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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, 2022

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:

Title of each class	**Trading Symbol(s)**	**Name of exchange on which registered:**
Common stock, par value $0.0001 per share	AGRX	The Nasdaq Capital Market

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or 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, 2022 was approximately $14.4 million.

As of March 14, 2023, there were 46,538,250 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2023 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed within 120 days of the registrant's fiscal year ended December 31, 2022, 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, 2022

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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 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 attractiveness of our business to potential investors or business partners, 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, 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 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.

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 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 accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;

- 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 Pharma Solutions. ("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 come into compliance with the listing requirements of the Nasdaq Capital Market;

- 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 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, 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;
- Existing and future legislation may increase the difficulty and cost for us to commercialize Twirla and may affect the prices we may obtain;
- We have incurred operating losses in each year since our inception and expect to continue to incur substantial losses for the foreseeable future. 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 continue to commercialize Twirla or to 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;
- 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 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;
- If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of Twirla;
- We are not in compliance with the Nasdaq continued listing requirements. If we are unable to comply with the continued listing requirements of the Nasdaq Capital Market, our common stock could be delisted, which could affect our common stock's market price and liquidity and reduce our ability to raise capital; and
- We expect that our stock price may fluctuate significantly.
- We have identified a material weakness in our internal control over financial reporting. This material weakness could continue to adversely affect our results of operations and financial condition accurately. In the future, we may identify additional material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting or adequate disclosure controls and procedures, which may result in material errors in our financial statements or cause us to fail to meet our period reporting obligations.

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.

Our first and only product, Twirla, is a once-weekly prescription combination hormonal contraceptive patch. It 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 2022, 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 initiated a relationship with Nurx®, which we believe can make Twirla nationally available on Nurx.com, part of the Thirty Madison telehealth platform focused on sexual and reproductive health. Nurx has provided contraception to over 1 million patients. 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. We also expect to continue exploring possible expansion through business development activities, such as acquiring access to new products through in-licensing, co-promotion or other collaborative 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 commitment and the post-marketing requirement studies of Twirla.

It should be noted that the possibility of continued public health threats could adversely affect our ongoing or planned business operations. For example, the coronavirus (“COVID-19”) pandemic previously resulted in federal, state and local governments and private entities mandating various restrictions, including travel restrictions, access restrictions, restrictions on public gatherings, and stay at home orders. The most significant impacts to our business were encountered by sales representatives promoting Twirla in the field, as some offices limited opportunities for face-to-face interactions with healthcare providers. Re-implementation of COVID-19 restrictions, if necessary in the future, may disrupt our business and/or could adversely affect our commercialization plans and results. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including personnel at third-party manufacturing facilities and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timeline presently planned could be materially and adversely impacted. Another shut down necessitating work in a completely remote environment could result in delays to our business activities and commercialization plan. We will continue to closely monitor events as they develop, and plan for alternative and mitigating measures that we can implement if needed.

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. 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 timelines. 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. We continue to discuss the results 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:

- oral contraceptive;
- vaginal ring;
- transdermal patch;

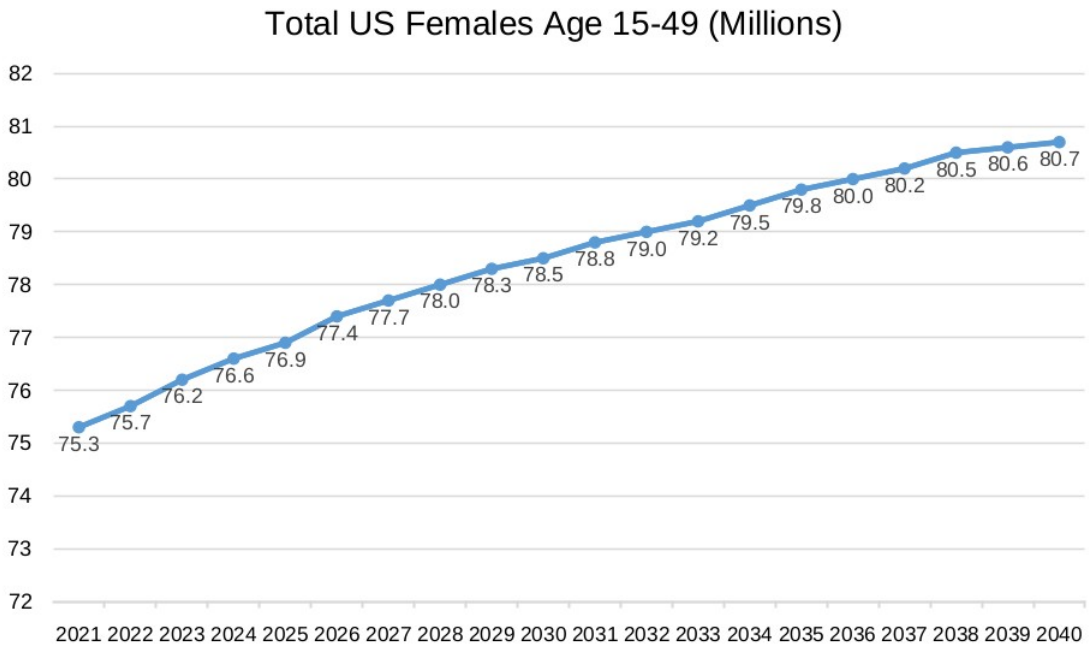
- hormonal IUD;
- subcutaneous implant; and
- injectable.

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 2018 to 2022 by 27%, from 76 million to 56 million; however the number of cycles dispensed (1 cycle = 1 month supply) declined by only 11% over the same time period, as the average TRx size (cycles/TRx) grew from 1.5 to 1.9 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 revenue per TRx increased from $183.67 in 2018 to $269.29 in 2022.

Despite the availability of generic contraceptives for over 30 years, branded products have maintained a significant, though declining, share of CHC sales, with 16% of sales in 2022. In the five years ended December 2022, the average annual price increase among the same branded products was 6.9%. The average price per cycle, referred to as the wholesale acquisition cost, or WAC, for a single 28-day cycle of the these branded products was $155.58 in 2018 and rose to $170.28 by December 2022. 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 $191.20. 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 $148.32 for generic versions. 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 ≥ 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 2.2% share in 2018 to a 2.8% share in 2022. Zafemy, a second generic of Ortho Evra launched in 2021, had a market share of 0.8% in December 2022.

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 $277 million in 2022. 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 $88.8 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 2022 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 establishing a relationship with Nurx, a leader in female-focused telehealth, to make Twirla available to patients through the Nurx telehealth platform. In 2023, 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 agencies 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 2023, 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. 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 focused 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.

