, or experience issues with our manufacturing capabilities, we could be required to expend significant additional financial resources and time with respect to the development of that product candidate. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, coupled with an assessment of each product candidate’s commercial potential. Substantially all of our resources are currently dedicated to continuing to commercialize Twirla.

Selling and Marketing Expenses

Selling and marketing expenses consist principally of the cost of salaries and related costs for personnel in sales and marketing, our contract sales force, brand building, advocacy, market research and consulting. Selling and marketing expenses are expensed as incurred.

For the years ended December 31, 2023, 2022 and 2021, our selling and marketing expenses totaled approximately $17.8 million, $30.4 million and $43.4 million, respectively. Since the commercial launch of Twirla in the United States, we have utilized a contract sales force. We anticipate that our selling and marketing expenses will continue to be significant as our commercialization efforts continue.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance and administrative functions including payroll taxes and health insurance, stock-based compensation and travel expenses. Other general and administrative expenses include facility-related costs, insurance and professional fees for legal, patent review, consulting and accounting services. General and administrative expenses are expensed as incurred.

For the years ended December 31, 2023, 2022 and 2021, our general and administrative expenses totaled approximately $10.5 million, $11.9 million and $14.7 million, respectively. We anticipate that our general and administrative expenses will stabilize in the future.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make significant estimates and judgments that affect the reported amounts of assets, liabilities and expenses and related disclosures. On an ongoing basis, our actual results may differ significantly from our estimates.

Our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this Annual Report on Form 10-K. We believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

Product revenues consist of sales of Twirla in the United States. In December 2020, we began shipping Twirla to our customers in the U.S., which consist primarily of specialty distributors. We recognize product revenues in accordance with ASC 606, *Revenue from Contracts with Customers* (ASC 606). The provisions of ASC 606 require the following steps to determine revenue recognition: (1) Identify the contract(s) with a customer; (2) Identify the performance obligations in the contract; (3) Determine the transaction price; (4) Allocate the transaction price to the performance obligations in the contract; and (5) Recognize revenue when (or as) the entity satisfies a performance obligation.

In accordance with ASC 606, we recognize revenue when our performance obligation is satisfied by transferring control of the product to a customer. Per our contracts with customers, control of the product is transferred upon the conveyance of title, which occurs when the product is sold to and received by a customer. Accounts receivable due to us from contracts with our customers are stated separately in the balance sheet, net of various allowances as described in the Accounts Receivable policy in Note 2 to the Financial Statements, “Summary of Significant Accounting Policies.”

The amount of revenue we recognize is equal to the amount of consideration which is expected to be received from the sale of product to our customers. Revenue is only recognized when it is probable that a significant reversal will not occur in future periods. To determine this, we assess both the likelihood and magnitude of any such potential reversal of revenue.

The product is sold to customers at the wholesale acquisition cost. However, we record product revenue, net of estimates for applicable variable consideration which consist primarily of wholesaler distribution fees, prompt pay and other discounts, rebates, chargebacks, product returns and co-pay assistance programs.

If any, or all, of our actual experiences vary from the estimates above, we may need to adjust prior period accruals, affecting revenue in the period of adjustment.

Warrants

We account for warrants to purchase common stock in accordance with Accounting Standards Codification, or ASC, 480, *Distinguishing Liabilities from Equity*. ASC 480 requires that a financial instrument – other than an outstanding share, that, at inception, is indexed to an obligation to repurchase the issuer's equity shares, regardless of the timing or the probability of the redemption feature and may require the issuer to settle the obligation by transferring assets, these warrants are classified as a liability. We measure the fair value of our warrant liability using the Black-Scholes option-pricing model with changes in fair value recognized as increases or reductions to other income (expense) in the statement of operations.

Certain of our warrants are accounted for in equity, and warrants associated with certain of our financings are accounted for as liabilities. In accordance with ASC Topic 815-40, Derivatives and Hedging, Contracts in Entity's Own Equity, these liabilities are measured at fair value upon issuance, with subsequent changes in fair value reported in the Statement of Operations each reporting period. Initial fair value measurements are recorded as liabilities with any excess value over net cash proceeds representing a current period loss, in the event fair value is less than the net cash proceeds, the remaining value is recorded in additional paid-in capital.

See Note 9 to our financial statements for further information regarding the accounting for the warrants we have issued in our various financings.

Stock-Based Compensation

We account for stock-based compensation under ASC 718, *Accounting for Stock Based Compensation*, under which compensation expense is generally recognized over the vesting period of the award. Determining the amount of stock-based compensation to be required requires us to develop estimates of fair values of stock options as of the grant date.

We account for stock-based compensation by measuring and recognizing expense for all stock-based payments made to employees and directors based on estimated grant date fair values. We use the straight-line method to allocate compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period. We estimate the fair value of our stock-based awards to employees and directors using the Black-Scholes option valuation model, or Black-Scholes model. The Black-Scholes model requires the input of subjective assumptions, including the expected stock price volatility, the calculation of expected term and the fair value of the underlying common stock on the date of grant, among other inputs. The risk-free interest rate was determined with the implied yield currently available for zero-coupon U.S. government issues with a remaining term approximating the expected life of the options.

We also award restricted stock units ("RSUs") to employees and our board of directors (the "Board"). RSUs are generally subject to forfeiture if employment terminates prior to the completion of the vesting restrictions. We expense the cost of the RSUs, which is determined to be the fair market value of the shares of common stock underlying the RSUs at the date of grant, ratably over the period during which the vesting restrictions lapse. Cost associated with performance-based RSUs with a performance condition which affects the vesting is recognized only if the performance condition is probable of being satisfied.

Comparison of Years Ended December 31, 2023 and 2022

	Year Ended December 31, (In thousands)		
	2023	2022	Change
Revenues, net	$ 19,593	$ 10,884	$ 8,709
Cost of product revenues	8,978	6,836	2,142
Gross profit	10,615	4,048	6,567
Operating expenses:			
Research and development	$ 2,225	$ 3,253	$ (1,028)
Selling and marketing	17,769	30,369	(12,600)
General and administrative	10,505	11,860	(1,355)
Loss on disposition of assets	—	11,122	(11,122)
Total operating expenses	30,499	56,604	(26,105)
Loss from operations	$ (19,884)	$ (52,556)	32,672
Other income (expense)			
Interest income	78	80	(2)
Interest expense	(1,419)	(3,131)	1,712
Unrealized gain on warrant liability	6,760	25,520	(18,760)
Total other income, net	5,419	22,469	(17,050)
Loss before benefit from income taxes	(14,465)	(30,087)	15,622
Benefit from income taxes	—	4,675	(4,675)
Net loss	$ (14,465)	$ (25,412)	$ 10,947

Revenues. Revenues, net increased by $8.7 million, or 80%, from $10.9 million for the year ended December 31, 2022, to $19.6 million for the year ended December 31, 2023. Unit sales increased by approximately 133,674 units, or 117%, from 114,546 units for the year ended December 31, 2022, to 248,220 units for the year ended December 31, 2023. The decrease percentage in growth between dollars and units pertains to increased price discounts offered to the non-retail sales channel. Revenue, net consists of sales of Twirla and reflects the shipment of Twirla to specialty distributors, net of estimates for applicable variable consideration, which consist primarily of wholesale distribution fees, prompt pay and other discounts, rebates, chargebacks, product returns and co-pay assistance programs.

Cost of product revenues. Costs of product revenues increased by $2.1 million, or 31% from $6.8 million for the year ended December 31, 2022, to $9.0 million for the year ended December 31, 2023. Costs of product revenues consist of direct and indirect costs related to the manufacturing of Twirla sold, including third-party manufacturing costs, packaging services, freight, obsolescence and allocation of overhead costs that are primarily fixed such as depreciation, salaries and benefits, and insurance. Cost of product revenues for the year ended December 31, 2023 included approximately $0.8 million of obsolescence reserves for inventory not expected to be sold prior to its shelf-life date.

Research and development expenses. Research and development expenses decreased by $1.0 million, or 32%, from $3.2 million for the year ended December 31, 2022 to $2.2 million for the year ended December 31, 2023. This decrease in research and development expenses was primarily due to a decrease in clinical development expenses related to a reduction in spending on our pipeline evaluation and development as well as decreased personnel and consulting costs.

Selling and marketing expenses. Selling and marketing expenses decreased by $12.6 million, or 42%, from $30.4 million for the year ended December 31, 2022 to $17.8 million for the year ended December 31, 2023. This decrease in selling and marketing expenses is due to reduced spending on marketing initiatives and the continued optimization of our contract sales force.

General and administrative expenses. General and administrative expenses decreased by $1.4 million, or 11% from $11.9 million for the year ended December 31, 2022 to $10.5 million for the year ended December 31, 2023. This decrease in general and administrative expense was primarily due to decreased personnel costs as a result of lower headcount.

Loss on disposition of assets. In accordance with ASC 610-20, we recognized an $11.1 million one-time, non-cash charge during the year ended December 31, 2022, which represented the loss on the transfer of fixed assets to Corium in connection with the amended Corium agreement (see Note 12 to the financial statements). There was no comparable expense during the year ended December 31, 2023.

Interest income. Interest income comprises interest income earned on cash, cash equivalents and marketable securities.

Interest expense. Interest expense is attributable to our term loan with Perceptive and includes the amortization of the discount associated with allocating value to the common stock warrants issued to Perceptive and the amortization of the deferred financing costs associated with the term loan. Interest expense decreased by $1.7 million, from $3.1 million for the year ended December 31, 2022 to $1.4 million for the year ended December 31, 2023, due to principal payments made throughout 2023.

Unrealized gain on warrant liability. The unrealized gain on warrant liability was $6.8 million and $25.5 million for the years ended December 31, 2023 and 2022, respectively. Unrealized gain is attributable to the subsequent non-cash changes in the estimated fair value of the warrants issued in various public offerings and transactions between October 2021 and December 2023 (see Note 9 to the financial statements).

Net Operating Losses and Tax Carryforwards

As of December 31, 2023, we had approximately $396.5 million of federal and $77.4 million of state net operating loss carryforwards. We also potentially have federal and state research and development tax credits which would offset future taxable income. We have not completed a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since our inception, due to the significant costs and complexities associated with such studies. Accordingly, our ability to utilize the aforementioned carryforwards may be limited. Additionally, for federal net operating losses generated prior to 2018, U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes. As of December 31, 2023, all of our net operating losses were fully offset by a valuation allowance.

Liquidity and Capital Resources

At December 31, 2023, we had cash and cash equivalents totaling $2.5 million. We invest our cash equivalents and marketable securities in short-term highly liquid, interest-bearing investment-grade and government securities in order to preserve principal.

The following table sets forth the primary sources and uses of cash for the periods indicated:

	Year Ended December 31,		
	2023	2022	2021
	(In thousands)		
Net cash used in operating activities	$ (9,577)	$ (35,947)	$ (65,202)
Net cash (used in) provided by investing activities	—	(133)	39,460
Net cash provided by financing activities	6,888	22,183	30,422
Net (decrease) increase in cash and cash equivalents	$ (2,689)	$ (13,897)	$ 4,680

Operating Activities

Net cash used in operating activities was $9.6 million for the year ended December 31, 2023 and consisted primarily of a net loss of $14.5 million, offset by a $6.8 million unrealized gain on outstanding warrants, non-cash stock-based compensation expense of $1.9 million, $1.4 of other non-cash charges, primarily interest expense and $7.0 of positive working capital changes, primarily an increase in accounts payable and accrued expenses and a decrease in deposits. Net cash used in operating activities was $35.9 million for the year ended December 31, 2022 and consisted primarily of a net loss of $25.4 million, a $25.5 million non-cash gain on the warrant liability and a net increase in working capital items of $2.1 million. These uses of cash were partially offset by non-cash stock-based compensation expense of $2.5 million, an $11.1 million non-cash loss on the disposition of assets, depreciation expense of $1.3 million and $2.2 million of other non-cash charges, primarily interest expense. Net cash used in operating activities was $65.2 million for the year ended December 31, 2021 and consisted primarily of a net loss of $71.1 million, a $3.8 million non-cash gain on the warrant liability and a net increase in working capital items of $2.9 million, largely an increase in inventory of $6.3 million and an increase in prepaid expenses of $1.0 million, offset by an increase in accounts payable and accrued expenses of $5.2 million. These uses of cash were partially offset by non-cash stock-based compensation expense of $3.3 million, a non-cash inventory reserve of $5.3 million, depreciation expense of $2.1 million and $1.8 million of other non-cash charges, primarily interest expense.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2023 was zero. Net cash provided by investing activities for the year ended December 31, 2022 was $0.1 million and represents purchases of property and equipment. Net cash provided by investing activities for the year ended December 31, 2021 was $39.5 million and primarily represents net sales and maturities of marketable securities.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2023 was $6.9 million, which consisted of net proceeds of $6.5 million from a public offering of common stock and pre-funded warrants, $1.7 million from the sale of 207,882 shares of our common stock through an at-the-market, or ATM, sales program partially offset by $1.0 million of principal payments on our debt. Net cash provided by financing activities for the year ended December 31, 2022 was $22.2 million, which primarily represents net proceeds of $21.9 million received from the issuance of 533,333 shares of our common stock through a public offering, net proceeds of $4.1 million from the sale of 4,850 shares of preferred stock in a registered direct offering, and net proceeds of $13.5 million from the sale of 253,115 shares of common stock through at-the-market, or ATM sales programs. These proceeds were partially offset by $17.4 million of long-term debt payments. Net cash provided by financing activities for the year ended December 31, 2021 was $30.4 million, which primarily represents net proceeds of $21.1 million received from the issuance of 13,333 shares of our common stock through a public offering and net proceeds of $9.3 million from the sale of 3,458 shares of common stock through at-the-market, or ATM sales programs.

Funding Requirements and Other Liquidity Matters

Shelf Registration Statement, At-The-Market ("ATM") Offerings and Equity Offerings

We closely monitor our cash and cash equivalents balances, in an effort to ensure we have adequate liquidity to fund the operations of the Company. If unforeseen factors impact our current business plan or our ability to generate revenue from the commercialization of Twirla, we believe we have the ability to revise our commercial plans, including curtailing sales and marketing spending, to allow us to continue to fund our operations.

ATM

On January 10, 2022, we filed a prospectus supplement to a Shelf Registration Statement which was originally filed and declared effective by the SEC in October 2020 registering the January 2022 ATM we entered into for the sale of up to $50.0 million of shares of our common stock. During the year three months ended March 31, 2022, we sold and issued 512 shares of common stock resulting in net proceeds of $0.3 million under the January 2022 ATM. On April 26, 2022, we terminated the January 2022 ATM.

On April 27, 2022, we entered into the April 2022 ATM Agreement under which we are authorized to sell up to an aggregate of $12.8 million in gross proceeds through the sale of shares of common stock from time to time in the April 2022 ATM. We agreed to pay a commission of up to 3% of the gross proceeds of any common stock sold under this agreement. Through September 30, 2022, we issued and sold a total of 173,750 shares of common stock under the April 2022 ATM Agreement, representing the entire capacity of the April 2022 ATM, resulting in net proceeds of approximately $12.2 million. On August 22, 2022, we increased the April 2022 ATM ("August 2022 ATM"). As increased, we were eligible to offer and sell, from time to time through the Sales Agent, shares of our common stock having an aggregate offering price of up to $75.0 million. During the year ended December 31, 2022, we issued and sold 78,853 shares of common stock under the August 2022 ATM resulting in net proceeds to us of approximately $0.9 million. On April 12, 2023, we filed a prospectus supplement to our registration statement on Form S-3 for the August 2022 ATM verifying that we were then eligible to sell up to $4.5 million worth of shares through our ATM. During the year ended December 31, 2023, we issued and sold 207,883 shares resulting in net proceeds of approximately $1.7 million.

2022 Equity Offerings

On March 13, 2022, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with a single healthcare-focused institutional investor (the "Purchaser"), pursuant to which the Company issued, in a registered direct offering (the "2022 Preferred Stock Offering"), 2,425 shares of Series A convertible preferred stock (the "Series A Preferred Stock") and 2,425 shares of Series B convertible preferred stock (the "Series B Preferred Stock") and Series A warrants (the "Series A Warrants") to purchase up to an aggregate of 12,125 shares of the common stock of the Company (the "Common Stock") and Series B warrants (the "Series B Warrants") to purchase up to an aggregate of 12,125 shares of Common Stock. Each share of Series A Preferred Stock and Series B Preferred Stock has a stated value of $1,000 per share and a conversion price of $400.00 per share. The shares of preferred stock issued in the offering are convertible into an aggregate of 12,125 shares of Common Stock. The Series A Warrants have an exercise price of $3.69 per share and became exercisable six months following the date of issuance and will expire 5 years following the initial exercise date. The Series B Warrants have an exercise price of $3.69 per share and became exercisable six months following the date of issuance and will expire one and one-half years following the initial exercise date. The Purchase Agreement contains customary representations and warranties and agreements of the Company and the Purchaser and customary indemnification rights and obligations of the parties. The 2022 Preferred Stock Offering closed on March 14, 2022 and total net proceeds were approximately $4.3 million.