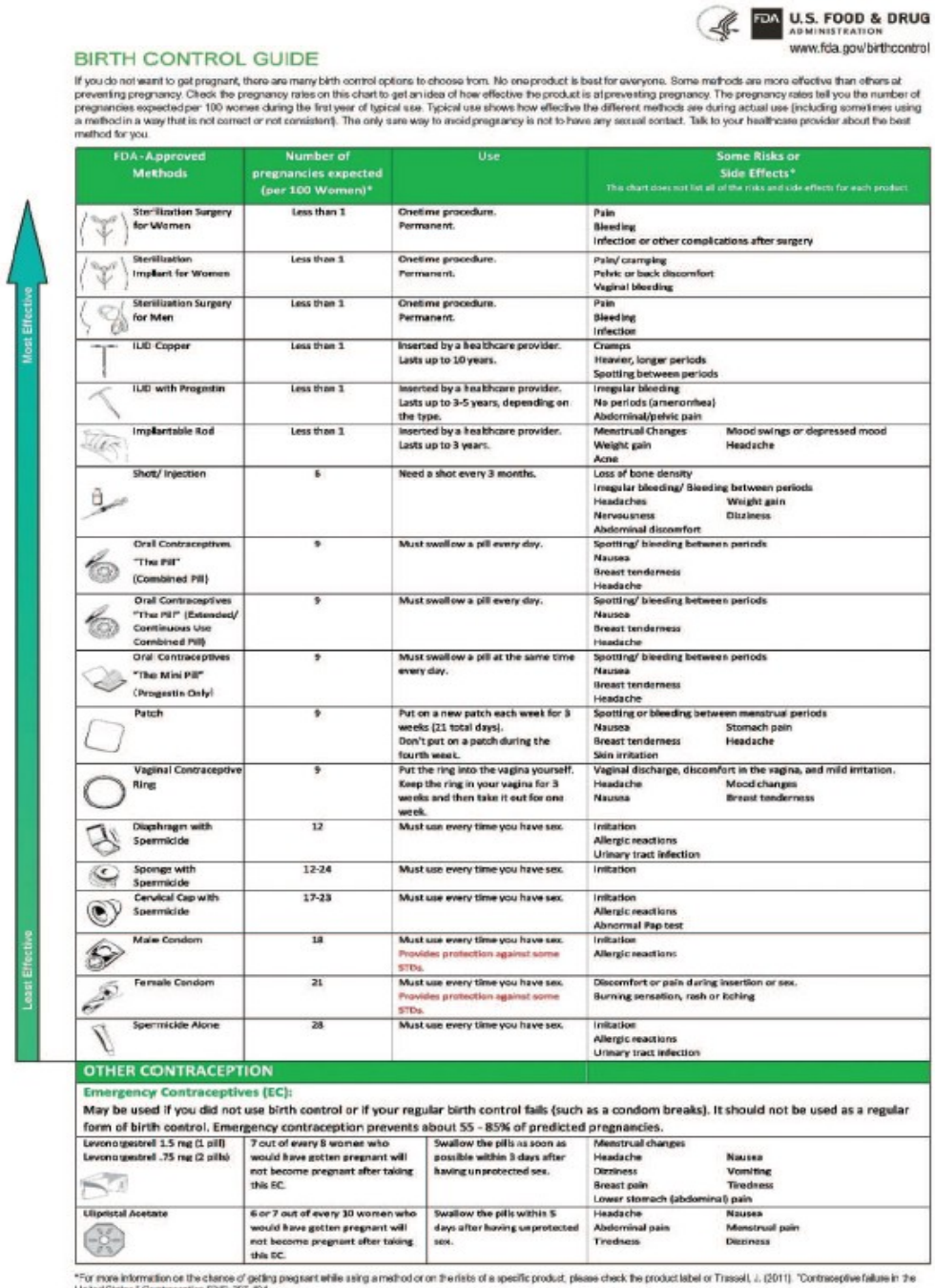
We do not expect to be required to conduct preclinical toxicology studies for any of these potential product candidates. Based upon a number of factors, including, but not limited to, our available capital resources and feedback from the FDA, we continue to review the clinical path and the budgetary 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 Merck, 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 $277 million in gross sales for Viatris in 2022. 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 $88.8 million in 2022. 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 or 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 new 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. Allergan has a P-only patch for which they received a CRL from the FDA in 2013.

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 September 2023. 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, which we refer to as Corium, a contract development and manufacturing organization (the "Corium Reorganization"). We, along with Corium, have made a significant investment in a proprietary process to manufacture Twirla. We believe we have developed 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 effect purchase orders after the notice of termination is given and until the time any such termination becomes effective. As of December 31, 2022, the minimum amount committed totals $233.8 million.

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, 2022, the minimum amount committed totals $3.5 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.

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. 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; and
- FDA review and approval of the NDA.

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 must also 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 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.

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. This review period was recently reaffirmed under the PDUFA User Fee Reauthorization Act, which was signed into law by President Biden on September 30, 2022.

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, 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 risk evaluation and mitigation strategy, or 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.

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. 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 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. 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 products, including samples, is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and 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. 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 recently 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. Under the final rule, OIG removed safe harbor protections under the Anti-Kickback Statute for rebates paid from drug manufacturers to Medicare Part D prescription drug plan sponsors or their pharmacy benefit managers and added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. Currently, the portion of the rule eliminating safe harbor protection for certain rebates related to the sale or purchase of a pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D has been delayed to January 1, 2026. Recent legislative proposals provided for a permanent prohibition on implementation of the rule. We do not currently have any products available through Medicare.

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 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 criminal federal 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; knowlingly 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. 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. In addition, other federal and state laws, such as the California Consumer Privacy 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 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 our potential product candidates or exclusion of 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 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 will 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. These reductions include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013. While President Biden previously signed legislation temporarily to eliminate this reduction through the end of 2021, recent legislation will restart the reductions, which will thereafter remain in effect through 2031 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. The FDA also released a final rule on September 24, 2020, which went into effect on November 30, 2020, providing guidance regarding the importation of drugs from Canada. 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. Implementation of this rule has been delayed to January 1, 2026, and recent legislative initiatives have proposed a permanent prohibition on implementation of the rule. 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. 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 $3.3 million, $6.2 million, and $13.5 million for the years ended December 31, 2022, 2021, and 2020, respectively. In 2023, we expect to continue to incur research and development expenses as we 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 and certain foreign jurisdictions 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. 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, 2022, we had 22 full time employees, including five in research and development and seventeen in selling, general and administrative roles. As of November 1, 2022, we reorganized and streamlined our executive leadership team and general workforce to align with our business plan to promote Twirla growth. As part of the reorganization, we appointed Geoffrey Gilmore to Chief Administrative Officer in order to consolidate and streamline our G&A functions and appointed Amy Welsh to serve as our Chief Commercial Officer. 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, 2022, 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 2022 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 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;
- 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 Related to Our Financial Position and Need for Capital

We have incurred operating losses in each year since our inception and expect to continue to incur substantial losses for the foreseeable future. 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 $25.4 million, $71.1 million and $51.9 million for the years ended December 31, 2022, 2021 and 2020, respectively. As of December 31, 2022, we had an accumulated deficit of approximately $409 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 into the second quarter of 2023, 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, 2022, we have cumulative net cash flows used by operating activities of $375.7 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.

Our operating activities may be restricted as a result of covenants related to the outstanding indebtedness under our loan agreement and we may be required to repay the outstanding indebtedness in an event of default, which could have a materially adverse effect on our business.

In February 2020, we entered into the Perceptive Credit Agreement, the terms of which are described in more detail in *Part 2, Item 7, Financial Overview*. The Perceptive Credit Agreement, as amended, subjects us to various customary affirmative and negative covenants, which are described in *Part 2, Item 8, Note 9 to Financial Statements*. Our business may be adversely affected by these restrictions on our ability to operate our business. The Perceptive Credit Agreement also subjects us to financial covenants in respect of minimum liquidity and minimum product revenue.

The loans provided under the Perceptive Credit Agreement are secured by substantially all of our property. The Perceptive Credit Agreement contains certain customary events of default, which include, among others, non-payment of principal, violation of covenants, inaccuracy of representations and warranties, bankruptcy and insolvency events, material judgments, certain regulatory-related events and events constituting a Change of Control (as defined in the Perceptive Credit Agreement). We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. We have received a waiver of certain financial covenants through the second quarter of 2023. In the event we do not pay off our indebtedness to Perceptive, we will need to negotiate for a waiver of our obligations to comply with the covenants relating to revenue for Twirla in the second quarter of 2023. If we cannot repay our indebtedness and do not receive a waiver, we may be required to delay, limit, reduce or terminate our pipeline development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Perceptive could also exercise its rights as collateral agent to take possession and dispose of the collateral securing the loan for its benefit, which collateral includes substantially all of our property. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

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 on 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 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 clinical trials 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 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. 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. Further, we cannot predict how the ongoing COVID-19 pandemic will affect Corium's ability to obtain raw materials in the future.

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 plan to engage 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 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

Public health emergencies, the ongoing COVID-19 pandemic, or pandemics could have a material adverse impact on our business, financial condition and results of operations, including our ability to successfully produce, market, and distribute Twirla.

As a result of public health emergencies, the ongoing COVID-19 pandemic or other pandemics, we may experience disruptions that could severely affect our business, including our plans to clinically develop and commercialize our products. The COVID-19 pandemic was extensive and affected many aspects of society and resulted in significant disruptions to global business activities and capital markets around the world. Some global business interruptions resulting from COVID-19 continue to persist, including ongoing global supply chain issues, which could impact the operations of our third-party manufacturer, Corium, as well as its suppliers of raw materials. If Corium or any of its suppliers of raw materials are adversely impacted a pandemic, we may experience delays or disruptions in our supply chain, which could have a material and adverse impact on our business. As a result, we may not be able to obtain sufficient quantities of Twirla, which could impair our ability to commercialize Twirla.

A public health emergency or pandemic could also adversely impact our ability to sell our products in the field. During the COVID-19 pandemic, social distancing orders and closures of doctor's offices limited the ability of our sales representatives to interact with healthcare providers and also restricted the ability of patients to interact with their healthcare providers and obtain prescriptions for our products. Patients may also be more reticent to visit their providers to obtain prescriptions in the midst of a pandemic. A resurgence of the COVID-19 pandemic may negatively affect our ability to commercialize Twirla.

If a public health crisis, pandemic, or other factors impact our current business plan, our ability to generate revenue may be adversely impacted. Significant delays in the timelines to manufacture commercial supply of Twirla, and/or the ability of a salesforce to engage with healthcare providers could delay, or even prevent, our ability to generate revenue, which in turn could require us to raise additional capital.

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, 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.

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 2019 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 not in compliance with the Nasdaq continued listing requirements. If we are unable to comply with the continued listing requirements of the Nasdaq Capital Market, our common stock could be delisted, which could affect our common stock's market price and liquidity and reduce our ability to raise capital.

On August 15, 2022 we received a letter from the Nasdaq Stock Market, or Nasdaq, indicating that we have failed to comply with the minimum bid price requirement, which requires that companies listed on The Nasdaq Capital Market maintain a minimum closing bid price of at least $1.00 per share ("Bid Price Requirement"). The notification of noncompliance had no immediate effect on the listing or trading of our common stock.

In accordance with Nasdaq rules, we had a 180-calendar day grace period, or until February 13, 2023 (the "Compliance Date"), to regain compliance with the Bid Price Requirement. The continued listing standard would have been met if our common stock had a minimum closing bid price of at least $1.00 per share for a minimum of ten consecutive business days during the 180-calendar day grace period. In February 2023, we requested and were granted by the Listing Qualifications Department of Nasdaq a 180-day extension to regain compliance with the minimum $1.00 per share requirement for continued inclusion on The Nasdaq Capital Market, giving us until August 14, 2023, to meet

the Bid Price Requirement, or effect a reverse stock split if necessary. On March 9, 2023 our shareholders approved a proposal to, at the Board's discretion, effect a reverse stock split with respect to our issued and outstanding Common Stock, at a ratio of 1-for-20 to 1-for-50, at any time prior to June 30, 2023, with the exact ratio to be determined within that range at the discretion of the Board and included in a public announcement.

There can be no assurance that our reverse stock split will enable us to regain compliance with the Bid Price Requirement or that we will otherwise be in compliance with other Nasdaq listing criteria. Even if the reverse stock split succeeds in bringing us into compliance with Bid Price Requirement in the short term, if we fail to maintain compliance through April 2024, our stock may be subject to delisting. At that time, we may appeal the determination to a Hearings Panel. If our securities are delisted, it could be 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 could also impair the liquidity of our common stock and could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in potential loss of confidence by investors, employees, and fewer business development opportunities.

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 Nasdaq Capital Market 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.

Certain of our outstanding common stock purchase warrants contain price protection provisions (and anti-dilution protection) in the event that we sell our securities at prices lower than the current exercise price of such warrants, which may have a negative impact on the trading price of our common stock or impair our ability to raise capital.

As of December 31, 2022, we had 46,250 common stock purchase warrants outstanding that were issued in connection with the Perceptive Credit Agreement that contain price protection provisions in the event that we sell securities at a price per share below their respective exercise prices on or before June 30, 2023 (collectively "Price Protection Warrants"). On March 22, 2023, in connection with the Waiver and Sixth Amendment to the Perceptive Credit Agreement, the current exercise price of the Price Protection Warrants was reset to $0.21 per share. In the event that we sell securities at a price per share lower than the current exercise price of the Price Protection Warrants on or before June 30, 2023, their exercise prices will be reduced to match that lower price. Any future adjustments to the exercise prices of the Price Protection Warrants may have a negative impact on the trading price of our common stock. Additionally, raising additional capital with new investors may be difficult as a result of the adjustment feature.

We have identified a material weakness in our internal control over financial reporting. This material weakness could continue to adversely affect our results of operations and financial condition. In the future, we may identify additional material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting or adequate disclosure controls and procedures, which may result in material errors in our financial statements or cause us to fail to meet our period reporting obligations.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, evaluating the effectiveness of our internal controls and disclosing any changes or material weaknesses identified through such evaluation. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

In February 2023, we determined that we incorrectly classified certain warrants that were issued to investors in connection with a public offering of our common stock in October 2021, a registered direct offering of our preferred stock in March 2022, and a public offering of our common stock in July 2022. Our management subsequently concluded that a material weakness existed and our internal control over financial reporting was not effective as of October 2021.

As a result, we determined that there were material errors in the financial statements that required a restatement of the December 31, 2021 financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2021 and our Forms 10-Q for the quarterly periods ended March 31, 2022, June 30, 2022 and September 30, 2022. This was due to the inadequate design and implementation of controls to evaluate the accounting for warrant classification between liability and equity.

Management is implementing enhanced internal controls to remediate the material weakness. Specifically, we expanded and improved our review process for complex securities and related accounting standards. We plan to further improve this process by enhancing access to accounting literature and identification of third-party accounting professionals with whom to consult regarding complex accounting applications. The elements of our remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. If we are not able to comply with the requirements of the Sarbanes-Oxley Act or if we are unable to maintain effective internal control over financial reporting, we may not be able to produce timely and accurate financial statements or guarantee that information required to be disclosed by us in the reports that we file with the SEC, is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms. Any failure of our internal control over financial reporting or disclosure controls and procedures could cause our investors to lose confidence in our publicly reported information, cause the market price of our stock to decline, expose us to sanctions or investigations by the SEC or other regulatory authorities, or impact our results of operations.

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 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. Beginning on January 3, 2019, our common stock has been listed on the Nasdaq Capital Market under the symbol "AGRX".

As of March 14, 2023, we had 11 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 15, 2023 was $0.22.