On April 25, 2022, we entered into a Letter Agreement with the Purchaser, pursuant to which the Purchasers consented to us entering into and effecting an ATM offering facility. Pursuant to the Letter Agreement, we issued to the Purchaser the New Warrant, on the same terms and conditions as the Series A Warrants, provided that such New Warrant shall be exercisable into 4,243 warrant shares, subject to adjustment thereunder. The Series A Warrants have an

exercise price of $3.69 per share and became exercisable six months after the date of the Letter Agreement, and will expire 5 years following the initial exercise date.

On July 6, 2022, we completed a best-efforts public offering (the "Offering") in which we raised net proceeds of $22.0 million through the sale of 382,966 shares of common stock and 150,366 pre-funded warrants ("Series B pre-funded warrants") to purchase 150,366 shares of common stock. Both the sales of shares of common stock and pre-funded warrants were accompanied by Series A-1 and Series A-2 warrants (together the "Series A warrants") to purchase shares of common stock. The Series A-1 warrants are exercisable immediately and will expire five years from the date of issuance, and the Series A-2 warrants expired unexercised in August 2023. H.C. Wainwright acted as the exclusive placement agent in connection with the Offering and, as compensation, received a cash fee of 7% of the aggregate proceeds raised in the Offering. We also issued to certain designees of H.C. Wainwright warrants to purchase up to 26,666 shares of commons stock with an exercise price of $56.25 per share.

2023 Equity Offering

On May 25, 2023 we completed a best-efforts public offering (the "May 2023 Offering") in which we raised net proceeds of $6.5 million through the sale of 1,896,286 shares of common stock (or pre-funded warrants in lieu thereof). Both the sales of shares of common stock and pre-funded warrants were accompanied by Series C-1 and Series C-2 warrants (together the "Series C warrants") to purchase shares of common stock. The Series C-1 warrants are exercisable immediately and will expire five years from the date of issuance, and the Series C-2 warrants are exercisable immediately and will expire eighteen months from the date of issuance. H.C. Wainwright acted as the exclusive placement agent in connection with the Offering and, as compensation, received a cash fee of 7% of the aggregate proceeds raised in the Offering. We also issued to certain designees of H.C. Wainwright warrants to purchase up to 94,814 shares of commons stock with an exercise price of $4.9439 per share (the "Placement Agent Warrants"). The Placement Agent Warrants expire on the fifth anniversary from the date of the commencement of sales in the May 2023 Offering.

February 2024 Warrant Exercise

As previously reported, we issued warrants on July 6, 2022 and May 25, 2023, each of which were amended on December 3, 2023 (collectively the "Warrants") to a certain investor, collectively representing the right to purchase up to an aggregate of 3,892,572 shares of the common stock, par value $0.0001 per share, of the Company ("Common Stock"), at an exercise price of $3.69 per share. On February 22, 2024, we entered into a warrant exercise agreement (the "Exercise Agreement") with this certain holder of its Warrants (the "Exercising Holder") wherein the Exercising Holder agreed to exercise the Warrants for cash, at an exercise price reduced by the Company to $1.25 per share (the "Warrant Exercise"). The gross proceeds from the Warrant Exercise were approximately $4.8 million. In consideration for the Warrant Exercise, we issued new unregistered warrants to purchase shares of Common Stock (the "New Warrants"). The New Warrants are exercisable for an aggregate of up to 7,785,144 shares of Common Stock, at an exercise price of $1.00 per share and will be immediately exercisable upon issuance. 3,992,572 of the New Warrants will have a term of five years from the issuance date and 3,792,572 of the New Warrants will have a term of eighteen months from the issuance date. The exercise price of the New Warrants is subject to adjustment for stock splits, reverse splits, and similar capital transactions as described in the New Warrants. H.C. Wainwright & Co., LLC acted as placement agent and financial advisor in connection with the transaction and received a cash fee of 7.0% of the gross proceeds resulting from the Warrant Exercise, a management fee of 1.0% of the gross proceeds resulting from the Warrant Exercise and warrants (the "Placement Agent Warrants") to purchase 194,629 of shares of Common Stock which is equal to 5.0% of the number of Warrants exercised at an exercise price of $1.5625.

We believe we may have the potential to access additional capital through selling additional debt or equity securities or obtaining a line of credit or other loan as required.

We expect to continue to incur significant operating expenses for the foreseeable future in connection with our ongoing activities as we:

- maintain a sales and marketing infrastructure and contract manufacturing arrangement to support the continued commercialization of Twirla in the United States;
- continue to commercialize Twirla and seek increased uptake of Twirla in the United States;
- conduct the post-marketing requirements from the FDA that we are obligated to perform;
- continue to evaluate additional line extensions for Twirla and initiate development of potential product candidates in addition to Twirla;
- maintain, leverage and expand our intellectual property portfolio; and
- maintain operational, financial and management information systems and personnel, including personnel to support our product development and future commercialization efforts.

We may also need to raise additional funds if we need to change components of our commercial plan or we encounter any unforeseen events that affect our current business plan, or we may choose to raise additional funds to provide us with additional working capital. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital when needed or on attractive terms or are unable to enter into strategic collaborations, we then may be unable to successfully commercialize Twirla and may also be required to further cut operating costs, forgo future development and other opportunities or even terminate our operations, which may involve seeking bankruptcy protection. Because of the numerous risks and uncertainties associated with such developments, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the commercialization of Twirla. Our future capital requirements will depend on many factors, including:

- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for Twirla;
- the revenue received from commercial sales of Twirla;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the costs associated with any potential business or product acquisitions, strategic collaborations, licensing agreements or other arrangements that we may establish.

We do not have any committed external source of funds. Until such time, if ever, as we can generate substantial cash flows from product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements.

Going Concern

As of December 31, 2023, we had cash and cash equivalents of $2.5 million. We closely monitor our cash and cash equivalents and expect that our current cash will fund our planned operations into April 2024. We plan to raise additional funds through debt issuances or the issuance and sale of our common stock to meet our projected operating requirements, including the continued commercialization of Twirla, the exploration and potential advancement of our existing pipeline and our possible expansion through business development activities.

Our future success depends on our ability to raise additional capital and/or implement various strategic alternatives. We continue to analyze strategic and financing alternatives, potential asset sales as well as mergers and acquisitions. We cannot be certain that these initiatives or raising additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to us or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, whether through the issuance of equity or convertible debt securities, or any combination thereof, these securities may have rights, preferences, or privileges senior to those of our common

stock, and our current shareholders may experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, including Twirla, or grant licenses on terms that may not be favorable to us. If we are unable to obtain funds when needed or on acceptable terms, we may be required to curtail our current development programs, cut operating costs, forego future development and other opportunities and may need to seek bankruptcy protection.

The financial statements as of December 31, 2023 have been prepared under the assumption that we will continue as a going concern for the next 12 months following the date this Annual Report on Form 10-K is filed. Our ability to continue as a going concern is dependent upon our uncertain ability to obtain additional capital, reduce expenditures and/or execute our business plan and successfully launch Twirla. The audited financial statements as of December 31, 2023 do not include any adjustments that might result from the outcome of this uncertainty.

Contractual Obligations and Commitments

In April 2020, we entered into a Manufacturing and Commercialization agreement (the 'Corium Agreement") with Corium Innovations, Inc. ("Corium") which replaced our previous development agreement. Pursuant to the Corium Agreement, Corium will manufacture and supply all of our product requirements for Twirla at certain specified rates. Under the terms of the Corium Agreement, Corium is to be the exclusive supplier of Twirla for ten years. The Corium Agreement included a quarterly minimum purchase commitment and a fixed price per unit for two years from December 2020, the date of the first commercial batch purchase order invoice, depending on annual purchase volume. During 2021, we did not meet all of our minimum quantity purchases from Corium, and as a result, paid penalties as required by our agreement with Corium. On July 25, 2022 we, along with Corium, amended the Corium Agreement to restructure the minimums applicable to the purchase of manufactured Twirla and to extend the term of the Corium Agreement until December 31, 2033. The Corium Agreement terminates automatically on December 31, 2033, but may be terminated for any reason upon the written mutual agreement of both parties; provided, however, that the parties must confer in good faith regarding possible mutual termination. In the event of such termination, we may still affect purchase orders after the notice of termination is given and until the time any such termination becomes effective. As of December 31, 2023, the minimum amount committed totals $225.0 million for the 10-year period from 2024 through 2033.

In April 2020, we entered into a project agreement with inVentiv Commercial Services, LLC, or inVentiv, a Syneos Health Group Company, which we refer to as the Syneos Agreement, under our Master Services Agreement with inVentiv. Pursuant to the Syneos Agreement, inVentiv, through its affiliate Syneos Selling Solutions, will provide a field force of sales representatives to provide certain detailing services, sales operation services, compliance services, and training services with respect to Twirla to us in exchange for an up-front implementation fee and a fixed monthly fee. Effective February 1, 2022, we entered into an amendment to the Syneos Agreement that extended the term until August 23, 2024. At that time, the Syneos Agreement will terminate automatically unless extended upon the mutual written agreement of the parties. We may terminate the Syneos Agreement for any reason upon timely written notice without incurring a termination fee. On September 28, 2023, we entered into the Seventh Amendment to the Syneos Agreement, pursuant to which we will pay Syneos a fixed weekly fee for the performance of Services (as defined in the Syneos Agreement) through August 23, 2024. As of December 31, 2023, the minimum amount committed totals $2.4 million.

Our operating lease commitment relates to our lease of office space in Princeton, New Jersey. The lease for this space commenced in December 2021, and the minimum payments over the remaining 15-month term totals $0.6 million as of December 31, 2023.

Recent Accounting Pronouncements

See Note 2 to our financial statements that discusses new accounting pronouncements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk [Reserved]

Item 8. Financial Statements and Supplementary Data

Agile Therapeutics, Inc.
Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Agile Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Agile Therapeutics, Inc. (the Company) as of December 31, 2023 and 2022, the related statements of operations and comprehensive loss, changes in stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has generated losses since inception, used substantial cash in operations, has a working capital deficiency, anticipates it will continue to incur net losses for the foreseeable future, requires additional capital to fund its operating needs and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Product Return Reserve Estimate

Description of the Matter	At December 31, 2023, the Company recorded a liability for product returns totaling $1.9 million. As discussed in Note 2 of the financial statements, the Company sells product primarily to wholesale distributors. The Company estimates variable consideration resulting from product returns based on quantitative and qualitative data from various internal and external sources. Auditing management's estimate of product returns was complex and judgmental due to the significant estimation required to determine inventory in the distribution channel that will not ultimately be sold to patients and will be returned. Sales into the distribution channel could exceed market demand.
How We Addressed the Matter in Our Audit	To test the estimated product return reserve, we performed audit procedures that included, among others, testing management's historical return rate calculation and testing the completeness and accuracy of sales and returns data used in the calculation. We performed analytical procedures to assess the correlation of quarterly sales to distributors and demand sales to end customers. In addition, we assessed the Company's quarterly analysis of inventory held at various stages in the distribution channel. We confirmed the channel inventory balance and contract terms directly with significant customers. We tested credit memos issued subsequent to year-end for recording in the proper period. We read significant customer contracts and performed direct inquiries with management including the supply chain, legal, and contracting departments to identify any terms or conditions not included in customer contracts that could impact the estimation for product returns.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2010.
Iselin, New Jersey
March 28, 2024

Agile Therapeutics, Inc.
Balance Sheets
(in thousands, except par value and share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 2,557	$ 5,246
Accounts receivable, net	3,392	3,377
Inventory, net	2,738	1,332
Prepaid expenses and other current assets	843	1,403
Total current assets	9,530	11,358
Property and equipment, net	75	177
Right of use asset	412	695
Other non-current assets	238	2,012
Total assets	$ 10,255	$ 14,242
Liabilities and stockholders' deficit		
Current liabilities:		
Long-term debt, current portion	$ 1,515	$ 1,426
Notes payable, current portion	191	—
Accounts payable	9,574	7,734
Accrued expenses	9,131	3,908
Lease liability, current portion	366	319
Total current liabilities	20,777	13,387
Lease liabilities, long-term	100	466
Warrant liability	5,696	5,934
Total liabilities	26,573	19,787
Commitments and contingencies (Note 12)		
Stockholders' deficit		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized, 4,850 issued and no shares outstanding at December 31, 2023 and no shares issued and outstanding at December 31, 2022	—	—
Common stock, $0.0001 par value, 300,000,000 shares authorized, 2,963,657 and 859,402 issued and outstanding at December 31, 2023 and December 31, 2022, respectively	4	—
Additional paid-in capital	406,846	403,157
Accumulated deficit	(423,168)	(408,702)
Total stockholders' deficit	(16,318)	(5,545)
Total liabilities and stockholders' deficit	$ 10,255	$ 14,242

See accompanying notes.

Agile Therapeutics, Inc.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Year ended December 31,		
	2023	2022	2021
Revenues, net	$ 19,593	$ 10,884	$ 4,101
Cost of product revenues	8,978	6,836	10,718
Gross profit	10,615	4,048	(6,617)
Operating expenses:			
Research and development	$ 2,225	$ 3,253	$ 6,246
Selling and marketing	17,769	30,369	43,444
General and administrative	10,505	11,860	14,698
Loss on disposition of assets	—	11,122	—
Total operating expenses	30,499	56,604	64,388
Loss from operations	(19,884)	(52,556)	(71,005)
Other income (expense)			
Interest income	78	80	25
Interest expense	(1,419)	(3,131)	(3,914)
Unrealized gain on warrant liability	6,760	25,520	3,827
Total other income (expense), net	5,419	22,469	(62)
Loss before benefit from income taxes	(14,465)	(30,087)	(71,067)
Benefit from income taxes	—	4,675	—
Net loss	$ (14,465)	$ (25,412)	$ (71,067)
Net loss per share (basic and diluted)	$ (6.71)	$ (58.79)	$ (1,464.20)
Weighted-average common shares (basic and diluted)	2,156,726	432,219	48,536
Comprehensive loss:			
Net loss	$ (14,465)	$ (25,412)	$ (71,067)
Other comprehensive income:			
Unrealized (loss) on marketable securities	—	—	(3)
Comprehensive loss	$ (14,465)	$ (25,412)	$ (71,070)

See accompanying notes.

Agile Therapeutics, Inc.
Statements of Changes in Stockholders' Equity (Deficit)
(in thousands, except share data)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Net Stockholders' Equity (Deficit)
	Number of Shares	Amount	Number of Shares	Amount				
Balance December 31, 2020	—	$ —	43,782	$ —	$ 361,548	$ 3	$ (312,223)	$ 49,328
Share-based compensation—stock options and RSUs	—	—	—	—	3,338	—	—	3,338
Issuance of common stock pursuant to at-the-market stock sales, net of expenses	—	—	3,458	—	9,266	—	—	9,266
Issuance of common stock in public offering, net of expenses	—	—	13,333	—	11,898	—	—	11,898
Issuance of common stock upon exercise of stock options	—	—	63	—	75	—	—	75
Vesting of RSUs	—	—	62	—	—	—	—	—
Warrants issued in connection with long-term debt	—	—	—	—	1,080	—	—	1,080
Unrealized net gain on marketable securities	—	—	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	—	—	(71,067)	(71,067)
Balance December 31, 2021	—	$ —	60,698	$ —	$ 387,205	$ —	$ (383,290)	$ 3,915
Share-based compensation - stock options and RSUs	—	—	—	—	2,492	—	—	2,492
Issuance of common stock pursuant to at-the-market stock sales, net of expenses	—	—	253,115	1	13,456	—	—	13,457
Issuance of series A and B convertible preferred stock in a registered direct offering (Note 9)	4,850	—	—	—	—	—	—	—
Conversion of series A convertible preferred stock	(2,425)	—	6,063	—	—	—	—	—
Conversion of series B convertible preferred stock	(2,425)	—	6,063	—	—	—	—	—
Issuance of common stock in public offering, net of expenses	—	—	533,333	3	—	—	—	3
Vesting of RSUs	—	—	130	—	—	—	—	—
Net loss	—	—	—	—	—	—	(25,412)	(25,412)
Balance December 31, 2022	—	$ —	859,402	$ 4	$ 403,153	$ —	$ (408,702)	$ (5,545)
Share-based compensation - stock options and RSUs	—	—	—	—	1,981	—	—	1,981
Issuance of common stock pursuant to at-the-market stock sales, net of expenses	—	—	207,883	—	1,725	—	—	1,725
Fractional shares retired as a result of reverse split	—	—	—	—	(13)	—	—	(13)
Issuance of common stock in public offering, net of expenses	—	—	95,000	—	—	—	—	—
Exercise of pre-funded common stock warrants	—	—	1,801,286	—	—	—	—	—
Vesting of RSUs	—	—	86	—	—	—	—	—
Net loss	—	—	—	—	—	—	(14,465)	(14,465)
Balance December 31, 2023	—	$ —	2,963,657	$ 4	$ 406,846	$ —	$ (423,168)	$ (16,318)

See accompanying notes.