Dividends

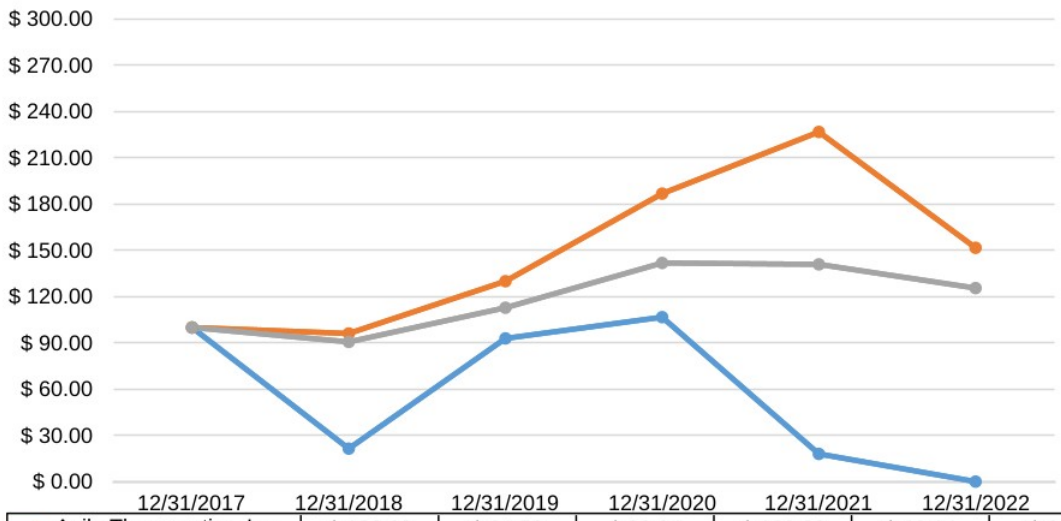
We have never declared or paid a cash dividend on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. In addition, our Credit Agreement and Guaranty among us, the guarantors from time-to-time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, L.P., as a lender and as Administrative Agent for the lenders, contains, and any other loan facilities that we may enter into may contain, restrictions on our ability to pay dividends. 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, 2017 through December 31, 2022 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, 2017 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, 2022



	12/31/2017	12/31/2018	12/31/2019	12/31/2020	12/31/2021	12/31/2022
Agile Therapeutics, Inc.	$ 100.00	$ 21.56	$ 92.94	$ 106.69	$ 18.14	$ 0.21
Nasdaq Composite	$ 100.00	$ 96.12	$ 129.97	$ 186.69	$ 226.63	$ 151.61
Nasdaq Biotechnology	$ 100.00	$ 90.68	$ 112.81	$ 141.78	$ 140.88	$ 125.52

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 2021, we generated minimal revenue and have never been profitable. Through December 31, 2022, we had an accumulated deficit of $409 million, and our net loss was $25.4 million, $71.1 million and $51.9 million for the years ended December 31, 2022, 2021 and 2020, respectively. We expect to continue to incur significant 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, 2022 and 2021, we had $5.2 million and $19.1 million in cash and cash equivalents, respectively.

Moving forward, we plan 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 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 pursue our post-marketing studies for Twirla, including conducting our long-term, prospective observational safety study, which is a post marketing requirement from the FDA, and evaluate the development of our pipeline. As of December 31, 2022, we have significantly reduced our operating expenses through several measures, including optimizing our sales force, reducing reliance on third-party service providers reducing our advertising spend, and reorganizing our executive leadership team and general personnel. We are committed to continuing to explore ways to reduce expenses and focus efforts and resources on commercialization and uptake 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, 2022, we had cash and cash equivalents of $5.2 million. We believe our current cash and cash equivalents will support operations into the second quarter of 2023**.**

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, 2022 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 on 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, 2022 and 2021, net sales totaled $10.9 million and $4.1 million, respectively, representing the sale of 114,546 units and 35,172 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, 2022 and 2021, cost of product revenues totaled $6.8 million and $10.7 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 reduced significantly over the past three years.

For the years ended December 31, 2022, 2021 and 2020, our research and development expenses were approximately $3.3 million, $6.2 million and $13.5 million, respectively. The following table summarizes our research and development expenses by functional area.

	Year ended December 31,		
	2022	2021	2020
		(In thousands)	
Clinical development	$ 977	$ 3,394	$ 2,022
Regulatory	480	282	951
Personnel related	1,426	2,115	2,086
Manufacturing—commercialization	—	(35)	7,790
Stock-based compensation	370	490	651
Total research and development expenses	$ 3,253	$ 6,246	$ 13,500

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, 2022, 2021 and 2020, our selling and marketing expenses totaled approximately $30.4 million, $43.4 million and $23.3 million, respectively. Our commercial launch of Twirla in the United States 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, 2022, 2021 and 2020, our general and administrative expenses totaled approximately $11.9 million, $14.7 million and $12.7 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. Trade 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 Trade Accounts Receivable policy in Note 3 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.

Cost of Product Revenues

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.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses, particularly for product development costs. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of services performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with service providers and make adjustments as necessary. Examples of estimated accrued research and development expenses include:

- fees paid to CROs in connection with clinical studies;
- fees paid to investigative sites in connection with clinical studies;
- fees paid to vendors in connection with preclinical development activities;
- fees paid to vendors related to product manufacturing, development and distribution of clinical supplies; and
- fees paid to a third-party manufacturer in connection with the development of our commercial manufacturing process.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed, enrollment of subjects, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrued liability or prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting amounts that are too high or too low in any particular period. Based on historical experience, actual results have not been materially different from our estimates. As of December 31, 2022, we did not have any ongoing clinical trials.

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.

All Perceptive Warrants are accounted for in equity, whereas all warrants associated with our various 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.

In February 2020 we entered into a senior secured term loan facility with Perceptive Credit Holdings III, L.P. ("Perceptive"), pursuant to which we issued warrants to purchase 35,000 shares of our common stock to Perceptive. In connection with an amendment to that facility in February 2021, we issued additional warrants to purchase 11,250 shares of our common stock (together with the February 2020 warrants, 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. The Perceptive Warrants are subject to repricing in the event of an offering of securities at a price lower than the existing strike price before December 31, 2022. In connection with the Waiver and Sixth Amendment to the Perceptive Credit Agreement (the "Sixth Amendment"), we amended and restated the Perceptive Warrants to reset the strike price of the Perceptive Warrants. See Note 10 for additional information.

In connection with an underwritten public offering completed in October 2021, we issued warrants to purchase 333,333 shares of our common stock. This offering 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 Note 10 for additional information.

In connection with a registered direct offering completed in March 2022 we issued warrants to purchase 1,242,813 shares of our common stock. 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 Note 10 for additional information.

In connection with a letter agreement and waiver entered into with an investor on April 2022, we issued warrants to purchase 212,188 shares of common stock. See Note 10 for additional information.

In connection with a public offering completed in July 2022 we issued warrants to purchase 54,666,665 shares of our common stock. 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.

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, 2022 and 2021

	Year Ended December 31, (In thousands)		
	2022	2021 (Restated)	Change
Revenues, net	$ 10,884	$ 4,101	$ 6,783
Cost of product revenues	6,836	10,718	(3,882)
Gross profit	4,048	(6,617)	10,665
Operating expenses:			
Research and development	$ 3,253	$ 6,246	$ (2,993)
Selling and marketing	30,369	43,444	(13,075)
General and administrative	11,860	14,698	(2,838)
Loss on disposition of assets	11,122	—	11,122
Total operating expenses	56,604	64,388	(7,784)
Loss from operations	$ (52,556)	$ (71,005)	18,449
Other income (expense)			
Interest income	80	25	55
Interest expense	(3,131)	(3,914)	783
Unrealized gain on warrant liability	25,520	3,827	21,693
Total other income (expense), net	22,469	(62)	22,531
Loss before benefit from income taxes	(30,087)	(71,067)	40,980
Benefit from income taxes	4,675	—	4,675
Net loss	$ (25,412)	$ (71,067)	$ 45,655

Revenues. Revenues, net increased by $6.8 million, or 165%, from $4.1 million for the year ended December 31, 2021, to $10.9 million for the year ended December 31, 2022. Unit sales increased by approximately 79,000 units, or 226%, from 35,172 units for the year ended December 31, 2021, to 114,546 units for the year ended December 31, 2022. 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, which was approved by the FDA in February 2020 and launched in the US in December 2020, 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 decreased by $3.9 million, or 36% from $10.7 million for the year ended December 31, 2021, to $6.8 million for the year ended December 31, 2022. 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, 2021 included approximately $5.3 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 $3.0 million, or 48%, from $6.2 million for the year ended December 31, 2021 to $3.3 million for the year ended December 31, 2022. This decrease in research and development expenses was primarily due to a decrease in clinical development expenses of $2.4 million for the year ended December 31, 2022 as compared to the year ended December 31, 2021. This decrease reflects a reduction in spending related to our pipeline evaluation and development.