Agile Therapeutics, Inc.
Statements of Cash Flows

	Year Ended December 31,		
	2023	2022	2021
Cash flows from operating activities:			
Net loss	$ (14,465)	$ (25,412)	$ (71,067)
Adjustments to reconcile net loss to net cash used in operating activities:			
Noncash inventory reserve	801	397	5,323
Depreciation	102	1,280	2,064
Amortization	284	254	159
Loss on disposition of assets	—	11,122	—
Noncash stock-based compensation	1,981	2,493	3,338
Noncash amortization of deferred financing costs	1,063	1,969	1,661
Unrealized gain on warrants	(6,760)	(25,520)	(3,827)
Changes in operating assets and liabilities:			
Accounts receivable	(15)	(1,844)	(668)
Inventory	(2,207)	(763)	(6,289)
Prepaid expenses and other assets	2,270	880	(967)
Accounts payable and accrued expenses	7,688	(628)	5,202
Lease liability	(319)	(175)	(131)
Net cash used in operating activities	(9,577)	(35,947)	(65,202)
Cash flows from investing activities:			
Sales and maturities of marketable securities	—	—	39,729
Acquisition of property and equipment	—	(133)	(269)
Net cash (used in) provided by investing activities	—	(133)	39,460
Cash flows from financing activities:			
Proceeds from issuance of preferred stock in registered direct offering, net of offering costs	—	4,128	—
Proceeds from At-the-Market sales of common stock, net of offering costs	1,725	13,494	9,266
Proceeds from the issuance of common stock in public offering, net of offering costs	6,510	21,936	21,081
Repayments of long-term debt	(975)	(17,375)	—
Proceeds from the exercise of stock options	—	—	75
Repayments of note payable	(372)	—	
Net cash provided by financing activities	6,888	22,183	30,422
Net (decrease) increase in cash and cash equivalents	(2,689)	(13,897)	4,680
Cash and cash equivalents, beginning of period	5,246	19,143	14,463
Cash and cash equivalents, end of period	$ 2,557	$ 5,246	$ 19,143
Supplemental disclosure of noncash financing activities			
Warrants issued in connection with long-term debt	$ —	$ —	1,080
Operating right-of-use assets obtained in exchange for new operating lease liabilities	—	—	969
Supplemental cash flow information			
Interest paid	$ 356	$ 1,162	$ 2,383

See accompanying notes.

Agile Therapeutics, Inc.
Notes to Financial Statements
December 31, 2023
(amounts in tables in thousands, except share and per share data)

1. Organization and Description of Business

Nature of Operations

Agile Therapeutics, Inc. ("Agile" or the "Company") was incorporated in Delaware on December 22, 1997. Agile is a women's healthcare company dedicated to fulfilling the unmet health needs of today's women. The Company's activities since inception have consisted principally of raising capital, performing research and development, including development of the Company's lead product, Twirla®, and more recently commercializing Twirla. The Company is headquartered in Princeton, New Jersey.

The Company's sole approved product, Twirla, is a once-weekly prescription contraceptive patch that received approval from the U.S. Food and Drug Administration, or FDA, in February 2020 and was commercially launched in early December 2020. Substantially all of the Company's resources are currently dedicated to commercializing Twirla in the United States. The Company has generated minimal product revenue to date and is subject to a number of risks similar to those of other early stage commercial companies, including, but not limited to, dependence on key individuals, the difficulties and uncertainties inherent in the development of commercially usable products, market acceptance of products, protection of proprietary technology, the need to obtain additional capital necessary to fund the development of its products, reliance on a consistent supply chain both for Twirla and in general, macroeconomic factors such as inflation, competition from larger companies, and compliance with FDA and other government regulations. If the Company does not continue to successfully commercialize Twirla, it will be unable to generate recurring product revenue or achieve profitability. The Company has incurred operating losses and negative cash flows from operating activities each year since inception. As of December 31, 2023, the Company had an accumulated deficit of approximately $423.2 million. The Company expects to continue to incur significant operating expenses for the foreseeable future in connection with its ongoing activities, as the Company:

- maintains a sales and marketing infrastructure and contract manufacturing arrangement to support the continued commercialization of Twirla in the United States;
- continues to commercialize Twirla and seek increased uptake of Twirla in the United States;
- continues to evaluate additional line extensions for Twirla and initiates development of potential product candidates in addition to Twirla;
- maintains, leverages, and expands the Company's intellectual property portfolio; and
- maintains operational, financial, and management information systems and personnel, including personnel to support the Company's product development and future commercialization efforts.

The Company has financed its operations to date primarily through the issuance and sale of its common stock in both public and private offerings (see Note 9), private placements of its convertible preferred stock, venture loans, and non-dilutive grant funding.

Going Concern

As of December 31, 2023, the Company had cash and cash equivalents of $2.5 million and a $11.2 million working capital deficit. The Company's current liquidity is sufficient to fund operations into April 2024. The Company closely monitors its cash and cash equivalents and will need to raise additional funds to meet its projected operating requirements, including the continued commercialization of Twirla, and exploring the advancement of its existing pipeline and its possible expansion through business development activities.

Agile Therapeutics, Inc.
Notes to Financial Statements (Continued)
December 31, 2023
(amounts in tables in thousands, except share and per share data)

The Company has generated losses since inception, used substantial cash in operations, has a working capital deficit as of December 31, 2023, and anticipates it will continue to incur net losses for the foreseeable future. The Company's future success depends on its ability to obtain additional capital and/or implement various strategic alternatives, and there can be no assurance that any financing can be realized by the Company, or if realized, what the terms of any such financing may be, or that any amount that the Company is able to raise will be adequate. Based upon the foregoing, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern through the 12 months following the date on which this Annual Report on Form 10-K is filed.

The Company continues to analyze various alternatives, including refinancing alternatives, asset sales and mergers and acquisitions. The Company's future success depends on its ability to raise additional capital as discussed above. The Company cannot be certain that these initiatives, or raising additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to it or, if available, will be on terms acceptable to the Company. If the Company issues additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of its common stock, and the Company's current stockholders will experience dilution. If the Company is unable to obtain funds when needed or on acceptable terms, the Company then may be unable to continue the commercialization of Twirla, and may also be required to cut operating costs, and forego future development and other opportunities.

The audited financial statements as of December 31, 2023 have been prepared under the assumption that the Company will continue as a going concern for the next 12 months. The Company's ability to continue as a going concern is dependent upon its uncertain ability to obtain additional capital, reduce expenditures and/or execute its business plan and successfully commercialize Twirla. The audited financial statements as of December 31, 2023 do not include any adjustments that might result from the outcome of this uncertainty. If the Company is unable to continue as a going concern, it may have to liquidate its assets and may receive less than the value at which those assets are carried on the financial statements.

2. Summary of Significant Accounting Polices

Basis of Presentation

The accompanying financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented.

Use of Estimates

The preparation of the Company's financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company bases its estimates and judgments on historical experience and various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheets and the amounts of revenue and expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, revenue recognition, inventory reserves, the accounting for common stock warrants, stock-based compensation, and accounting for research and development costs. As future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates.

Risks and Uncertainties

While Twirla has been approved by the FDA, other potential product candidates developed by the Company will require approval from the FDA prior to commercial sales. There can be no assurance that the Company's other product candidates will receive the required approval. If the Company is denied approval or such approval is delayed or is unable

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to obtain the necessary financing to complete development and approval, there could be a material adverse impact on the Company's financial condition and results of operations.

Cash and Cash Equivalents

The Company considers all highly-liquid investments with an original maturity of three months or less when purchased to be cash equivalents. All cash and cash equivalents are held in United States financial institutions. Cash and cash equivalents include money market funds that invest primarily in commercial paper and U.S. government and U.S. government agency obligations.

The Company maintains balances with financial institutions in excess of the Federal Deposit Insurance Corporation limit.

Accounts Receivable and Allowances

Accounts receivable are amounts owed to the Company by its customers for product that has been delivered. The accounts receivable are recorded at the invoice amount, less prompt pay and other discounts, chargebacks, and an allowance for credit losses, if any. The allowance for credit losses represents the Company's estimate of losses over the life of the receivables. The Company evaluates forward-looking economic factors and uses professional judgment to determine the allowance for credit losses. The credit loss reserves are reviewed and adjusted periodically. Credit loss reserves were not material as of December 31, 2023 and 2022, respectively.

Accounts receivable are aged based on the contractual payment terms. When the collectability of an invoice is no longer probable, the Company will create a reserve for that specific receivable. If a receivable is determined to be uncollectible, it is charged against the general credit loss reserve or the reserve for the specific receivable, if one exists.

Fair Value of Financial Instruments

In accordance with Accounting Standards Codification ("ASC") 825, *Financial Instruments*, disclosures of fair value information about financial instruments are required, whether or not recognized in the balance sheet, for which it is practicable to estimate that value. Cash and cash equivalents (see Note 3) and the Company's warrant liability (see Note 3) are carried at fair value. The warrant liability is measured at fair value in accordance with ASC 815.

Other financial instruments, including accounts receivable, accounts payable and accrued liabilities, are carried at cost which approximates fair value given their short-term nature.

Inventory

Inventory is valued utilizing the weighted average costing method. The Company records an inventory reserve for losses associated with dated, expired, excess or obsolete items. This reserve is based on management's current knowledge with respect to inventory levels, planned production and sales volume assumptions. As of December 31, 2023 and 2022 inventory reserves approximated $1.4 million and $0.6 million, respectively.

Property and Equipment

Property and equipment, consisting of office equipment, computer equipment and manufacturing equipment, is stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Expenditures incurred after the fixed assets have been put into operation, such as repairs and maintenance, are charged to earnings in the period in which costs are incurred. Improvements and additions are capitalized in accordance with Company policy.

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In the third quarter of 2022, the Company transferred manufacturing equipment with a book value of $11.1 million to Corium in exchange for relief from minimum material purchase requirements. The Company recorded a loss of $11.1 million for the year ended December 31, 2022 on this disposition.

Long-Lived Assets

In accordance with ASC 360, *Property, Plant and Equipment*, the Company's policy is to review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Management does not believe the carrying values of any long-lived assets are impaired as of December 31, 2023.

Research and Development Expense

Research and development costs are expensed as incurred. Research and development expense consists primarily of costs related to personnel, including salaries and other personnel-related expenses, expenses related to manufacturing, clinical trial expenses, consulting fees and support services used in drug development. All research and development costs are charged to operations as incurred in accordance with ASC 730, *Research and Development*.

In certain circumstances, the Company is required to make advance payments to vendors for goods or services that will be received in the future for use in research and development activities. In such circumstances, the advance payments are deferred and are expensed when the activity has been performed or when the goods have been received.

Advertising Costs

The Company has elected to expense advertising costs when incurred. Advertising costs totaled zero, $8.2 million and $13.8 million for the years ended December 31, 2023, 2022 and 2021, respectively.

Deferred Financing Costs

Costs directly attributable to the Company's term loan (see Note 8) are deferred and reported as a reduction of the related term loan. These costs represent legal fees and other costs related to the term loan and are being amortized utilizing the straight-line method over the term of the loan. Amortization of deferred financing costs charged to interest expense was approximately $185,000, $342,000 and $277,000 for the years ended December 31, 2023, 2022 and 2021, respectively.

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to credit risk consist principally of cash, cash equivalents, and accounts receivable. The Company invests its cash and cash equivalents in interest-bearing accounts in United States financial institutions, the balances of which exceed federally insured limits. The Company mitigates credit risk by limiting the investment type and maturity to securities that preserve capital, maintain liquidity, and have a high credit quality. The Company has not recognized any losses from credit risks on such accounts. The Company has no financial instruments with off balance sheet risk of accounting loss.

Major customers of the Company are defined as those constituting greater than 10% of its total revenue. In 2023, the Company had sales to five customers that individually accounted for more than 10% of total revenue. These customers had sales of $4.7 million, $3.8 million, $3.7 million, $3.5 million and $2.8 million, respectively, which represented 94% of the Company's total revenue for 2023. Accounts receivable related to these five customers comprised 6%, 30%, 30%, 29% and 0% of the Company's total accounts receivable, respectively, as of December 31, 2023. In 2022, the Company had sales to four customers that individually accounted for more than 10% of total revenue. These customers had sales of

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$2.9 million, $2.7 million, $2.6 million and $1.2 million, respectively, which represented 86% of the Company's total revenue for 2022.

Revenue Recognition

The Company recognizes revenue from the sale of its product, Twirla, in accordance with ASC 606, *Revenue from Contracts with Customers* (ASC 606). The provisions of ASC 606 require the following steps to determine revenue recognition: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation.

In accordance with ASC 606, the Company recognizes revenue at the point in time when its performance obligation is satisfied by transferring control of the promised goods or services to a customer. In accordance with the Company's contracts with customers, control of the product is transferred upon the conveyance of title, which occurs when the product is sold to and received by a customer. The Company's customers are located in the United States and consist primarily of wholesale distributors. Accounts receivable due to the Company from contracts with its customers are stated separately in the balance sheet, net of various allowances as described later in this section and in the Accounts Receivable and Allowance policy.

The amount of revenue recognized by the Company is equal to the amount of consideration that is expected to be received from the sale of product to its customers. Revenue is only recognized when it is probable that a significant reversal will not occur in future periods. To determine whether a significant reversal will occur in future periods, the Company assesses both the likelihood and magnitude of any such potential reversal of revenue.

Twirla is sold to customers at the wholesale acquisition cost ("WAC"). However, the Company records product revenue, net of reserves for applicable variable consideration. These types of variable consideration items reduce revenue and include the following:

- Distribution services fees;
- Prompt pay and other discounts;
- Product returns;
- Chargebacks;
- Rebates; and
- Co-payment assistance.

An estimate for each variable consideration item is made and is recorded in conjunction with the revenue being recognized. Generally, if the estimated amount is payable to a customer, it is recorded as a reduction to accounts receivable. If the estimated amount is payable to an entity other than a customer, it is recorded as a current liability. An estimated amount of variable consideration may differ from the actual amount. At each balance sheet date, these provisions are analyzed, and adjustments are made if necessary. Any adjustments made to these provisions would affect net product revenue and earnings in the current period.

In accordance with ASC 606, the Company must make judgments to determine the estimate for certain variable consideration. For example, the Company must estimate the percentage of end-users that will obtain the product through public insurance such as Medicaid or through private commercial insurance. To determine these estimates, the Company had relied on quantitative and qualitative data from various internal and external sources to estimate its variable consideration.

The specific considerations that the Company uses in estimating these amounts related to variable considerations are as follows:

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Distribution services fees – The Company pays distribution service fees primarily to its wholesale distributors. These fees are a contractually fixed percentage of WAC and are calculated at the time of sale based on the purchase amount. The Company records these fees as contra accounts receivable on the balance sheet.

Prompt pay and other discounts – The Company incentivizes its customers to pay their invoices on time through prompt pay discounts. These discounts are an industry standard practice and the Company offers a prompt pay discount to each wholesale distributor customer. The specific prompt pay terms vary by customer and are contractually fixed. Prompt pay discounts are typically taken by the Company's customers, so an estimate of the discount is recorded at the time of sale based on the WAC. Prompt pay discount estimates are recorded as contra accounts receivable on the balance sheet.

The Company may also give other discounts to its customers to incentivize purchases and promote customer loyalty. The terms of such discounts may vary by customer. These discounts reduce gross product revenue at the time the revenue is recorded.

Product returns – Customers have the right to return product that is within six months or less of the labeled expiration date or that is past the expiration date by no more than twelve months. Twirla was commercially launched in December 2020, an estimate for product returns as of December 31, 2023 was made based on: (i) data provided to the Company by its distributors (including weekly reporting of distributors' sales and inventory held by distributors that provided the Company with visibility into the distribution channel in order to determine what quantities were sold to retail pharmacies and other providers), (ii) information provided to the Company from retail pharmacies, (iii) data provided to the Company by third-parties including a third-party data provider which collects and publishes prescription data (iv) expired returns credits issued to date, and (v) the estimated remaining shelf life of Twirla previously shipped and currently being shipped to distributors. Estimated product returns are recorded as accrued expenses on the balance sheet.