Selling and marketing expenses. Selling and marketing expenses of $30.4 million for the year ended December 31, 2022 decreased by $13.1 million, from $43.4 million for the year ended December 31, 2021. This decrease in selling and marketing expenses is due to reduced spending on marketing initiatives and the optimization of our contract sales force.

General and administrative expenses. General and administrative expenses of $11.9 million for the year ended December 31, 2022 decreased by $2.8 million, or 19%, from $14.7 million for the year ended December 31, 2021. This decrease in general and administrative expense was primarily due to reduced headcount.

Loss on disposition of assets. In accordance with ASC 610-20, we recognized an $11.1 million one-time, non-cash charge, which represents the loss on the transfer of fixed assets to Corium in connection with the amended Corium agreement (see Note 13 to the financial statements).

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 $0.8 million, from $3.9 million for the year ended December 31, 2021 to $3.1 million for the year ended December 31, 2022, due to principal payments made throughout 2022.

Unrealized gain on warrant liability. The unrealized gain was $25.5 million and $3.8 million for the years ended December 31, 2022 and 2021, respectively. Unrealized gain is attributable to the subsequent non-cash changes in the estimated fair value of the warrants associated with a public offering of the Company's stock in October 2021, a registered direct offering of the Company's preferred stock in March 2022 and a public offering of the Company's Common Stock in July 2022.

Net Operating Losses and Tax Carryforwards

As of December 31, 2022, we had approximately $390.6 million of federal and $79.90 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, 2022, all of our net operating losses were fully offset by a valuation allowance.

Liquidity and Capital Resources

At December 31, 2022, we had cash and cash equivalents totaling $5.2 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,		
	2022	2021	2020
	(In thousands)		
Net cash used in operating activities	$ (35,947)	$ (65,202)	$ (47,311)
Net cash (used in) provided by investing activities	(133)	39,460	(40,690)
Net cash provided by financing activities	22,183	30,422	67,985
Net (decrease) increase in cash and cash equivalents	$ (13,897)	$ 4,680	$ (20,016)

Operating Activities

We incurred significant costs in the area of research and development, including CRO fees, manufacturing, regulatory and other clinical trial costs, as Twirla was being developed. With the approval of Twirla early in 2020, our operating expenses shifted substantially to selling and marketing as we built out our commercial infrastructure. 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. Net cash used in operating activities was $47.3 million for the year ended December 31, 2021 and consisted primarily of a net loss of $51.9 million, offset by non-cash stock-based compensation expense of $2.8 million, and $1.6 million of other non-cash charges, primarily interest expense. Our net change in operating assets and liabilities was negligible.

Investing Activities

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. Net cash used in investing activities for the years ended December 31, 2020 was $40.7 million. Cash used in investing activities for the year ended December 31, 2020 primarily represents net purchases of marketable securities of $40.3 million with the balance being the acquisition of equipment to be used in the commercialization of Twirla.

Financing Activities

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 26,666,666 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 12,655,773 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 666,666 shares of our common stock through a public offering and net proceeds of $9.3 million from the sale of 172,8749 shares of common stock through at-the-market, or ATM sales programs. Net cash provided by financing activities for the year ended December 31, 2020 was $68.0 million, which primarily represents net proceeds of $48.4 million received from the issuance of 431,250 shares of our common stock

through a public offering, proceeds of $20.0 million from the Perceptive term loan, and stock option exercise proceeds of $0.6 million. These proceeds were partially offset by debt financing costs of $1.0 million.

Funding Requirements and Other Liquidity Matters

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 the residual effects of the COVID-19 pandemic or other 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. On October 2, 2020 we 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, we may periodically offer one or more of these securities in amounts, at prices, and on terms to be announced when and if the securities are offered. At any 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.

On March 18, 2021, we filed a prospectus supplement to our 2020 Shelf Registration Statement registering an at-the-market offering program we entered into for the sale of up to $50.0 million of shares of our common stock. During the year ended December 31, 2021, we sold 172,879 shares of our common stock under the at-the-market program resulting in net proceeds of approximately $9.3 million.

On October 8, 2021, we filed a prospectus supplement to our 2020 Shelf Registration Statement registering a public offering of 666,666 shares of common stock sold together with warrants to purchase up to 333,333 shares of our common stock at a combined offering price of $34.00 per share of common stock and one-half of a warrant to purchase one share of common stock. The warrants have an exercise price of $340.00 per share, are exercisable immediately, and will expire five years from the date of issuance. On October 13, 2021, we completed the offering and realized proceeds of approximately $21.1 million, net of underwriting discounts, commissions and offering expenses.

On January 10, 2022, we filed a prospectus supplement to our 2020 Shelf Registration Statement registering the January 2022 ATM. During the year ending December 31, 2022, we sold and issued 25,623 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 a new at-the-market offering program ("April 2022 ATM") with H.C. Wainwright LLC and Co. (the "Sales Agent"), under which we may, from time to time in its sole discretion, issue and sell through or to the Sales Agent, acting as our agent, up to $12,841,000 of shares of our common stock (the "Placement Shares"). We agreed to pay the Sales Agent a commission of up to 3.0% of the gross sales proceeds of any Placement Shares sold under the April 2022 ATM. Through September 30, 2022, we issued and sold a total of 8,687,502 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 may now 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 3,942,648 shares of common stock under the August 2022 ATM resulting in net proceeds to us of approximately $0.9 million.

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 24,250,000 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 24,250,000 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 $0.20 per share. The shares of preferred stock issued in the offering

are convertible into an aggregate of 24,250,000 shares of Common Stock. The Series A Warrants have an exercise price of $0.26 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 $0.26 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. 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 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 19,148,332 shares of common stock and 7,518,334 pre-funded warrants ("Series B pre-funded warrants") to purchase 7,518,334 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 are exercisable immediately and will expire thirteen 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 1,333,333 shares of commons stock with an exercise price of $1.125 per share.

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 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;
- 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, 2022, we had cash and cash equivalents of $5.2 million. We closely monitor our cash and cash equivalents and expect that our current cash will fund our planned operations into the second quarter of 2023. 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. Prior to raising additional funds, we believe we need to regain compliance with the Nasdaq listing requirements because our stock price is currently trading below $1.00. As previously disclosed, we have been notified by Nasdaq that we have until August 14, 2023 to regain compliance. To that end, we conducted a special meeting of shareholders on March 9, 2023 where the vote on a reverse stock split was approved, enabling us to attempt to raise additional funds through the issuance and sale of our common stock.

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, 2022 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 on our business plan and successfully launch Twirla. The audited financial statements as of December 31, 2022 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 with Corium, Inc., which we refer to as the Corium Agreement, and 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 effect purchase orders after the notice of termination is given and until the time any such termination becomes effective. As of December 31, 2022, the minimum amount committed totals $233.8 million.

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, 2022, the minimum amount committed totals $3.5 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 27-month term totals $0.9 million as of December 31, 2022.

Shelf Registration Statements

On October 2, 2020, we filed the 2020 Shelf Registration Statement. On October 14, 2020, the 2020 Shelf Registration Statement was declared effective by the SEC. The 2020 Shelf is effective through October 14, 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

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. Market risk is the risk of change in fair value of a financial instrument due to changes in interest rates, equity prices, financing, exchange rates or other factors. These market risks are principally limited to interest rate fluctuations.

We had cash, cash equivalents and marketable securities of $5.2 million and $19.1 million at December 31, 2022 and December 31, 2021, respectively, consisting primarily of funds in cash and money market accounts. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our investment portfolio, we do not believe an immediate 10.0% increase in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

Our results of operations and cash flows are subject to fluctuations due to changes in interest rates. We do not believe that we are materially exposed to changes in interest rates. We do not currently use interest rate derivative instruments to manage exposure to interest rate changes. Based on average invested cash of $5.4 million for the year ended December 31, 2022, a 1% increase or decrease in interest rates would have increased or decreased interest income by $0.1 million for the year ended December 31, 2022. Based on average debt outstanding of $9.8 million for the year ended December 31, 2022, a 1% increase or decrease in interest rates would have increased or decreased interest expense by $0.1 million for the year ended December 31, 2022.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and pricing of contracts and agreements. We do not believe that inflation had a material effect on our business, financial condition, or results of operations during the year ended December 31, 2022.