Chargebacks – Certain covered entities and government entities will be able to purchase the product at a price discounted below WAC. The difference between the government or covered entity purchase price and the wholesale distributor purchase price of WAC will be charged back to the Company. The Company estimates the amount in chargebacks based on the expected number of claims and related cost that is associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Estimated chargebacks are recorded as contra accounts receivable on the balance sheet.

Rebates – The Company is subject to mandatory discount obligations under the Medicaid and Tricare programs. The rebate amounts for these programs are determined by statutory requirements or contractual arrangements. Rebates are owed after the product has been dispensed to an end user and the Company has been invoiced. Rebates for Medicaid and Tricare are typically invoiced in arrears. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel at the end of each reporting period. Rebate estimates are recorded as accrued expenses on the balance sheet.

Co-payment assistance – The Company offers a co-payment assistance program to commercially insured patients whose insurance requires a co-payment to be made when filling their prescription. This is a voluntary program that is intended to provide financial assistance to patients meeting certain eligibility requirements. The Company estimates the amount of co-payment assistance based on the expected number of claims and related cost that is associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Co-payment assistance estimates are recorded as accrued expenses on the balance sheet.

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The following table provides a summary of the Company's sales allowances and related accruals for the year ended December 31, 2023 which have been deducted in arriving at revenues, net.

	Customer credits, discounts and allowances (contra accounts receivable)	Rebates and co-pay assistance (accrued expenses)	Product returns (accrued expenses)	Total
Balance as of December 31, 2021	$ 371	$ 528	$ 141	$ 1,040
Allowances for current period sales	5,891	4,035	399	10,325
Payments and credits	(3,268)	(2,574)	(197)	(6,039)
Balance as of December 31, 2022	2,994	1,989	343	5,326
Allowances for current period sales	18,385	8,192	2,964	29,541
Payments and credits	(16,665)	(5,564)	(1,432)	(23,661)
Balance as of December 31, 2023	$ 4,714	$ 4,617	$ 1,875	$ 11,206

Warrants

The Company accounts for its warrants to purchase common stock in accordance with ASC 480, *Distinguishing Liabilities from Equity*.

In connection with entering into a senior secured term loan facility in February 2020 (the "Perceptive Credit Agreement"), the Company issued warrants to purchase 700 shares of its common stock to the lender, Perceptive Credit Holdings III, L.P. ("Perceptive"). In connection with an amendment to that facility in February 2021, the Company issued warrants to purchase 225 shares of the Company's common stock (collectively, the "Perceptive Warrants"). The Perceptive Warrants qualify for equity classification and have been allocated based upon the relative fair value of the base instrument and the warrant. In March 2023, in connection with the Waiver and Sixth Amendment to the Perceptive Credit Agreement, the Company amended and restated the Perceptive Warrants to reset the strike price of the Perceptive Warrants. In October 2023, in connection with the Seventh Amendment to the Perceptive Credit Agreement, the Company reset the strike price of the Perceptive Warrants. See Notes 8 and 9 for additional information.

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In connection with an underwritten public offering completed in October 2021, the Company issued warrants to purchase 6,660 shares of its common stock. These warrants are classified as liabilities, were measured at fair value upon issuance, with subsequent changes in fair value reported in the Statements of Operations and Comprehensive Loss each reporting period. This offering also triggered an adjustment to the exercise price of the Perceptive Warrants, which resulted in a reduction of the strike price for these warrants. This reduction resulted in an immaterial increase to additional paid-in-capital. See Notes 8 and 9 for additional information.

In connection with a registered direct offering completed in March 2022, the Company issued warrants to purchase 24,856 shares of its common stock. These warrants are classified as liabilities, were measured at fair value upon issuance, with subsequent changes in fair value reported in the Statement of Operations and Comprehensive Loss each reporting period. This offering also triggered an adjustment to the exercise price of the Perceptive Warrants, which resulted in a reduction of the strike price for these warrants. This reduction resulted in an immaterial increase to additional paid-in-capital. See Notes 8 and 9 for additional information.

In connection with a letter agreement and waiver entered into with an investor in April 2022, the Company issued warrants to purchase 4,243 shares of common stock. These warrants are classified as liabilities, were measured at fair value upon issuance, with subsequent changes in fair value reported in the Statement of Operations and Comprehensive Loss each reporting period. See Note 9 for additional information.

In connection with a public offering completed in July 2022, the Company issued warrants to purchase 1,093,333 shares of its common stock, of which 533,333 warrants expired unexercised in July 2023. These warrants are classified as liabilities, were measured at fair value upon issuance, with subsequent changes in fair value reported in the Statement of Operations and Comprehensive Loss each reporting period. This offering also triggered an adjustment to the exercise price of the Perceptive Warrants, which resulted in a reduction of the strike price for these warrants.

In connection with a public offering completed in May 2023, the Company issued warrants to purchase 3,792,572 shares of its common stock. These warrants are classified as liabilities, were measured at fair value upon issuance, with subsequent changes in fair value reported in the Statement of Operations and Comprehensive Loss each reporting period. This offering also triggered an adjustment to the exercise price of the Perceptive Warrants, which resulted in a reduction of the strike price for these warrants.

On December 3, 2023, the Company entered into a Warrant Amendment and Additional Issuance Agreement ("Warrant Amendment and Additional Issuance Agreement") relating to the amendment of warrants to purchase shares of common stock that were issued in transactions on March 14, 2022, April 25, 2022, and May 25, 2023 (collectively, the "Warrants"). Collectively, the Warrants represent the right to purchase approximately 3.8 million shares of common stock. See Note 9 for additional information.

Income Taxes

The Company accounts for deferred taxes using the asset and liability method as specified by ASC 740, *Income Taxes*. Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and the tax basis of assets and liabilities, operating losses and tax credit carryforwards. Deferred income taxes are measured using the enacted tax rates and laws that are anticipated to be in effect when the differences are expected to reverse. The measurement of deferred income tax assets is reduced, if necessary, by a valuation allowance for any tax benefits which are not expected to be realized. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

The Company has adopted the authoritative guidance on accounting for and disclosure of uncertainty in tax positions, which prescribes a comprehensive model for the financial statement recognition, measurement, presentation, and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. The Company has no

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uncertain tax positions as of December 31, 2023 that qualify for either recognition or disclosure in the financial statements under this guidance.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC 718, *Compensation-Stock Compensation*. The Company grants stock options for a fixed number of shares to employees and non-employees with an exercise price equal to the fair value of the shares at grant date. Compensation cost is recognized for all share-based payments granted and is based on the grant-date fair value estimated using the weighted-average assumption of the Black-Scholes option pricing model based on key assumptions such as stock price, expected volatility and expected term. The Company elects to account for forfeitures when they occur. The equity instrument is not considered to be issued until the instrument vests. As a result, compensation cost is recognized over the requisite service period with an offsetting credit to additional paid-in capital.

The Company also awards restricted stock units ("RSUs") to employees and its board of directors. RSUs are generally subject to forfeiture if employment terminates prior to the completion of the vesting restrictions. The Company expenses the cost of the RSUs, which is determined to be the fair market value of the shares of common stock underlying the RSUs at the date of grant, ratably over the period during which the vesting restrictions lapse.

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, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating and reporting segment, which is the business of commercializing its transdermal patch for use in contraception.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding plus the effect of dilutive potential common shares outstanding during the period determined using the treasury-stock and if-converted methods. For purposes of the diluted net loss per share calculation, common stock warrants, unvested RSUs and stock options are considered to be potentially dilutive securities but are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive and therefore, basic and diluted net loss per share were the same for all periods presented.

The following table sets forth the outstanding potentially dilutive securities that have been excluded from the calculation of diluted net loss per share for the years ended December 31, 2023, 2022 and 2021, respectively, because to do so would be anti-dilutive (in common equivalent shares):

	Year Ended December 31,		
	2023	2022	2021
Common stock warrants	5,589,637	1,130,025	7,592
Unvested restricted stock units	173,517	129	167
Common stock options	43,043	7,956	5,183
Total	5,806,197	1,138,111	12,941

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Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (the "FASB") or other standard setting bodies that are adopted by the Company as of the specified effective date. The Company did not adopt any new accounting pronouncements during the year ended December 31, 2023 that had a material effect on its financial statements.

In November 2023, the FASB issued Accounting Standards Update ("ASU") No. 2023-07, Segment Reporting (Topic 280) ("ASU 2023-07"). The guidance in ASU 2023-07 expands prior reportable segment disclosure requirements by requiring entities to disclose significant segment expenses that are regularly provided to the Chief Operating Decision Maker ("CODM") and details of how the CODM uses financial reporting to assess their segment's performance. The guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2023, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2023-07 may have on its financial statements.

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09"). The guidance in ASU 2023-09 improves the transparency of income tax disclosures by greater disaggregation of information in the rate reconciliation and income taxes paid disaggregated by jurisdiction. The standard is effective for public companies for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2023-09 may have on its financial statements.

Management does not believe that any other recently issued, but not yet effective accounting pronouncements, if adopted, would have a material impact on the accompanying financial statements.

3. Fair Value Measurements

ASC 820, *Fair Value Measurements and Disclosures*, describes the fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value.

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. Assets and liabilities that are measured at fair value are reported using a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1 — Quoted prices in active markets for identical assets or liabilities. The Company's Level 1 assets consist of cash and cash equivalents. The Company has no Level 1 liabilities.

- Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted market prices for similar assets or liabilities in active markets or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets and liabilities. The Company has no Level 2 assets or liabilities.

- Level 3 — Unobservable inputs that are supported by little or no market data and which require internal development of assumptions about how market participants price the fair value of the assets or liabilities. The Company has no Level 3 assets. Level 3 liabilities consist of warrant liability.

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The following tables set forth the Company's financial instruments measured at fair value by level within the fair value hierarchy as of December 31, 2023 and 2022:

	Level 1	Level 2	Level 3
December 31, 2023			
Assets:			
Cash and cash equivalents	$ 2,557	$ —	$ —
Total assets at fair value	$ 2,557	$ —	$ —
Liabilities:			
Warrant Liability	$ —	$ —	$ 5,696
Total assets at fair value	$ —	$ —	$ 5,696

	Level 1	Level 2	Level 3
December 31, 2022			
Assets:			
Cash and cash equivalents	$ 5,246	$ —	$ —
Total assets at fair value	$ 5,246	$ —	$ —
Liabilities:			
Warrant Liability	$ —	$ —	$ 5,934
Total assets at fair value	$ —	$ —	$ 5,934

The significant assumptions used in preparing the option pricing model for valuing the Company's warrants as of December 31, 2023 include (i) volatility 101.5% - 126.0%, (ii) risk-free interest rate 3.8% - 4.0%, (iii) strike price for the common warrants $3.69 and $1,700.00, (iv) fair value of common stock $1.95, and (v) expected life 2.8 – 4.4 years. The significant assumptions used in preparing the option pricing model for valuing the Company's warrants as of December 31, 2022 include (i) volatility 136.8% - 137.4%, (ii) risk-free interest rate 4.2% - 4.7%, (iii) strike price for the common warrants $45.00 and $1,700.00, (iv) strike price for the preferred warrants of $520.00, (v) fair value of common stock $11.50 and (vi) expected life 0.7 - 4.5 years.

The following is a roll forward of the fair value of Level 3 warrants:

Beginning balance at December 31, 2022	$ 5,934
Warrants issued	12,537
Change in fair value	(12,775)
Ending Balance December 31, 2023	$ 5,696

There were no transfers between Level 1, 2 or 3 during 2023 or 2022.

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4. Prepaid Expenses

Prepaid expenses consist of the following:

	December 31, 2023	December 31, 2022
Prepaid insurance	$ 441	$ 628
Other	402	775
Total prepaid expenses and other current assets	$ 843	$ 1,403

5. Property and Equipment

Property and equipment, consisting of manufacturing, office and computer equipment, is stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Property and equipment consist of the following:

	December 31, 2023	December 31, 2022	Estimated Life
Office equipment	$ 132	$ 132	5 years
Computer equipment	121	121	3 Years
Manufacturing equipment	—	—	7 years
	253	253	
Less: accumulated depreciation	(178)	(76)	
Property and equipment	$ 75	$ 177	

In accordance with Amendment No. 1 to the Corium Agreement (the "Amendment"), the Company transferred all of its manufacturing equipment to Corium during the third quarter of 2022.

6. Accrued Liabilities

Accrued liabilities consist of the following:

	December 31, 2023	December 31, 2022
Gross to net accruals	$ 6,492	$ 2,332
Accrued compensation	832	833
Accrued professional fees and other	1,807	743
Total accrued liabilities	$ 9,131	$ 3,908

7. Leases

The Company has no finance leases and one operating lease for its corporate headquarters in Princeton, NJ. The current lease commenced on December 1, 2021 and terminates on March 31, 2025. The lease provides the Company with an option to extend the lease for an additional five years. Under the terms of the lease, the Company pays base annual rent subject to a fixed dollar amount increase each year, a fixed monthly charge for electricity, and other normal operating expenses such as taxes, 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 lease does not require variable lease payments, residual value guarantees, or restrictive covenants.

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The lease does not provide an implicit rate; therefore, the Company used its incremental borrowing rate as the discount rate when measuring the operating 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.

Operating lease expense was $355,000, $355,000 and $180,000 for the years ended December 31, 2023, 2022 and 2021, respectively. Operating cash flows used for operating leases during the years ended December 31, 2023, 2022 and 2021 were $319,000, $175,000 and $131,000, respectively. As of December 31, 2023, the weighted-average remaining lease term was 1.25 years, and the weighted average discount rate was 11.8%.

Future minimum lease payments under non-cancellable leases as of December 31, 2023 were as follows:

2024	$	397
2025		101
Total	$	498
Less: Interest		(32)
Present value of lease liability	$	466

8. Credit Agreement and Guaranty

On February 10, 2020, the Company entered into a Credit Agreement and Guaranty with Perceptive Credit Holdings III, LP ("Perceptive") for a senior secured term loan credit facility of up to $35.0 million (the "Perceptive Credit Agreement"). A first tranche of $5.0 million was funded on execution of the Perceptive Credit Agreement. A second tranche of $15.0 million was funded as a result of the approval of Twirla by the FDA. The other tranches of debt under the Perceptive Credit Agreement are no longer available to the Company. On January 7, 2022, the Company prepaid $5.0 million of the outstanding debt, and Perceptive waived the prepayment premium. On July 8, 2022, the Company prepaid $5.0 million of the outstanding debt, and Perceptive waived the prepayment premium. On July 25, 2022, the Company entered into a fifth amendment to the Perceptive Credit Agreement, as amended (the "Fifth Amendment"). Pursuant to the Fifth Amendment, Perceptive agreed to release its security interest in certain assets being transferred from the Company to Corium in connection with an amendment to the Company's Manufacturing and Commercialization Agreement with Corium and waive the Company's obligations to comply with certain financial covenants through the end of 2022. In exchange, the Company agreed to prepay $7.0 million of outstanding principal which was paid on July 25, 2022. On March 21, 2023, the Company and Perceptive entered into a sixth amendment to the Perceptive Credit Agreement (the "Sixth Amendment"). The Sixth Amendment waived the Company's obligations to (1) comply with certain financial covenants relating to minimum revenue requirements and minimum liquidity through June 30, 2023, and (2) file financial statements along with its Annual Report on Form 10-K for the fiscal year ended December 31, 2022 that are not subject to any "going concern" qualification. On October 30, 2023, the Company and Perceptive entered into a seventh amendment to the Perceptive Credit Agreement (the "Seventh Amendment"). The Seventh Amendment: (1) amends the Company's obligations to comply with certain financial covenants relating to minimum revenue requirements, (2) amends and waives the Company's obligations to comply with certain financial covenants relating to minimum liquidity through December 31, 2023, and (3) requires the Company to make principal payments on its outstanding loan balance of $150,000 per month beginning on December 1, 2023.

The facility was scheduled to mature on February 10, 2024 ("Maturity Date") but was extended to March 11, 2024 (see Note 13).

Borrowings under the Perceptive Credit Agreement accrue interest at an annual rate equal to the Secured Overnight Financing Rate for one-month deposits ("SOFR") plus 10.25%. The rate of interest in effect as of December 31, 2023 was 15.60%. Upon the occurrence and during the continuance of any event of default under the Perceptive Credit Agreement, the interest rate automatically increases by 3.0% per annum.

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The Company may prepay any outstanding loans in whole or in part. Any such prepayment of the loans is subject to a prepayment premium of 2.0%.

All of the Company's obligations under the Perceptive Credit Agreement are secured by a first-priority lien and security interest in substantially all of the Company's tangible and intangible assets, including intellectual property. The Perceptive Credit Agreement contains certain representations and warranties, affirmative covenants, negative covenants and conditions that are customary for similar financings. The negative covenants restrict or limit the ability of the Company to, among other things and subject to certain exceptions contained in the Perceptive Credit Agreement, incur new indebtedness; create liens on assets; engage in certain fundamental corporate changes, such as mergers or acquisitions, or changes to the Company's business activities; make certain investments or restricted payments (each as defined in the Perceptive Credit Agreement); change its fiscal year; pay dividends; repay other certain indebtedness; engage in certain affiliate transactions; or enter into, amend or terminate any other agreements that have the impact of restricting the Company's ability to make loan repayments under the Perceptive Credit Agreement. In addition, as amended by the Seventh Amendment, the Company must (i) at all times for the period from June 30, 2023 to October 31, 2023 maintain a minimum cash balance of $0.5 million for the period from November 1, 2023 to December 31, 2023 maintain a minimum cash balance of $1.0 million, and after December 31, 2023 to the Maturity Date maintain a minimum cash balance of $3.0 million; and (ii) as of the last day of each fiscal quarter commencing with the fiscal quarter ending September 30, 2023, report net revenues for the trailing 12-month period that are not less than $5.0 million. Pursuant to the Seventh Amendment, the Company has received a waiver of certain financial covenants through December 31, 2023.

In connection with the Perceptive Credit Agreement, the Company issued to Perceptive two warrants to purchase an aggregate of 700 shares of the Company's common stock (together, the "2020 Perceptive Warrants"). The first warrant is exercisable for 350 shares of common stock at an exercise price of $7,480 per share. The second warrant is exercisable for 350 shares of common stock at an exercise price of $9,340 per share. The 2020 Perceptive Warrants expire on February 10, 2027. In connection with the Perceptive Credit Agreement, the Company issued to Perceptive a warrant to purchase 225 shares of the Company's common stock (the "2021 Perceptive Warrant" and, together with the 2020 Perceptive Warrants, the "Perceptive Warrants") at an exercise price of $5,740 per share. The 2021 Perceptive Warrant expires on February 26, 2028. In connection with the Sixth Amendment, the Company amended the Perceptive Warrants to reset the exercise price to $10.50 per warrant. In connection with the Seventh Amendment, the Company further amended the Perceptive Warrants to reset the exercise price to $1.82 per warrant. The Perceptive Warrants contain anti-dilution provisions and other warrant holder protections and are not exercisable to the extent that Perceptive would beneficially own more than 19.99% of the Company's common stock because of the exercise.

As a result of the public offering of the Company's common stock completed in October 2021 (see Note 9), the antidilution provision of the Perceptive Warrants was triggered, resulting in a reduction of the strike price for the Perceptive Warrants. Warrants to purchase 350 shares of common stock that had an exercise price of $9,340 per share were reduced to $7,080 per share, warrants to purchase 350 shares of common stock that had an exercise price of $7,480 per share were reduced to $5,760 per share, and warrants to purchase 225 shares of common stock that had an exercise price of $5,740 per share were reduced to $4,540 per share.

As a result of the registered direct offering completed in March 2022 (see Note 8), the anti-dilution provision of the Perceptive Warrants was again triggered resulting in a further reduction of the strike price for the Perceptive Warrants. Warrants to purchase 350 shares of common stock that had an adjusted exercise price of $7,080 per share were reduced to $5,276 per share, warrants to purchase 350 shares of common stock that had an adjusted exercise price of $5,760 per share were reduced to $4,330.50 per share, and warrants to purchase 225 shares of common stock that had an adjusted exercise price of $4,540 per share were reduced to $3,456.50 per share.

As a result of the public offering of the Company's common stock completed in July 2022 (see Note 8), the antidilution provision of the Perceptive Warrants was again triggered resulting in a reduction of the strike price for the

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Perceptive Warrants. Warrants to purchase 350 shares of common stock that had an exercise price of $5,276 per share were reduced to $745 per share, warrants to purchase 350 shares of common stock that had an exercise price of $4,330.50 per share were reduced to $618.50 per share, and warrants to purchase 225 shares of common stock that had an exercise price of $3,456.50 per share were reduced to $501.50 per share.

As a result of the public offering of the Company's common stock completed in May 2023 (see Note 8), the antidilution provision of the Perceptive Warrants was again triggered resulting in a reduction of the strike price for the Perceptive Warrants. Warrants to purchase 350 shares of common stock that had an exercise price of $745 per share were reduced to $3.69 per share, warrants to purchase 350 shares of common stock that had an exercise price of $618.50 per share were reduced to $3.69 per share, and warrants to purchase 225 shares of common stock that had an exercise price of $501.50 per share were reduced to $3.69 per share.

The Company allocated the proceeds of $20.0 million in accordance with ASC 470 based on the relative fair values of the debt and the Perceptive Warrants. The relative fair value of the Perceptive Warrants of approximately $3.6 million at the time of issuance, which was determined using the Black-Scholes option-pricing model, was recorded as additional paid-in capital and reduced the carrying value of the debt. The significant assumptions used in the preparation of the option pricing model for valuing the Perceptive Warrants issued include (i) volatility (70.0%), (ii) risk free interest rate of 1.47% (estimated using treasury bonds with a 7-year life), (iii) strike prices of $7,480 and $9,340 for the common stock warrants, (iv) fair value of common stock ($8,020) and (v) expected life (7 years). The fair value of the 2021 Perceptive Warrants of approximately $1.1 million at the time of issuance, which was determined using the Black-Scholes option-pricing model, was recorded as additional paid-in capital and reduced the carrying value of the debt. The significant assumptions used in preparing the option pricing model for valuing the 2021 Perceptive Warrants issued include (i) volatility (103.5%), (ii) risk free interest rate of 1.15% (estimated using treasury bonds with a 7-year life), (iii) strike price of $5,740 for the common stock warrant, (iv) fair value of common stock ($5,740) and (v) expected life (7 years). The fair value of the warrants as well as the debt issue costs incurred in connection with the entry into the Perceptive Credit Agreement, including a facility fee of 1% of the total amount of loans available under the facility, are presented as a direct deduction from the carrying amount of the term loan on the consolidated balance sheet as detailed below (in thousands).

	December 31, 2023	December 31, 2022
Long-term debt	$ 1,650	$ 2,625
Debt issuance costs	(23)	(209)
Warrant discount	(112)	(990)
Total debt	$ 1,515	$ 1,426
Less, current portion	1,515	1,426
Long-term debt, less current portion	$ —	$ —

The fair value of the warrants and the debt issue costs are being amortized utilizing the effective interest method over the term of the loan. The Company recorded interest expense for the amortization of the fair value of the warrants and debt issue costs of $1,063,000, $1,969,000 and $1,661,000 for the years ended December 31, 2023, 2022, and 2021 respectively.

9. Stockholders' Equity (Deficit)

On January 7, 2022, the Company's stockholders approved an amendment to the Company's Amended and Restated Certificate of Incorporation to increase the number of shares of common stock authorized for issuance from 150,000,000 shares to 300,000,000 shares.

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Reverse Stock Split

On April 10, 2023, the Company filed with the Secretary of State of the State of Delaware a certificate of amendment, or the Certificate of Amendment, to the Company's Amended and Restated Certificate of Incorporation, which became effective on April 10, 2023. The Certificate of Amendment implemented a 1-for-50 reverse stock split of the Company's common stock. On the effective date of April 10, 2023, the number of the Company's issued and outstanding shares of common stock was decreased from 46,605,134 to 932,101, and the par value remained unchanged. No fractional shares were issued as a result of the reverse stock split. Stockholders who would otherwise have been entitled to receive a fractional share received a cash payment in lieu thereof. The reverse stock split affected all shares of the Company's common stock outstanding immediately prior to the effective date of the reverse stock split, as well as the number of shares of common stock available for issuance under the Company's equity incentive plans. In addition, the reverse stock split effected a reduction in the number of shares of common stock issuable upon the exercise of stock options, restricted stock units, or warrants outstanding.

Shelf Registration Statement

On October 2, 2020, the Company filed a universal shelf registration statement with the SEC for the issuance of common stock, preferred stock, warrants, rights, debt securities and units up to an aggregate amount of $200.0 million (the "2020 Shelf Registration Statement"). On October 14, 2020, the 2020 Shelf Registration Statement was declared effective by the SEC. In the future, the Company may periodically offer one or more of these securities in amounts, prices and terms to be announced when and if the securities are offered. At the time any of the securities covered by the 2020 Shelf Registration Statement are offered for sale, a prospectus supplement will be prepared and filed with the SEC containing specific information about the terms of any such offering. The 2020 Shelf Registration Statement expired on October 13, 2023.

Public Offerings

In October 2021, the Company completed a public offering of 13,333 shares of its common stock and warrants to purchase 6,660 shares of its common stock at a combined price of $1,700 per share of common stock and one-half of a warrant to purchase one share of common stock. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses were approximately $21.1 million.

In July 2022, the Company completed a best efforts public offering (the "2022 Offering") in which the Company raised net proceeds of $22.0 million through the sale of 382,966 shares of common stock and 150,366 pre-funded warrants ("Series B pre-funded warrants") to purchase 150,367 shares of common stock at a combined price of $45.00 per share of common stock and warrants. Both the sales of shares of common stock and pre-funded warrants were accompanied by Series A-1 and Series A-2 warrants (together the "Series A warrants") to purchase shares of common stock. The Series A-1 warrants are exercisable immediately and will expire five years from the date of issuance, and the Series A-2 warrants expired unexercised in August 2023. H.C. Wainwright acted as the exclusive placement agent in connection with the 2022 Offering and, as compensation, received a cash fee of 7% of the aggregate proceeds raised in the 2022 Offering. The Company also issued to certain designees of H.C. Wainwright warrants to purchase up to 26,666 shares of common stock with an exercise price of $56.25 per share.

In May 2023, the Company completed a best-efforts public offering of an aggregate of 95,000 shares of common stock and 1,801,286 pre-funded warrants in lieu of shares of common stock and warrants to purchase a total of 3,792,572 shares of common stock at combined public offering price of $3.9551 per share. Proceeds from the public offering, net of underwriting discounts, commissions, and offering expenses were approximately $6.5 million. Through December 31, 2023 all of the 1,801,286 pre-funded warrants had been exercised. H.C. Wainwright acted as the exclusive placement agent in connection with the Offering and, as compensation, received a cash fee of 7% of the aggregate proceeds raised

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in the Offering. The Company also issued to certain designees of H.C. Wainwright warrants to purchase up to 94,814 shares of commons stock with an exercise price of $4.9439 per share.

In December 2023, the Company entered into a Warrant Amendment and Additional Issuance Agreement relating to the amendment of warrants to purchase shares of common stock that were issued in transactions on March 14, 2022, April 25, 2022, and May 25, 2023. Collectively, the Warrants represent the right to purchase approximately 3.8 million shares of common stock. Under the terms of the Warrant Amendment and Additional Issuance Agreement, the holder agreed to revise certain provisions and in exchange for the holder's agreement to amend the Warrants, the Company agreed to issue an additional new warrant (the "New Warrant") to purchase 1,005,560 shares of common stock. The New Warrant has an exercise price of $2.09 per share of common stock. The New Warrant is exercisable six months after issuance and will expire five years from the date that the New Warrant is initially exercisable. The exercise price of the New Warrant is subject to adjustment for stock splits, reverse splits, and similar capital transactions as described in the New Warrant.

The Company has accounted for the warrants as liabilities, while the pre-funded warrants are classified as a component of permanent equity within additional paid-in capital because they are freestanding financial instruments that are legally detachable and separately exercisable from the shares of common stock with which they were issued, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, and permit the holders to receive a fixed number of shares of common stock upon exercise. The Company also determined that the pre-funded warrants should be included in the determination of basic earnings per share in accordance with ASC 260, *Earnings per Share*.

ATM Sales Agreements

In March 2021, the Company entered into a common stock sales agreement (the "Sales Agreement") under which the Company may sell up to an aggregate of $50.0 million in gross proceeds through the sale of shares of common stock from time to time in "at-the-market" equity offerings (as defined in Rule 415 promulgated under the Securities Act of 1933, as amended). The Company agreed to pay a commission of up to 3% of the gross proceeds of any common stock sold under the Sales Agreement. During the year ended December 31, 2021, the Company issued and sold 3,458 shares of common stock under the Sales Agreement resulting in net proceeds to the Company of approximately $9.3 million.

On January 10, 2022, the Company filed a prospectus supplement to its 2020 Shelf Registration Statement registering an at-the-market offering program (the "2022 ATM") the Company entered into for the sale of up to $50.0 million of shares of its common stock. The Company agreed to pay a commission of up to 3% of the gross proceeds of any common stock sold under the Sales Agreement. During the three months ended March 31, 2022, the Company issued and sold 512 shares of common stock under the Sales Agreement resulting in net proceeds to the Company of approximately $0.3 million. On April 26, 2022, the Company terminated the 2022 ATM.

On April 27, 2022, the Company entered into a new at-the-market offering program (the "April 2022 ATM Agreement") with H.C. Wainwright LLC and Co. (the "Sales Agent") under which the Company is authorized to sell up to an aggregate of $12.8 million in gross proceeds through the sale of shares of common stock from time to time. The Company agreed to pay a commission of up to 3.0% of the gross proceeds of any common stock sold under the April 2022 ATM Agreement. Through September 30, 2022, the Company issued and sold a total of 173,750 shares of common stock under the April 2022 ATM Agreement, representing the entire capacity of the April 2022 ATM, resulting in net proceeds of approximately $12.2 million. On August 22, 2022, the Company increased the April 2022 ATM ("August 2022 ATM"). As increased, the Company was eligible to offer and sell, from time to time through the Sales Agent, shares of its common stock having an aggregate offering price of up to $75.0 million. During the year ended December 31, 2022, the Company issued and sold 78,853 shares of common stock under the August 2022 ATM resulting in net proceeds of approximately $0.9 million. On April 12, 2023, the Company filed a prospectus supplement to its registration statement on Form S-3 for the August 2022 ATM verifying that it is now eligible to sell up to $4.5 million

worth of shares through its ATM. During the year ended December 31, 2023, the Company issued and sold 207,883 shares for net proceeds of approximately $1.7 million.

Registered Direct Offering

On March 14, 2022, the Company filed a prospectus supplement to its 2020 Shelf Registration Statement registering a direct offering (the "2022 Preferred Stock Offering") of 2,425 shares of Series A convertible preferred stock (the "Series A Preferred Stock") and 2,425 shares of Series B convertible preferred stock (the "Series B Preferred Stock") and Series A warrants (the "Series A Warrants") to purchase up to an aggregate of 12,125 shares of the common stock of the Company and Series B warrants (the "Series B Warrants") to purchase up to an aggregate of 12,125 shares of common stock. Each share of Series A Preferred Stock and Series B Preferred Stock has a stated value of $1,000 per share and a conversion price of $400.00 per share. The shares of preferred stock issued in the 2022 Preferred Stock Offering are convertible into an aggregate of 12,125 shares of common stock. The Series A Warrants have an exercise price of $520.00 per share, will become exercisable six months following the date of issuance, and will expire 5 years following the initial exercise date. The Series B Warrants have an exercise price of $520.00 per share, will become exercisable six months following the date of issuance, and will expire one and one-half years following the initial exercise date. Proceeds from the 2022 Preferred Stock Offering, net of the placement agent's fees and offering expenses were approximately $4.1 million. A portion of the placement agent's fees included warrants to purchase 606 shares of the common stock of the Company at a strike price of $500.00 per share. The warrants become exercisable six months following the date of issuance and will expire 5 years following the commencement of sales in the 2022 Preferred Stock Offering.

On March 15, 2022, 2,425 shares of the Series A Preferred Stock were converted into 6,063 shares of the Company's common stock. On April 4, 2022, 2,425 shares of the Series B Preferred Stock were converted into 6,063 shares of the Company's common stock.