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, 2022 and 2021, the related statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 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.

Restatement of 2021 Financial Statements

As discussed in Note 2 of the Financial Statements, the 2021 financial statements have been restated to correct certain misstatements.

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.

Revenues, net

Description of the Matter	The Company sells approved product primarily to wholesale distributors. As discussed in Note 3, revenue is recorded net of reserves for applicable variable consideration. When recognizing revenue, the Company estimates the transaction price and assesses whether to constrain variable consideration. Limited historical data is available for use in developing such estimates. The Company's estimates of Medicaid rebates, chargebacks, and copayment assistance depend on the identification of key customer contract terms and conditions, as well as estimates of sales volumes to different classes of payers. Auditing the Company's net revenues was complex due to the Company's limited history of product sales, and the revenue recognition process involves significant judgment to identify and assess the terms and conditions of customer agreements and related government regulations.
How We Addressed the Matter in Our Audit	Among other procedures performed to test management's estimates of Medicaid rebates, chargebacks, and co-payment assistance, we developed an independent expectation of the reserve based on the relevant terms of the customer contracts and/or obtained management's calculations of the respective reserve and tested management's estimate by tracing relevant inputs to the customer contracts and underlying sales data. We obtained and reviewed the Company's estimated channel and payer mix, compared relevant inputs to underlying sales data and analyzed the impact of changes to the inputs on the estimate. We also evaluated credits and adjustments subsequent to the balance sheet date, if any, and tested the underlying sales data by confirming a sample of receivable balances directly with the Company's customers and performed alternative procedures for confirmations not received.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2010.
Iselin, New Jersey
March 22, 2023

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

	December 31, 2022	December 31, 2021 (Restated)
Assets		
Current assets:		
Cash and cash equivalents	$ 5,246	$ 19,143
Accounts receivable, net	3,377	1,533
Inventory, net	1,332	966
Prepaid expenses and other current assets	1,403	2,283
Total current assets	11,358	23,925
Property and equipment, net	177	12,447
Right of use asset	695	949
Other non-current assets	2,012	2,012
Total assets	$ 14,242	$ 39,333
Liabilities and stockholders' equity		
Current liabilities:		
Long-term debt, current portion	$ 1,426	$ 16,833
Accounts payable	7,734	8,707
Accrued expenses	3,908	3,563
Lease liability, current portion	319	175
Total current liabilities	13,387	29,278
Lease liabilities, long-term	466	784
Warrant liability	5,934	5,356
Total liabilities	19,787	35,418
Commitments and contingencies (Note 13)		
Stockholders' equity		
Preferred stock, $.0001 par value, 10,000,000 shares authorized, 4,850 issued and no shares outstanding at December 31, 2022 and no shares issued and outstanding at December 31, 2021	—	—
Common stock, $.0001 par value, 300,000,000 shares authorized, 42,970,134 and 3,034,901 issued and outstanding at December 31, 2022 and December 31, 2021, respectively	4	—
Additional paid-in capital	403,153	387,205
Accumulated deficit	(408,702)	(383,290)
Total stockholders' equity	(5,545)	3,915
Total liabilities and stockholders' equity	$ 14,242	$ 39,333

See accompanying notes.

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

	Year ended December 31,		
	2022	2021 (Restated)	2020
Revenues, net	$ 10,884	$ 4,101	$ 749
Cost of product revenues	6,836	10,718	282
Gross profit (loss)	4,048	(6,617)	467
Operating expenses:			
Research and development	$ 3,253	$ 6,246	$ 13,500
Selling and marketing	30,369	43,444	23,285
General and administrative	11,860	14,698	12,735
Loss on disposition of assets	11,122	—	—
Total operating expenses	56,604	64,388	49,520
Loss from operations	(52,556)	(71,005)	(49,053)
Other income (expense)			
Interest income	80	25	309
Interest expense	(3,131)	(3,914)	(3,109)
Unrealized gain on warrant liability	25,520	3,827	—
Total other income (expense), net	22,469	(62)	(2,800)
Loss before benefit from income taxes	(30,087)	(71,067)	(51,853)
Benefit from income taxes	4,675	—	—
Net loss	$ (25,412)	$ (71,067)	$ (51,853)
Net loss per share (basic and diluted)	$ (1.18)	$ (29.28)	$ (24.40)
Weighted-average common shares (basic and diluted)	21,610,947	2,426,821	2,117,077
Comprehensive loss:			
Net loss	$ (25,412)	$ (71,067)	$ (51,853)
Other comprehensive income:			
Unrealized (loss) gain on marketable securities	—	(3)	3
Comprehensive loss	$ (25,412)	$ (71,070)	$ (51,850)

See accompanying notes.

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

	Preferred Stock		Common Stock		Additional	Accumulated		Net
	Number of Shares	Amount	Number of Shares	Amount	Paid-in Capital	Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
Balance December 31, 2019	—	$ —	1,745,264	$ —	$ 306,115	$ —	$ (260,370)	$ 45,745
Share-based compensation—stock options and RSUs	—	—	—	—	2,818	—	—	2,818
Proceeds from issuance of common stock in public offering, net of expenses	—	—	431,250	—	48,435	—	—	48,435
Issuance of common stock upon exercise of stock options	—	—	12,586	—	610	—	—	610
Warrants issued in connection with long-term debt	—	—	—	—	3,570	—	—	3,570
Unrealized net gain on marketable securities	—	—	—	—	—	3	—	3
Net loss	—	—	—	—	—	—	(51,853)	(51,853)
Balance December 31, 2020	—	$ —	2,189,100	$ —	$ 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	—	—	172,879	—	9,266	—	—	9,266
Issuance of common stock in public offering, net of expenses (Restated)	—	—	666,666	—	11,898	—	—	11,898
Issuance of common stock upon exercise of stock options	—	—	3,160	—	75	—	—	75
Vesting of RSUs	—	—	3,096	—	—	—	—	—
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 (Restated)	—	$ —	3,034,901	$ —	$ 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	—	—	12,655,773	1	13,456	—	—	13,457
Issuance of series A and B convertible preferred stock in a registered direct offering (Note 10)	4,850	—	—	—	—	—	—	—
Conversion of series A convertible preferred stock	(2,425)	—	303,125	—	—	—	—	—
Conversion of series B convertible preferred stock	(2,425)	—	303,125	—	—	—	—	—
Issuance of common stock in public offering, net of expenses	—	—	26,666,666	3	—	—	—	3
Vesting of RSUs	—	—	6,555	—	—	—	—	—
Fractional shares retired as a result of reverse split	—	—	(11)	—	—	—	—	—
Net loss	—	—	—	—	—	—	(25,412)	(25,412)
Balance December 31, 2022	—	$ —	42,970,134	$ 4	$ 403,153	$ —	$ (408,702)	$ (5,545)

See accompanying notes.