On April 25, 2022, the Company entered into a letter agreement and waiver (the "Letter Agreement") with Armistice Capital Master Fund Ltd. ("Armistice"), pursuant to which Armistice consented to the Company entering into and effecting an at-the-market ("ATM") offering facility. On March 14, 2022, the Company entered into the 2022 Preferred Stock Offering with Armistice, under which agreement, the Company was restricted from entering into and effecting an ATM offering facility until the 180-day anniversary of the Closing Date. Pursuant to the Letter Agreement, the Company issued to Armistice a new common stock purchase warrant ("New Warrant"), on the same terms and conditions as the Series A Warrants, provided that such New Warrant shall be exercisable into 4,243 warrant shares. The Series A Warrants have an exercise price of $520.00 per share and will become exercisable six months following the date of issuance and will expire 5 years following the initial exercise date. The New Warrant is exercisable 6 months after the date of the Letter Agreement.

10. Equity Incentive Plans

Stock options

The Company had granted stock options under an amended and restated 1997 Equity Incentive Plan (the "1997 Plan") and a 2008 Equity Incentive Plan (the "2008 Plan"). The plans provided for the granting of incentive and non-statutory options and stock awards to consultants, directors, officers and employees. Such options are exercisable for a period of ten years and generally vest over a four-year period. In conjunction with the adoption of the 2008 Plan in April 2008, no additional grants were made from the 1997 Plan and issued options from the 1997 Plan remain outstanding. In 2014, the Board approved the 2014 Incentive Compensation Plan (the "2014 Plan"). The 2014 Plan is the successor to the Company's 2008 Plan and 1997 Plan. In conjunction with the adoption of the 2014 Plan in 2014, no additional grants were made from the 2008 Plan and options from the 1997 Plan and the 2008 Plan remain outstanding. In June

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2018, the 2014 Plan was amended and restated, and the Amended and Restated 2014 Incentive Compensation Plan is now referred to as the Amended 2014 Plan. In June 2023 the Company's stockholders approved the Agile Therapeutics, Inc. 2023 Equity Incentive Plan. As of December 31, 2023, there were 6,200 shares available for future grant under the 2023 Plan.

Through December 31, 2023, the Company granted options to certain employees and non-employees to purchase shares of common stock at exercise prices ranging from $10.00 to $21,500.00 per share. The Company recorded noncash stock-based compensation expense for the years ended December 31, 2023, 2022 and 2021 based on the fair market value of the options and shares granted at the grant date. Stock-based compensation expense was as follows:

	Year Ended December 31,		
	2023	2022	2021
Cost of product revenues	$ 107	$ 133	$ 271
Research and development	358	372	490
Selling and marketing	102	155	148
General and administrative	1,414	1,832	2,429
Total	$ 1,981	$ 2,492	$ 3,338

The following assumptions were used to compute employee stock-based compensation under the Black-Scholes option pricing model:

	2023	2022	2021
Risk-free interest rate	3.87%-3.90 %	1.71% - 4.22 %	.66% - 1.51 %
Expected volatility	115.9%-118.6 %	107% - 118 %	105% - 106 %
Expected dividend yield	0 %	0 %	0 %
Expected life (in years)	6.25	6.25	6.25

Risk-free interest rate. The Company bases the risk-free interest rate assumption on observed interest rates appropriate for the expected term of the stock option grants.

Expected dividend yield. The Company bases the expected dividend yield assumption on the fact that it has never paid cash dividends and has no present intention to pay cash dividends.

Expected volatility. Since August 2020, the Company transitioned to its own expected volatility based on historical data.

Expected term. The expected term represents the period of time that options are expected to be outstanding. Because the Company does not have historical exercise behavior, management determined the expected life assumption using the simplified method, which is an average of the contractual term of the option and its ordinary vesting period.

Forfeitures. The Company has elected to record forfeitures as they occur.

As of December 31, 2023, the unrecorded deferred stock-based compensation balance related to stock options was approximately $1.4 million and will be recognized over an estimated weighted-average amortization period of 2.8 years. The weighted average grant date fair value of options granted during the year ended December 31, 2023 was $2.64.

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The following table summarizes the options outstanding, options vested and the options exercisable as of December 31, 2023, 2022 and 2021:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2021	5,183	5,666.50	6.1	
Options granted	3,749	198.50		
Options exercised	—	—		
Options cancelled/forfeited	(1,004)	4,872.00		
Options outstanding at December 31, 2022	7,928	3,187.50	7.7	
Options granted	35,825	2.64		
Options exercised	—	—		
Options cancelled/forfeited	(710)	2,398.42		
Options outstanding at December 31, 2023	43,043	548.70	9.0	$ —
Options exercisable at December 31, 2023	5,007	4,438.73	5.8	$ —
Vested and expected to vest at December 31, 2023	43,043			$ —

Intrinsic value in the tables was calculated as the difference between the Company's stock price at December 29, 2023, of $1.95 per share, and the exercise price, multiplied by the number of options.

Restricted Stock Units

During the year ended December 31, 2021, the Company granted a total of 35 RSUs to certain employees of the Company. These RSUs vested on the one-year anniversary of the grant date. During the year ended December 31, 2021, the Company granted a total of 113 RSUs to directors of the Company. These RSUs vest ratably over one and three years.

During the year ended December 31, 2022, the Company granted a total of 94 RSUs to directors of the Company. These RSUs vest ratably over one year.

During the year ended December 31, 2023, the Company granted a total of 155,004 RSUs to certain employees and directors of the Company. These RSUs vest ratably over one and four years.

As of December 31, 2023, the unrecorded deferred stock-based compensation balance related to RSUs was approximately $0.3 million and will be recognized over an estimated weighted-average amortization period of 3.11 years. The following table shows the Company's restricted stock unit activity during the years ended December 31, 2023, and 2022:

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	Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Restricted stock units outstanding at December 31, 2021	167		$ 163
Granted	94	52.50	
Vested	(135)	3,815.00	
Restricted stock units outstanding at December 31, 2022	125	—	$ 163
Granted	155,004	2.46	
Vested	(112)	674.63	
Forfeited	(1,500)	2.48	
Restricted stock units outstanding at December 31, 2023	153,517		$ 299

11. Income Taxes

On March 27, 2020 the US government enacted the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) which includes numerous modifications to income tax provisions, including a limitation on business interest expense and net operating loss provisions and the acceleration of alternative minimum tax credits. Given the Company's history of losses, the CARES Act did not have a material impact on its tax provision.

As of December 31, 2023, the Company had available net operating loss carryforwards ("NOLs") of approximately $396.5 million for federal and $77.4 million for state income tax reporting purposes. Under the TCJA, the federal NOLs generated after 2017, approximately $209.6 million, can be carried forward indefinitely, while the NOLs generated through taxable years ending December 31, 2017, approximately $186.9 million, are available to offset future federal taxable income, if any, through 2037 and will begin to expire in 2024 in varying amounts if not utilized. The Company also has research and development tax credit carryforwards of approximately $6.3 million and $0.9 million for federal and state income tax reporting purposes, respectively, which are available to reduce federal income taxes, if any, through 2042 and state income taxes, if any, through 2037. The federal credits will begin to expire in 2024 in varying amounts if not utilized.

The Internal Revenue Code of 1986, as amended (the "Code") provides for a limitation on the annual use of NOLs and other tax attributes (such as research and development tax credit carryforwards) following certain ownership changes, as defined by the Code that could significantly limit the Company's ability to utilize these carryforwards. At this time, the Company has not completed a study to assess whether an ownership change under Section 382 of the Code has occurred, or whether there have been multiple ownership changes since the Company's formation, due to the costs and complexities associated with such a study. The Company is likely to have experienced various ownership changes, as defined by the Code, as a result of past financings. Accordingly, the Company's ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes. Therefore, the Company may not be able to take full advantage of these carryforwards for federal and state income tax purposes. The Company does not have any significant unrecognized tax benefits.

The Company's policy is to recognize interest and penalties related to uncertain tax positions in the income tax provision; however, as of December 31, 2023, the Company has not accrued any interest or penalties related to uncertain tax positions. The Company's tax returns for the years ended December 31, 2020 through December 31, 2022 are still subject to examination by major tax jurisdictions. However, the Internal Revenue Service ("IRS") and state tax jurisdictions can audit the NOLs generated in prior years in the years that those NOLs are utilized.

For all years through December 31, 2023, the Company generated research credits but has not conducted a study to document the qualified activities. This study may result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and

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development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the deferred tax asset established for the research and development credit carryforwards and the valuation allowance.

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets are presented below:

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 88,279	$ 87,216
Research credit carryforward	7,026	7,071
Capitalized research and development expenses	164	205
Stock options and other	5,028	2,092
Total gross deferred tax assets	100,497	96,584
Valuation allowance for deferred tax assets	(100,497)	(96,584)
Net deferred tax assets	$ —	$ —

The net change in the valuation allowance for the years ended December 31, 2023 and 2022 was an increase of $3.9 million and an increase of $5.4 million, respectively.

A reconciliation of the U.S. statutory income tax rate to the Company's effective tax rate is as follows:

	December 31,		
	2023	2022	2021
Federal income tax at statutory rate	21.0 %	21.0 %	21.0 %
State income tax benefit, net of federal benefit	0.9 %	0.1 %	0.2 %
Unrealized gain on warrants	9.8 %	17.8 %	1.1 %
Research and development tax credits	— %	0.1 %	0.2 %
Other	(4.6)%	(5.5)%	(2.2)%
Increase to valuation allowance	(27.1)%	(18.0)%	(20.3)%
Effective income tax rate	0.0 %	15.5 %	0.0 %

Sale of New Jersey Net Operating Losses

The Company has participated in the State of New Jersey's Technology Business Tax Certificate Transfer Program (the "Program") sponsored by The New Jersey Economic Development Authority. The Program enables approved biotechnology companies with unused NOLs and unused research and development credits to sell these tax benefits for at least 80% of the value of the tax benefits to unaffiliated, profitable corporate taxpayers in the State of New Jersey. The Program is administered by The New Jersey Economic Development Authority and the New Jersey Department of the Treasury's Division of Taxation. The Company had previously reached the maximum lifetime benefit of $15.0 million under the historical Program, however in January 2021 the Program was amended to extend the maximum lifetime benefit to $20.0 million. In March 2022, the Company completed the sale of NOLs totaling approximately $44.3 million and research and development credits totaling approximately $1.0 million for net proceeds of approximately $4.7 million. Such proceeds are reflected as a tax benefit for year ended December 31, 2022.

12. Commitments and Contingencies

The Company has several firm purchase commitments, primarily related to the manufacture and supply of Twirla and the supply of a field force of sales representatives to provide certain detailing services, sales operation services, compliance services, and training services. Future firm purchase commitments under these agreements, the last of which

ends in 2033, as well as the Company's operating lease (see Note 7) total $227.9 million. This amount does not represent all of the Company's anticipated purchases in the future, but instead represents only purchases that are the subject of contractually obligated minimum purchases. The minimum commitments disclosed are determined based on non-cancelable minimum spend in 2024 or termination amounts. Additionally, the Company purchases products and services as needed with no firm commitment.

In April 2020, the Company entered into a manufacturing and commercialization agreement with Corium (the "Corium Agreement"). Under the Corium Agreement, the Company has a requirement to order quarterly minimum volumes of approximately $5.6 million of product. In the event that the Company does not order the minimum volume, the Company is required to pay an additional fee equal to twenty-five percent (25%) per unit of the transfer price for all units ordered in that quarter. The Company did not meet the minimum volume order in the first or second quarter of 2022, and has, therefore, paid the additional 25% per unit fee as a penalty for all units ordered during the period. Based on then-current demand expectations for Twirla, the Company did not expect to meet the minimum volume order for the balance of 2022 and would be subject to the additional fee on future purchases. On July 25, 2022 the Company and Corium entered into Amendment No. 1 to the Corium Agreement (the "Amendment") that is designed to restructure the contract minimums applicable to the purchase of manufactured Twirla and other services provided by Corium, transfer equipment ownership to Corium to support the manufacture of Twirla and extend the term of the Corium Agreement. Pursuant to the Amendment, the parties agreed to adjust the process for the Company providing Corium certain binding and non-binding forecasts required under the Corium Agreement. Additionally, Corium will not enforce the original quantity minimums in the Corium Agreement, which are waived and replaced by new minimums that are based on Corium's revenue for product purchased by the Company, expiring raw materials, and other services billed by Corium to support batch production and release. The guaranteed minimum revenue requirement for 2024 and each year thereafter is $22.5 million. In the event that the Company does not meet the guaranteed minimum revenue requirements in any given year, the Company will be required to make additional payments to Corium for the shortfall. The Company agreed to make certain monthly supplemental payments to Corium through December 2023, which payments are eligible to be retroactively reduced based upon product orders placed by the Company during 2023 meeting certain designated thresholds. In connection with the supplemental payments, Corium will retain the proceeds for the sale of certain raw materials to which the Company would otherwise have economic right to offset such supplemental payments. Further, the Company agreed to reimburse Corium for any unused raw materials in the event the Company's actual product requirements are lower than initially forecasted. Pursuant to the Amendment, the term of the Corium Agreement was extended to December 31, 2033. Pursuant to the Amendment, the parties agreed to transfer ownership of certain manufacturing equipment used in the manufacture of Twirla from the Company to Corium under a Bill of Sale dated July 25, 2022.

The Company records a provision for contingent losses when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. An unfavorable outcome to any legal matter, if material, could have an adverse effect on the Company's operations or its financial position. As of December 31, 2023, the Company has not recorded a provision for any contingent losses.

Agile Therapeutics, Inc.
Notes to Financial Statements (Continued)
December 31, 2023
(amounts in tables in thousands, except share and per share data)

13. Subsequent Events

Warrant Exercise

On February 22, 2024, the Company entered into a warrant exercise agreement (the "Exercise Agreement") with a certain holder of its Warrants issued on July 6, 2022 and May 23, 2022 which were amended on December 3, 2023 (the "Exercising Holder") wherein the Exercising Holder agreed to exercise a total of 3,892,572 warrants for cash, at an exercise price reduced by the Company to $1.25 per share (the "Warrant Exercise").

The gross proceeds from the Warrant Exercise were approximately $4.8 million before deducting placement agent fees and other expenses.

In consideration for the Warrant Exercise, the Company issued new unregistered warrants to purchase shares of Common Stock (the "New Warrants"). The New Warrants are exercisable for an aggregate of up to 7,785,144 shares of Common Stock, at an exercise price of $1.00 per share and will be immediately exercisable upon issuance. 3,992,572 of the New Warrants will have a term of five years from the issuance date and 3,792,572 of the New Warrants will have a term of eighteen months from the issuance date. The exercise price of the New Warrants is subject to adjustment for stock splits, reverse splits, and similar capital transactions as described in the New Warrants.

H.C. Wainwright & Co., LLC acted as placement agent and financial advisor in connection with the transaction and will receive a cash fee of 7.0% of the gross proceeds resulting from the Warrant Exercise, a management fee of 1.0% of the gross proceeds resulting from the Warrant Exercise and warrants (the "Placement Agent Warrants") to purchase a number of shares of Common Stock equal to 5.0% of the number of Warrants exercised at an exercise price of $1.5625.

Perceptive Credit Agreement

On February 9, 2024, the Company and Perceptive entered into an eighth amendment to the Perceptive Credit Agreement (the "Eighth Amendment"). The Eighth Amendment extended the maturity date of the Perceptive Credit Agreement from February 10, 2024 until March 11, 2024 (the "Maturity Date"). Effective December 1, 2023, the Company has been making monthly payments of $150,000 on the outstanding loan balance and on March 11, 2024, the Company paid off the remainder of the principal balance of $1.35 million.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2022. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2023, our chief executive officer and principal financial officer have concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable level.

Management's Annual Report on Internal Controls Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act and is a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel, 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, and includes those policies and procedures that pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of our management and directors; and

- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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 assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2023. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework. Based on its evaluation, our management has concluded that, as of December 31, 2023, our internal control over financial reporting was effective.

Changes in Internal Control over Financial Reporting

The Company concluded that the material weakness identified under Item 9A of our Annual Report on Form 10-K for the year ended December 31, 2022, pertaining to the design and operating effectiveness of the Company's review procedures related to complex securities, has been remediated (the "Remediated Material Weakness").

During the year ended December 31, 2023, the Company expanded and improved its review process for complex securities and related accounting standards to address the Remediated Material Weakness.

Except for the foregoing, there has been no change in the Company's internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) that occurred during the quarter ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of the Registered Public Accounting Firm

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to the attestation by our independent registered public accounting firm because as a non-accelerated filer, we are exempt from this requirement.

Item 9B. Other Information

During the three months ended December 31, 2023, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) informed us of the adoption, modification or termination of any contract, instruction, or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act 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 an amendment to this Annual Report on Form 10-K or incorporated by reference from our definitive proxy statement to be filed pursuant to Regulation 14A.

Item 11. Executive Compensation

The information required by this item will be included in an amendment to this Annual Report on Form 10-K or incorporated by reference from our definitive proxy statement to be filed pursuant to Regulation 14A.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item will be included in an amendment to this Annual Report on Form 10-K or incorporated by reference from our definitive proxy statement to be filed pursuant to Regulation 14A.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required by this item will be included in an amendment to this Annual Report on Form 10-K or incorporated by reference from our definitive proxy statement to be filed pursuant to Regulation 14A.

Item 14. Principal Accounting Fees and Services

The information required by this item will be included in an amendment to this Annual Report on Form 10-K or incorporated by reference from our definitive proxy statement to be filed pursuant to Regulation 14A.

PART IV

Item 15. Exhibits, Financial Statement Schedules

The following documents are filed as a part of this Annual Report on Form 10-K:

(a) Financial Statements

The information concerning our financial statements, and Report of Independent Registered Public Accounting Firm required by this Item is incorporated by reference herein to the section of this Annual Report on Form 10-K in Item 8, entitled "Financial Statements and Supplementary Data."

(b) Financial Statement Schedules

All schedules have been omitted because the required information is not present or not present in amounts sufficient to require submission of the schedules, or because the information required is included in the financial statements or notes thereto.

(c) Exhibits

The list of exhibits filed with this report is set forth in the Exhibit Index immediately preceding the signature page and is incorporated herein by reference.

Exhibit Number	
3.1	Amended and Restated Certificate of Incorporation of the Registrant. (Incorporated by reference, Exhibit 3.1 to Company's Current Report on Form 8-K, file number 001-36464, filed May on 30, 2014.)
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Secretary of State of the State of Delaware on January 7, 2022 (Incorporated by reference, Exhibit 3.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on January 10, 2022.)
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Secretary of State of the State of Delaware on April 26, 2022 (Incorporated by reference, Exhibit 3.1 to Company's Current Report on Form 8-K, file number 001-36454, filed on April 27, 2022.)
3.4	Amended and Restated Bylaws of the Registrant. (Incorporated by reference, Exhibit 3.2 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 30, 2014.)
3.5	Amended and Restated Bylaws of the Registrant. (Incorporated by reference, Exhibit 3.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on January 26, 2023.)
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock filed with the Secretary of State of the State of Delaware on March 14, 2022 (Incorporated by reference, Exhibit 3.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on March 15, 2022.)
3.7	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock filed with the Secretary of State of the State of Delaware on March 14, 2022 (Incorporated by reference, Exhibit 3.2 to Company's Current Report on Form 8-K, file number 001-36464, filed on March 15, 2022.)
3.8	Certificate of Designation of Preferences, Rights, and Limitations of Series C Preferred Stock filed with the Secretary of State of the State of Delaware on January 26, 2023 (Incorporated by reference, Exhibit 3.2 to Company's Current Report on Form 8-K, file number 001-36464, filed on January 26, 2023.)

Exhibit Number	
3.9	Certificate of Amendment to Amended and Restated Certificate of Incorporation, as filed with the Secretary of State of Delaware on April 10, 2023 (Incorporated by reference, Exhibit 3.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on April 10, 2023.)
4.1	Specimen Certificate evidencing shares of Registrant's common stock (Incorporated by reference, Exhibit 4.1 to Company's Third Amendment of Registration Statement on Form S-1, file number 333-194621, filed on May 9, 2014.)
4.2	Amended and Restated Common Stock Purchase Warrant between Agile Therapeutics, Inc. and Perceptive Credit Holdings III, LP, dated as of March 21, 2023 (Incorporated by reference, Exhibit 4.2 to Company's Annual Report on Form 10-K, file number 001-36464, filed on March 23, 2023.)
4.3	Amended and Restated Common Stock Purchase Warrant between Agile Therapeutics, Inc. and Perceptive Credit Holdings III, LP, dated as of March 21, 2023 (Incorporated by reference, Exhibit 4.3 to Company's Annual Report on Form 10-K, file number 001-36464, filed on March 23, 2023.)
4.4	Amended and Restated Common Stock Purchase Warrant between Agile Therapeutics, Inc. and Perceptive Credit Holdings III, LP, dated as of March 21, 2023 (Incorporated by reference, Exhibit 4.4. to Company's Annual Report on Form 10-K, file number 001-36464, filed on March 23, 2023.)
4.5	Form of Warrant (Incorporated by reference, Exhibit 4.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on October 8, 2021.)
4.6	Form of Series A Warrant (Incorporated by reference, Exhibit 4.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on March 15, 2022.)
4.7	Form of Series B Warrant (Incorporated by reference, Exhibit 4.2 to Company's Current Report on Form 8-K, file number 001-36464, filed on March 15, 2022.)
4.8	Form of Placement Agent Warrant (Incorporated by reference, Exhibit 4.3 to Company's Current Report on Form 8-K, file number 001-36464, filed on March 15, 2022.)
4.9	Form of Series A-1 Warrant (Incorporated by reference, Exhibit 4.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on July 8, 2022.)
4.10	Form of Series A-2 Warrant (Incorporated by reference, Exhibit 4.2 to Company's Current Report on Form 8-K, file number 001-36464, filed on July 8, 2022.)
4.11	Form of Series B Pre-Funded Warrant (Incorporated by reference, Exhibit 4.3 to Company's Current Report on Form 8-K, file number 001-36464, filed on July 8, 2022.)
4.12	Form of Placement Agent Warrant (Incorporated by reference, Exhibit 4.4 to Company's Current Report on Form 8-K, file number 001-36464, filed on July 8, 2022.)
4.13	Form of Series C-1 Warrant (Incorporated by reference, Exhibit 4.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.)
4.14	Form of Series C-2 Warrant (Incorporated by reference, Exhibit 4.2 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.)
4.15	Form of Series D Pre-funded Warrant (Incorporated by reference, Exhibit 4.3 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.)

Exhibit Number	
4.16	Form of Placement Agent Warrant (Incorporated by reference, Exhibit 4.4 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.)
4.17	Form of Amended and Restated Common Stock Purchase Warrant between Agile Therapeutics, Inc. and an institutional investor, dated October 8, 2021 (Incorporated by reference, Exhibit 4.5 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.)
4.18	Form of Amended and Restated Series A Common Stock Purchase Warrant between Agile Therapeutics, Inc. and an institutional investor, dated March 14, 2022 (Incorporated by reference, Exhibit 4.6 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.)
4.19	Form of Amended and Restated Series A Common Stock Purchase Warrant between Agile Therapeutics, Inc. and an institutional investor, dated April 25, 2022 (Incorporated by reference, Exhibit 4.7 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.)
4.20	Form of Amended and Restated Series A-1 Common Stock Purchase Warrant between Agile Therapeutics, Inc. and an institutional investor, dated July 6, 2022 (Incorporated by reference, Exhibit 4.8 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.)
4.21	Form of Amended and Restated Series A-2 Common Stock Purchase Warrant between Agile Therapeutics, Inc. and an institutional investor, dated July 6, 2022 (Incorporated by reference, Exhibit 4.9 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.)
4.22	Form of Amended and Restated Series B Common Stock Purchase Warrant between Agile Therapeutics, Inc. and an institutional investor, dated March 14, 2022 (Incorporated by reference, Exhibit 4.10 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.)
4.23	Form of New Warrant (Incorporated by reference, Exhibit 4.1 to Company's Current Report on Form 8-K, file number 001-36464, filed December 4, 2023.)
4.24	Form of New Warrant (Incorporated by reference, Exhibit 4.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on February 23, 2024.)
4.25	Form of New Warrant (Incorporated by reference, Exhibit 4.2 to Company's Current Report on Form 8-K, file number 001-36464, filed on February 23, 2024.)
4.26	Form of Placement Agent Warrant (Incorporated by reference, Exhibit 4.3 to Company's Current Report on Form 8-K, file number 001-36464, filed on February 23, 2024.)
4.27	Amendment to Warrants and Certificate of Adjustment between Agile Therapeutics, Inc. and Perceptive Credit Holdings III, LP, dated as of October 30, 2023 (Incorporated by reference, Exhibit 4.25 to Company's Registration on Form S-1, file number 333-194621, filed on December 11, 2023.)
4.28	Description of Capital Stock (Incorporated by reference, Exhibit 4.4 to Company's Annual Report on Form 10-K, file number 001-36464, filed on February 20, 2020.)
10.1+	Form of Indemnification Agreement. (Incorporated by reference, Exhibit 10.1 to Company's Second Amendment of Registration Statement on Form S-1, file number 333-194621, filed on May 5, 2014.)
10.2+	Agile Therapeutics, Inc. Amended and Restated 1997 Equity Incentive Plan, as amended, and form of Stock Option Agreement thereunder. (Incorporated by reference, Exhibit 10.2 to Company's Registration Statement on Form S-1, file number 333-194621, filed on March 17, 2014.)

Exhibit Number	
10.3+	Agile Therapeutics, Inc. Amended and Restated 2008 Equity Incentive Plan and form of Nonqualified Stock Option Agreement and form of Incentive Stock Option Agreement thereunder. (Incorporated by reference, Exhibit 10.3 to Company's Registration Statement on Form S-1, file number 333-194621, filed on March 17, 2014.)
10.4+	Form of Performance Unit Issuance Agreement (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on January 26, 2018.)
10.5	Lease Agreement, dated August 6, 2021 by and between Agile Therapeutics, Inc. and 500 College Road Venture, LLC (Incorporated by reference, Exhibit 10.1 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on November 2, 2021.)
10.6	Common Stock Sales Agreement dated November 8, 2019 by and between Agile Therapeutics, Inc. and H.C. Wainwright & Co., LLC (Incorporated by reference, Exhibit 1.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on November 8, 2019.)
10.7	Common Stock Sales Agreement dated March 18, 2021, by and between Agile Therapeutics, Inc. and H.C. Wainwright & Co., LLC (Incorporated by reference, Exhibit 1.1 to the Company's Current Report on Form 8-K, file number 001-036464, filed on March 18, 2021.)
10.8	Common Stock Sales Agreement dated April 27, 2022 by and between Agile Therapeutics, Inc. and H.C. Wainwright & Co., LLC (Incorporated by reference, Exhibit 1.1 to Company's Current Report on Form 8-K, file number 001-036464, filed on April 27, 2022.)
10.9	Controlled Equity Offering℠ Sales Agreement dated January 10, 2022 by and among Agile Therapeutics, Inc. and Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC (Incorporated by reference, Exhibit 1.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on January 10, 2022.)
10.10	Engagement Agreement, by and between Agile Therapeutics, Inc. and H.C. Wainwright & Co., LLC (Incorporated by reference, Exhibit 10.32 to Company's Amendment No. 1 to Registration Statement on Form S-1/A, file number 333-264960, filed on June 29, 2022.)
10.11	Amendment to Engagement Agreement, by and between Agile Therapeutics, Inc. and H.C. Wainwright & Co., LLC (Incorporated by reference, Exhibit 10.33 to Company's Amendment No. 1 to Registration Statement on Form S-1/A, file number 333-264960, filed on June 29, 2022.)
10.12	Credit Agreement and Guaranty among Agile Therapeutics, Inc., the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, dated as of February 10, 2020 (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on February 12, 2020.)
10.13	Waiver and First Amendment to Credit Agreement and Guaranty among Agile Therapeutics, Inc., the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, dated as of February 26, 2021(Incorporated by reference, Exhibit 10.11 to Company's Annual Report on Form 10-K, file number 001-36464, filed on March 1, 2021.)
10.14	Waiver and Second Amendment to Credit Agreement and Guaranty among Agile Therapeutics, Inc., the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, dated as of January 7, 2022 (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on January 10, 2022.)

Exhibit Number	
10.15	Waiver and Third Amendment to Credit Agreement and Guaranty among Agile Therapeutics, Inc., the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, dated as of March 10, 2022 (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on March 11, 2022.)
10.16	Waiver and Fourth Amendment to Credit Agreement and Guaranty among Agile Therapeutics, Inc., the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, dated as of May 11, 2022 (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 12, 2022.)
10.17	Fifth Amendment to Credit Agreement and Guaranty among Agile Therapeutics, Inc., the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, L.P. dated as of July 25, 2022 (Incorporated by reference, Exhibit 10.1 to Company's Quarterly Report on form 10-Q, file number 001-36464, filed on November 7, 2022.)
10.18	Waiver and Sixth Amendment to Credit Agreement and Guaranty among Agile Therapeutics, Inc., the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, dated as of March 21, 2023 (Incorporated by referenced, Exhibit 10.18 to Company Registration on Form S-1, file number 333-271249, filed on April 14, 2023.)
10.19	Seventh Amendment to Credit Agreement and Guaranty among Agile Therapeutics, Inc., the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, dated as of October 30, 2023 (Incorporated by reference, Exhibit 10.19 to Company's Registration on Form S-1, file number 333-194621, filed on December 11, 2023.)
10.20	Eighth Amendment to Credit Agreement and Guaranty, by and among Agile Therapeutics, Inc., the guarantors from time to party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, dated as of February 9, 2024 (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on February 15, 2024.)
10.21	Form of Securities Purchase Agreement, dated March 13, 2022, by and between Agile Therapeutics, Inc. and the purchaser signatory thereto (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on March 15, 2022.)
10.22	Form of Securities Purchase Agreement by and between Agile Therapeutics, Inc. and the purchasers signatory thereto (Incorporated by reference, Exhibit 10.31 to Company's Amendment No. 1 to Registration Statement on Form S-1/A, file number 333-264960, filed on June 29, 2022.)
10.23	Form of Securities Purchase Agreement, by and between Agile Therapeutics, Inc., and certain purchasers (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on July 8, 2022.)
10.24	Form of Securities Purchase Agreement, dated May 22, 2023, by and between Agile Therapeutics, Inc. and certain purchasers (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.)
10.25	Form of Warrant Amendment Agreement, dated May 22, 2023, by and between Agile Therapeutics, Inc. and certain holders (Incorporated by reference, Exhibit 10.2 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.)
10.26	Form of Exercise Agreement (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on February 23, 2024.)

Exhibit Number	
10.27*	Project Agreement, dated April 30, 2020, by and between Agile Therapeutics, Inc. and inVentiv Commercial Services, LLC (Incorporated by reference, Exhibit 10.1 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on August 11, 2020.)
10.28*	First Amendment to Project Agreement, dated June 1, 2020, by and between Agile Therapeutics, Inc. and inVentiv Commercial Services, LLC (Incorporated by reference, Exhibit 10.13 to Company's Annual Report on Form 10-K, file number 001-36464, filed on March 1, 2021.)
10.29*	Second Amendment to Project Agreement, dated January 1, 2021, by and between Agile Therapeutics, Inc. and inVentiv Commercial Services, LLC (Incorporated by reference, Exhibit 10.2 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on November 2, 2021.)
10.30*	Third Amendment to Project Agreement, dated July 1, 2021, by and between Agile Therapeutics, Inc. and inVentiv Commercial Services, LLC. (Incorporated by reference, Exhibit 10.3 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on November 2, 2021.)
10.31*	Fourth Amendment to Project Agreement, dated September 1, 2021, by and between Agile Therapeutics, Inc. and inVentiv Commercial Services, LLC. (Incorporated by reference, Exhibit 10.24 to Company's Annual Report on Form 10-K, file number 001-36464, filed on March 30, 2022.)
10.32*	Fifth Amendment to Project Agreement, dated February 1, 2022, by and between Agile Therapeutics, Inc. and inVentiv Commercial Services LLC (Incorporated by reference, Exhibit 10.5 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on May 12, 2022.)
10.33*	Sixth Amendment to Project Agreement, dated January 3, 2023, by and between Agile Therapeutics, Inc. and inVentiv Commercial Services, LLC (Incorporated by reference, Exhibit 10.27 to the Company's Annual Report on Form 10-K, file number 001-36464, filed on March 23, 2023.)
10.34*	Seventh Amendment to Project Agreement, dated September 28, 2023, by and between Agile Therapeutics Inc., and Syneos Health Commercial Services, LLC (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on September 28, 2023.)
10.35*	Master Service Agreement, dated October 11. 2017, by and between Agile Therapeutics, Inc. and inVentiv Commercial Services, LLC (Incorporated by reference, Exhibit 10.2 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on August 11, 2020.)
10.36*	First Amendment to Master Service Agreement, dated April 30, 2020, by and between Agile Therapeutics, Inc. and inVentiv Commercial Services, LLC (Incorporated by reference, Exhibit 10.3 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on August 11, 2020.)
10.37*	Manufacturing and Commercialization Agreement, dated April 30, 2020, by and between Agile Therapeutics, Inc. and Corium, Inc. (Incorporated by reference, Exhibit 10.4 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on August 11, 2020.)
10.38	Amendment No. 1 to Manufacturing and Commercialization Agreement, by and between Corium, Inc. and Agile Therapeutics, Inc., dated as of July 25, 2022, and Bill of Sale by Agile Therapeutics, Inc. to Corium Inc., dated as of July 25, 2022 (Incorporated by reference, Exhibit 10.2 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on November 7, 2022.)
10.39+	Agile Therapeutics, Inc. Amended and Restated 2014 Incentive Compensation Plan (Incorporated by reference, Appendix A to Registrant's Proxy Statement pursuant to Section 14(a) of the Securities Exchange Act of 1934, file number 001-36464, filed on April 25, 2018.)