Agile Therapeutics, Inc.
Statements of Cash Flows

	Year Ended December 31,		
	2022	2021 (Restated)	2020
Cash flows from operating activities:			
Net loss	$ (25,412)	$ (71,067)	$ (51,853)
Adjustments to reconcile net loss to net cash used in operating activities:			
Noncash inventory reserve	—	5,323	—
Depreciation	1,280	2,064	105
Amortization	254	159	171
Loss on disposition of assets	11,122	—	—
Noncash stock-based compensation	2,493	3,338	2,818
Noncash amortization of deferred financing costs	1,969	1,661	1,341
Unrealized gain on warrants	(25,520)	(3,827)	—
Changes in operating assets and liabilities:			
Accounts receivable	(1,844)	(668)	(865)
Inventory	(366)	(6,289)	—
Prepaid expenses and other assets	880	(967)	(2,485)
Accounts payable and accrued expenses	(628)	5,202	3,641
Lease liability	(175)	(131)	(184)
Net cash used in operating activities	(35,947)	(65,202)	(47,311)
Cash flows from investing activities:			
Purchases of marketable securities	—	—	(54,837)
Sales and maturities of marketable securities	—	39,729	14,500
Acquisition of property and equipment	(133)	(269)	(353)
Net cash (used in) provided by investing activities	(133)	39,460	(40,690)
Cash flows from financing activities:			
Proceeds from issuance of preferred stock in registered direct offering, net of offering costs	4,128	—	—
Proceeds from issuance of common stock in public offering, net of offering costs	21,936	21,081	48,434
Proceeds from At-the-Market sales of common stock, net of offering costs	13,494	9,266	—
Proceeds from issuance of long-term debt	—	—	20,000
Repayments of long-term debt	(17,375)	—	—
Debt financing costs paid	—	—	(1,059)
Proceeds from exercise of stock options	—	75	610
Net cash provided by financing activities	22,183	30,422	67,985
Net (decrease) increase in cash and cash equivalents	(13,897)	4,680	(20,016)
Cash and cash equivalents, beginning of period	19,143	14,463	34,479
Cash and cash equivalents, end of period	$ 5,246	$ 19,143	$ 14,463
Supplemental disclosure of noncash financing activities			
Warrants issued in connection with long-term debt	$ —	$ 1,080	$ 3,570
Operating right-of-use assets obtained in exchange for new operating lease liabilities	—	969	—
Supplemental cash flow information			
Interest paid	$ 1,162	$ 2,383	$ 2,099

See accompanying notes.

Agile Therapeutics, Inc.
Notes to Financial Statements
December 31, 2022
(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, also known prior to its approval as AG200-15, 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 potential 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 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, 2022, the Company had an accumulated deficit of approximately $408 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 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 10), private placements of its convertible preferred stock, venture loans, and non-dilutive grant funding.

Going Concern

As of December 31, 2022, the Company had cash and cash equivalents of $5.2 million and a $2.0 million working capital deficit. The Company's current liquidity is sufficient to fund operations only into the second quarter of 2023. 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.

The Company has generated losses since inception, used substantial cash in operations, has a working capital deficit at December 31, 2022 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, 2022 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 on its business plan and successfully launch Twirla. The audited financial statements as of December 31, 2022 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. Restatement of Previously Issued Financial Statements

In February 2023, the Company concluded that it incorrectly classified certain warrants (the "Warrants") that were issued to investors in connection with a public offering of the Company's common stock ("Common Stock") in October 2021, a registered direct offering of the Company's preferred stock ("Preferred Stock") in March 2022 and a public offering of the Company's Common Stock in July 2022.

Historically, the Warrants were reflected as a component of equity as opposed to liabilities on the balance sheets and the statements of operations did not include the subsequent non-cash changes in estimated fair value of the Warrants. The Company reassessed its accounting for the Warrants and determined that the Warrants should be classified as liabilities measured at fair value upon issuance, with subsequent changes in fair value reported in the Company Statement of Operations each reporting period.

Impact of the Restatement

The Company has restated herein its audited financial statements at December 31, 2022 for the year ended December 31, 2021. We have also restated interim financial statement periods for the first, second and third quarters of 2022, see Note 14.

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

The following tables represent the restated balance sheet, restated statements of operations and comprehensive loss, statements of changes in stockholders' equity and statement of cash flows for the year ended December 31, 2021. These tables also present a reconciliation from the prior period as previously reported to the restated amounts. The amounts as previously reported for fiscal year 2021 was derived from the Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed on March 30, 2022.

Balance Sheet

	December 31, 2021		
	As Previously Reported	Adjustment	As Restated
Assets			
Current assets:			
Cash and cash equivalents	$ 19,143	$ —	$ 19,143
Accounts receivable, net	1,533	—	1,533
Inventory, net	966	—	966
Prepaid expenses and other current assets	2,283	—	2,283
Total current assets	23,925	—	23,925
Property and equipment, net	12,447	—	12,447
Right of use asset	949	—	949
Other non-current assets	2,012	—	2,012
Total assets	$ 39,333	$ —	$ 39,333
Liabilities and stockholders' equity			
Current liabilities:			
Long-term debt, current portion	$ 16,833	—	$ 16,833
Accounts payable	8,707	—	8,707
Accrued expenses	3,563	—	3,563
Lease liability, current portion	175	—	175
Total current liabilities	29,278	—	29,278
Lease liabilities, long-term	784	—	784
Warrant liability	—	5,356	5,356
Total liabilities	30,062	5,356	35,418
Commitments and contingencies (Note 13)			
Stockholders' equity			
Preferred stock, $.0001 par value, 10,000,000 shares authorized, 4,850 issued and no shares outstanding at December 31, 2022 and no shares issued and outstanding at December 31, 2021	—	—	—
Common stock, $.0001 par value, 300,000,000 shares authorized, 42,970,134 and 3,034,901 issued and outstanding at December 31, 2022 and December 31, 2021, respectively *	—	—	—
Additional paid-in capital *	396,388	(9,183)	387,205
Accumulated deficit	(387,117)	3,827	(383,290)
Total stockholders' equity	9,271	(5,356)	3,915
Total liabilities and stockholders' equity	$ 39,333	$ —	$ 39,333

* Adjustment reflected as a result of the 1-for-40 reverse stock split effectuated on April 26, 2022.

Agile Therapeutics, Inc.
Notes to Financial Statements (Continued)
December 31, 2022
(amounts in tables in thousands, except share and per share data)

Statement of Operations and Comprehensive Loss

	Year Ended December 31, 2021		
	As Previously Reported	Adjustment	As Restated
Revenues, net	$ 4,101	$ —	$ 4,101
Cost of product revenues	10,718	—	10,718
Gross profit (loss)	(6,617)	—	(6,617)
Operating expenses:			
Research and development	$ 6,246	$ —	$ 6,246
Selling and marketing	43,444	—	43,444
General and administrative	14,698	—	14,698
Loss on disposition of assets	—	—	—
Total operating expenses	64,388	—	64,388
Loss from operations	(71,005)	—	(71,005)
Other income (expense)			
Interest income	25	—	25
Interest expense	(3,914)	—	(3,914)
Unrealized gain on warrant liability	—	3,827	3,827
Total other income (expense), net	(3,889)	3,827	(62)
Loss before benefit from income taxes	(74,894)	3,827	(71,067)
Benefit from income taxes	—	—	—
Net loss	$ (74,894)	$ 3,827	$ (71,067)
Net loss per share (basic and diluted)*	$ (30.86)	$ 1.58	$ (29.28)
Weighted-average common shares (basic and diluted)	2,426,821	2,426,821	2,426,821
Comprehensive loss:			
Net loss	$ (74,894)	$ 3,827	$ (71,067)
Other comprehensive income:			
Unrealized (loss) gain on marketable securities	(3)	—	(3)
Comprehensive loss	$ (74,897)	$ 3,827	$ (71,070)

* Adjustment reflected as a result of the 1-for-40 reverse stock split effectuated on April 26, 2022.