Exhibit Number	
10.40+	Agile Therapeutics, Inc. 2023 Equity Incentive Plan effective June 8, 2023 (Incorporated by reference, Exhibit 99.1 to Company's Registration Statement on Form S-8, file number 333-272576, filed on June 9, 2023.)
10.41+	Amended and Restated Employment Agreement, dated November 22, 2022 by and between Agile Therapeutics, Inc. and Alfred Altomari (Incorporated by referenced, Exhibit 10.33 to the Company's Annual Report on Form 10-K, file number 001-36464, filed on March 23, 2023.).
10.42+	Amended and Restated Employment Agreement, dated November 1, 2022 by and between Agile Therapeutics, Inc. and Geoffrey P. Gilmore (Incorporated by referenced, Exhibit 10.34 to the Company's Annual Report on Form 10-K, file number 001-36464, filed on March 23, 2023.).
10.43+	Amended and Restated Employment Agreement, dated November 1, 2022 by and between Agile Therapeutics, Inc. and Paul Korner, MD (Incorporated by referenced, Exhibit 10.35 to the Company's Annual Report on Form 10-K, file number 001-36464, filed on March 23, 2023.).
10.44+	Employment Agreement, dated August 16, 2023, by and between Agile Therapeutics, Inc. and Scott Coiante (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K/A, file number 001-36464, filed August 22, 2023.)
10.45+	Transition and Separation Agreement, dated August 17, 2023, by and between Agile Therapeutics, Inc. and Jason Butch (Incorporated by reference, Exhibit 10.3 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on November 9, 2023.)
10.46	Form of Warrant Amendment and Additional Issuance Agreement (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on December 4, 2023.)
23.1**	Consent of Independent Registered Public Accounting Firm.
31.1**	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2**	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1**	Agile Therapeutics, Inc. Compensation Recoupment Policy.
101	The following materials from the Company's Annual Report on Form 10-K for the period ended December 31, 2022 formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Balance Sheets, (ii) Statements of Operations and Comprehensive Loss, (iii) Statements of Stockholders' Equity, (iv) Statements of Cash Flows, and (v) the Notes to Financial Statements.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

\+ Indicates management contract or compensatory plan or arrangement.

* Portions of this exhibit have been redacted in accordance with Regulation S-K Item 601(b)(10).

** Filed or furnished, as applicable, herewith.

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, on March 28, 2024.

AGILE THERAPEUTICS, INC.

By /s/ ALFRED ALTOMARI
Alfred Altomari
Chief Executive Officer

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 in the capacities and on the dates indicated.

Signature	Title	Date
/s/ ALFRED ALTOMARI Alfred Altomari	Chief Executive Officer and Director (Principal Executive Officer)	March 28, 2024
/s/ SCOTT M. COIANTE Scott M. Coiante	Chief Financial Officer (Principal Accounting Officer)	March 28, 2024
/s/ SHARON BARBARI Sharon Barbari	Director	March 28, 2024
/s/ SANDRA CARSON Sandra Carson, M.D., FACOG	Director	March 28, 2024
/s/ SETH H.Z. FISCHER Seth H.Z. Fischer	Director	March 28, 2024
/s/ JOHN HUBBARD John Hubbard, Ph.D.	Director	March 28, 2024
/s/ JOSEPHINE TORRENTE Josephine Torrente	Director	March 28, 2024

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-199441), pertaining to Agile Therapeutics, Inc. 2014 Incentive Compensation Plan,

(2) Registration Statement (Form S-8 No. 333-205116), pertaining to Agile Therapeutics, Inc. 2014 Incentive Compensation Plan,

(3) Registration Statement (Form S-8 No. 333-210045), pertaining to Agile Therapeutics, Inc. 2014 Incentive Compensation Plan,

(4) Registration Statement (Form S-8 No. 333-217807), pertaining to Agile Therapeutics, Inc. 2014 Incentive Compensation Plan,

(5) Registration Statement (Form S-8 No. 333-228151), pertaining to Agile Therapeutics, Inc. Amended and Restated 2014 Incentive Compensation Plan,

(6) Registration Statement (Form S-8 No. 333-232989), pertaining to Agile Therapeutics, Inc. Amended and Restated 2014 Incentive Compensation Plan,

(7) Registration Statement (Form S-8 No. 333- 254428), pertaining to Agile Therapeutics, Inc. Amended and Restated 2014 Incentive Compensation Plan (filed on March 18, 2021),

(8) Registration Statement (Form S-3 No. 333-249273) of Agile Therapeutics, Inc.,

(9) Registration Statement (Form S-1 No. 333-264960) of Agile Therapeutics, Inc.,

(10) Registration Statement (Form S-1MEF No. 333-265959) of Agile Therapeutics, Inc.,

(11) Registration Statement (Form S-1 No. 333-271249) of Agile Therapeutics, Inc.,

(12) Registration Statement (Form S-1 No. 333-275995) of Agile Therapeutics, Inc. and

(13) Registration Statement (Form S-8 No. 333-272576), pertaining to Agile Therapeutics, Inc. 2023 Equity Incentive Plan

of our report dated March 28, 2024, with respect to the financial statements of Agile Therapeutics, Inc., included in this Annual Report (Form 10-K) of Agile Therapeutics, Inc. for the year ended December 31, 2023.

/s/ Ernst & Young LLP

Iselin, New Jersey
March 28, 2024

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Alfred Altomari, certify that:

1. I have reviewed this Annual Report on Form 10-K of Agile Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2024

/s/ ALFRED ALTOMARI
Alfred Altomari
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott M. Coiante, certify that:

1. I have reviewed this Annual Report on Form 10-K of Agile Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2024

/s/ SCOTT M. COIANTE

Scott M. Coiante
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

STATEMENT OF CHIEF EXECUTIVE OFFICER OF
AGILE THERAPEUTICS, INC.
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 of Agile Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2023 as filed with the Securities and Exchange Commission (the "Report"), I, Alfred Altomari, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2024

/s/ ALFRED ALTOMARI
Alfred Altomari
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

STATEMENT OF CHIEF ACCOUNTING OFFICER OF
AGILE THERAPEUTICS, INC.
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 of Agile Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2023 as filed with the Securities and Exchange Commission (the "Report"), I, Scott M. Coiante, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2024

/s/ SCOTT M. COIANTE
Scott M. Coiante
Chief Financial Officer
(Principal Financial Officer)

AGILE THERAPEUTICS, INC.
COMPENSATION RECOUPMENT POLICY

I. Purpose.

The Board of Directors ("Board") of Agile Therapeutics, Inc. (the "Company") based upon the recommendation of its Compensation Committee (the "Committee"), has adopted this Compensation Recoupment Policy (this "Policy") in order to implement a mandatory clawback policy in the event of a Restatement in compliance with the Applicable Rules. Any capitalized terms used, but not immediately defined, in this Policy have the meanings set forth in Section VIII.

II. Administration.

This Policy shall be administered by the Committee, which shall make all determinations with respect to this Policy in its sole discretion; *provided* that this Policy shall be interpreted in a manner consistent with the requirements of the Applicable Rules. Notwithstanding the foregoing, subject to the Applicable Rules, the Board may assume any or all powers and authority of the Committee with respect to this Policy, in which case references to the Committee shall be deemed to include the Board, as applicable.

III. Recovery on a Restatement.

In the event that the Company is required to prepare a Restatement, the Company shall reasonably promptly recover from an Executive Officer the amount of any erroneously awarded Incentive-Based Compensation that is Received by such Executive Officer during the Recovery Period. The amount of erroneously Received Incentive-Based Compensation will be the excess of the Incentive-Based Compensation Received by the Executive Officer (whether in cash or shares) based on the erroneous data in the original financial statements over the Incentive-Based Compensation (whether in cash or in shares) that would have been Received by the Executive Officer had such Incentive-Based Compensation been based on the restated results, without respect to any tax liabilities incurred or paid by the Executive Officer.

Recovery of any erroneously awarded compensation under this Policy is not dependent on fraud or misconduct by any Executive Officer in connection with a Restatement.

Without limiting the foregoing, for Incentive-Based Compensation based on the Company's stock price or total shareholder return, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in the Restatement, (i) the amount shall be based on the Company's reasonable estimate of the effect of the Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was Received and (ii) the Company shall maintain documentation of the determination of that reasonable estimate and provide such estimate to the Regulators as required by the Applicable Rules.

In addition to the foregoing, in the event that an Executive Officer fails to repay or reimburse erroneously awarded compensation that is subject to recovery, the Committee may require an Executive Officer to reimburse the Company for any and all expenses reasonably incurred (including legal fees) by the Company in recovering erroneously awarded compensation under this Policy.

IV. Coverage and Application.

This Policy covers all persons who are Executive Officers at any time during the Recovery Period for which Incentive-Based Compensation is Received. Incentive-Based Compensation shall not be recovered under this Policy to the extent Received by any person before the date the person served as an Executive Officer. Subsequent changes in an Executive Officer's employment status, including retirement or termination of employment, do not affect the Company's right to recover Incentive-Based Compensation pursuant to this Policy.

This Policy shall apply to Incentive-Based Compensation that is Received by any Executive Officer on or after the Effective Date and that results from attainment of a Financial Reporting Measure based on or derived from financial information for any fiscal period ending on or after the Effective Date. For the avoidance of doubt, this will include Incentive-Based Compensation that may have been approved, awarded, or granted to an Executive Officer on or before the Effective Date if such Incentive-Based Compensation is Received after the Effective Date.

V. Exceptions to Policy.

No recovery of Incentive-Based Compensation shall be required if any of the following conditions are met and the Committee determines that, on such basis, recovery would be impracticable:

(a) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered; *provided* that prior to making a determination that it would be impracticable to recover any Incentive-Based Compensation based on the expense of enforcement, the Company shall (i) have made a reasonable attempt to recover the Incentive-Based Compensation, (ii) have documented such reasonable attempts to recover, and (iii) provide the documentation to the Regulators as required by the Applicable Rules;

(b) recovery would violate home country law where that law was adopted prior to November 28, 2022; or

(c) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees, to fail to meet the requirements of Section 401(a)(13) or Section 411(a) of the Internal Revenue Code of 1986, as amended (the "Code"), and U.S. Treasury regulations promulgated thereunder.

VI. Methods of Recovery.

In the event of a Clawback Event, subject to applicable law, the Committee may take any such actions as it deems necessary or appropriate, including, without limitation:

(a) the reduction or cancellation of any Incentive-Based Compensation in the form of vested or unvested equity or equity-based awards that have not been distributed or otherwise settled prior to the date of determination;

(b) the recovery of any Incentive-Based Compensation that was previously paid to the Executive Officer;

(c) the recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any Incentive-Based Compensation in the form of equity or equity-based awards;

(d) the offset, withholding, or elimination of any amount that could be paid or awarded to the Executive Officer after the date of determination;

(e) the recoupment of any amount in respect of Incentive-Based Compensation contributed to a plan that takes into account Incentive-Based Compensation (excluding certain tax-qualified plans, but including long-term disability, life insurance, supplemental executive retirement plans and deferred compensation plans, in each case to the extent permitted by applicable law, including Section 409A of the Code) and any earnings accrued to date on any such amount; and

(f) the taking any other remedial and recovery action permitted by law, as determined by the Committee.

In addition, the Committee may authorize legal action for breach of fiduciary duty or other violation of law and take such other actions to enforce the Executive Officer's obligations to the Company as the Committee deems appropriate.

VII. Miscellaneous.

(a) *Effective Date*. This Policy shall be effective as of October 2, 2023 ("Effective Date").

(b) *Public Disclosure*. The Company shall make all required disclosures and filings with the Regulators with respect to this Policy in accordance with the requirements of the Applicable Rules, and any other requirements applicable to the Company, including any disclosures required in connection with SEC filings.

(c) *Notice*. Before the Company takes action to seek recovery of compensation pursuant to this Policy against an Executive Officer, the Company shall take commercially reasonable steps to provide such individual with advance written notice of such clawback; provided that this notice requirement shall not in any way delay the reasonably prompt recovery of any erroneously awarded Incentive-Based Compensation.

(d) *No Indemnification*. The Company shall not indemnify any current or former Executive Officer against the loss of erroneously awarded compensation and shall not pay or reimburse any Executive Officer for premiums incurred or paid for any insurance policy to fund such Executive Officer's potential recovery obligations.

(e) *No Substitution of Rights; Non-Exhaustive Rights*. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to (i) any equity or equity-based incentive compensation plan or any successor plan thereto, or any other incentive plan of the Company or any of its subsidiaries or affiliates or (ii) the terms of any similar policy or provision in any employment agreement, compensation agreement or arrangement, or similar agreement and any other legal remedies available to the Company. In addition to recovery of compensation as provided for in this Policy, the Company may take any and all other actions as it deems necessary, appropriate and in the Company's best interest in connection with a Clawback Event, including termination of an Executive Officer's employment and initiating legal action against an Executive Officer, and nothing in this Policy limits the Company's rights to take any such or other appropriate actions.

(f) *Governing Law*. This Policy and all determinations made and actions taken pursuant hereto, to the extent not otherwise governed by mandatory provisions of the Applicable Rules, shall be governed by and construed in accordance with the laws of the State of Delaware without regard to choice of law principles. If any provision of this Policy shall be held illegal or invalid for any reason, such illegality or invalidity shall not affect the remaining parts of this Policy, but this Policy shall be construed and enforced as if the illegal or invalid provision had never been included in this Policy.

(g) *Amendment; Termination; Sunset*. The Board, based upon the recommendation of the Committee, may amend this Policy at any time for any reason, subject to any limitations under the Applicable Rules. Unless otherwise required by applicable law, this Policy shall no longer be effective from and after the date that the Company no longer has a class of securities publicly listed on a U.S. national securities exchange or is otherwise not subject to the Applicable Rules.

VIII. Defined Terms.

(a) "Applicable Rules" means Section 10D of the Exchange Act and Rule 10D-1 promulgated thereunder, Listing Rule 5608 of the Listing Rules of Nasdaq, and any other national stock exchange rules that the Company is or may become subject to.

(b) "Clawback Event" means a required recoupment of Incentive-Based Compensation in the event of a Restatement under the Applicable Rules.

(c) "Exchange Act" means the Securities Exchange Act of 1934, as amended.

(d) "Executive Officer" means each officer of the Company who is the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice president of the Company in charge of a principal business unit, division or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar significant policy-making functions for the Company, as determined under 17 CFR §229.401(b).

(e) "Financial Reporting Measures" means (i) measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures, (ii) the Company's stock price, and (iii) total shareholder return in respect of the Company. A "Financial Reporting Measure" need not be presented within the financial statements or included in a filing with the SEC.

(f) "Incentive-Based Compensation" means any compensation that is granted, earned, or vested, based wholly or in part upon the attainment of a Financial Reporting Measure. Incentive-Based Compensation does not include, among other forms of compensation, equity awards that vest exclusively upon completion of a specified employment period, without any performance condition, and bonus awards that are discretionary or based on subjective goals or goals unrelated to Financial Reporting Measures.

(g) "Nasdaq" means the Nasdaq Stock Market LLC.

(h) "Received" – Incentive-Based Compensation is deemed "Received" for the purposes of this Policy in the Company's fiscal period during which the Financial Reporting Measure applicable to the Incentive-Based Compensation award is attained, even if the payment or grant of the Incentive-Based Compensation occurs after the end of that period.

(i) "Recovery Period" means the three completed fiscal years immediately preceding the date on which the Company is required to prepare a Restatement, which date is the earlier of (i) the date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare a Restatement or (ii) a date that a court, regulator, or other legally authorized body directs the Company to prepare a Restatement.

(j) "Regulators" means, as applicable, the SEC and Nasdaq.

(k) "Restatement" means that the Company is required to prepare an accounting restatement due to a material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements (i) that is material to the previously issued financial statements, or (ii) that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period. Changes to the Company's financial statements that do not represent error corrections under the then-current relevant accounting standards will not constitute Restatements.

(l) "SEC" means the U.S. Securities and Exchange Commission.