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

Statement of Changes in Stockholders' Equity

	Common Stock		Additional Paid-in Capital *	Accumulated Other Comprehensive Income	Accumulated Deficit	Net Stockholders' Equity
	Number of Shares *	Amount				
As Previoulsy Reported						
Balance December 31, 2020	2,189,100	$ —	$ 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	172,879	—	9,266	—	—	9,266
Issuance of common stock in public offering, net of expenses	666,666	—	21,081	—	—	21,081
Issuance of common stock upon exercise of stock options	3,160	—	75	—	—	75
Vesting of RSUs	3,096	—	—	—	—	—
Warrants issued in connection with long-term debt	—	—	1,080	—	—	1,080
Unrealized net gain on marketable securities	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	(74,894)	(74,894)
Balance December 31, 2021	3,034,901	$ —	$ 396,388	$ —	$ (387,117)	$ 9,271
Adjustment						
Balance December 31, 2020	—	—	—	—	—	—
Share-based compensation - stock options and RSUs	—	—	—	—	—	—
Issuance of common stock pursuant to at-the-market stock sales, net of expenses	—	—	—	—	—	—
Issuance of common stock in public offering, net of expenses	—	—	(9,183)	—	—	(9,183)
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—
Vesting of RSUs	—	—	—	—	—	—
Warrants issued in connection with long-term debt	—	—	—	—	—	—
Unrealized net gain on marketable securities	—	—	—	—	—	—
Net loss	—	—	—	—	3,827	3,827
Total adjustment December 31, 2021	—	$ —	$ (9,183)	$ —	$ 3,827	$ (5,356)
As Restated						
Balance December 31, 2020	2,189,100	$ —	$ 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	172,879	—	9,266	—	—	9,266
Issuance of common stock in public offering, net of expenses	666,666	—	11,898	—	—	11,898
Issuance of common stock upon exercise of stock options	3,160	—	75	—	—	75
Vesting of RSUs	3,096	—	—	—	—	—
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 (Restated)	3,034,901	$ —	$ 387,205	$ —	$ (383,290)	$ 3,915

* Adjustment reflected as a result of the 1-for-40 reverse stock split effectuated on April 26, 2022.

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

Statement of Cash Flows

	Year Ended December 31, 2021		
	As Previously Reported	Adjustment	As Restated
Cash flows from operating activities:			
Net loss	$ (74,894)	$ 3,827	$ (71,067)
Adjustments to reconcile net loss to net cash used in operating activities:			
Noncash inventory reserve	5,323	—	5,323
Depreciation	2,064	—	2,064
Amortization	159	—	159
Noncash stock-based compensation	3,338	—	3,338
Noncash amortization of deferred financing costs	1,661	—	1,661
Unrealized gain on warrants	—	(3,827)	(3,827)
Changes in operating assets and liabilities:			
Accounts receivable	(668)	—	(668)
Inventory	(6,289)	—	(6,289)
Prepaid expenses and other assets	(967)	—	(967)
Accounts payable and accrued expenses	5,202	—	5,202
Lease liability	(131)	—	(131)
Net cash used in operating activities	(65,202)	—	(65,202)
Cash flows from investing activities:			
Purchases of marketable securities	—	—	—
Sales and maturities of marketable securities	39,729	—	39,729
Acquisition of property and equipment	(269)	—	(269)
Net cash provided by investing activities	39,460	—	39,460
Cash flows from financing activities:			
Proceeds from issuance of preferred stock in registered direct offering, net of offering costs	—	—	—
Proceeds from issuance of common stock in public offering, net of offering costs	21,081	—	21,081
Proceeds from At-the-Market sales of common stock, net of offering costs	9,266	—	9,266
Proceeds from exercise of stock options	75	—	75
Net cash provided by financing activities	30,422	—	30,422
Net (decrease) increase in cash and cash equivalents	4,680	—	4,680
Cash and cash equivalents, beginning of period	14,463	—	14,463
Cash and cash equivalents, end of period	$ 19,143	$ —	$ 19,143
Supplemental disclosure of noncash financing activities			
Warrants issued in connection with long-term debt	$ 1,080	$ —	$ 1,080
Operating right-of-use assets obtained in exchange for new operating lease liabilities	969	—	969
Supplemental cash flow information			
Interest paid	$ 2,383	$ —	$ 2,383

3. 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, costs of product revenues, 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 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.

It should be noted that current public health threats could adversely affect the Company's ongoing or planned business operations. In particular, the ongoing COVID-19 pandemic has resulted in federal, state and local governments and private entities mandating various restrictions, including travel restrictions, access restrictions, restrictions on public gatherings, and stay at home orders. The effect of these orders, government imposed quarantines and measures the Company has taken, such as implementing work-at-home policies, may negatively impact productivity, disrupt the Company's business and could delay the Company's commercialization timeline. The Company cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if the Company or any of the third parties with whom it engages, including personnel at third-party manufacturing facilities and other third parties with whom the Company conducts business, were to experience shutdowns or other business disruptions, the Company's ability to conduct its business in the manner and on the timeline presently planned could be materially and adversely impacted. It is unknown how long these conditions will last and what the complete effect will be on the Company. While to date we have been able to continue to execute our overall business plan, some of our business activities have been slowed and taken longer to complete and we continue to adjust to the challenges of operating in a largely remote setting with our employees. We have only recently launched our commercial activities for Twirla and begun engaging with healthcare providers to promote Twirla. We expect that, as we broaden our sales detailing activities, in some instances our sales force may encounter challenges engaging with healthcare providers during this on-going pandemic. Although many areas of the United States have begun to re-open access to offices and other commercial facilities, there continue to be areas where restrictions remain in place, which may have the potential to affect our ability to conduct our business. Further, new variants, including those which are more easily transmissible or resistant to existing vaccines, may lead to new shutdowns or business disruptions in the future. The Company will continue to closely monitor events as they develop and evaluate alternative, mitigating measures it can implement if needed.

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.

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

Trade Accounts Receivable and Allowances

Trade accounts receivable are amounts owed to the Company by its customers for product that has been delivered. The trade 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 is 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, 2022 and 2021, respectively.

Trade 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 and Warrant liability are carried at fair value (see Note 3).

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. During the year ended December 31, 2021, the Company established a reserve of approximately $5.3 million for inventory not expected to be sold prior to its shelf-life date. As of December 31, 2022 inventory reserves approximated $0.6 million.

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.

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 that there has been any impairment of the carrying value of any long-lived assets as of December 31, 2022.

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

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 $8.2 million, $13.8 million and $5.5 for the years ended December 31, 2022 and 2021 and 2020, respectively.

Deferred Financing Costs

Costs directly attributable to the Company's term loan (see Note 9) 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 $342,000, $277,000 and $231,000 for the years ended December 31, 2022, 2021 and 2020, respectively.

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to credit risk consist principally of cash, cash equivalents and marketable securities. The Company invests its cash, cash equivalents and marketable securities in debt instruments and interest-bearing accounts in United States financial institutions, the balances of which exceed federally insured limits. The Company has not recognized any losses from credit risks on such accounts. 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 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 2022, the Company had sales to four customers that individually accounted for more than 10% of its total revenue. These customers had sales of $2.9 million, $2.7 million, $2.6 million and $1.2 million, respectively, which represented 86% of total revenues in the aggregate. In 2021, the Company had sales to three customers that individually accounted for more than 10% of our total revenue. These customers had sales of $1.3 million, $1.3 million, and $1.2 million, respectively, which represented 93% of total revenues in the aggregate. Accounts receivable related to the four comprised 28%, 29%, 25% and 15%, respectively.

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.

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Notes to Financial Statements (Continued)
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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. Trade accounts receivable due to the Company from contracts with its customers are stated separately in the balance sheet, net of various allowances as described in the Trade 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
- 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 significant 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 relied on industry standard data and trend analysis since historical sales data was not available as Twirla was launched in December 2020. As historical data becomes available, the Company will incorporate that data into its estimates of variable consideration.

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

Distribution services fees – The Company pays distribution service fees 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 trade 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.

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

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 trade 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 and with limited historical sales data, an estimate for product returns as of December 31, 2022 was made based on industry standard data and trend analysis. Estimated product returns are recorded as contra trade accounts receivable on the balance sheet.

Chargebacks – Certain government entities and covered 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 trade accounts receivable on the balance sheet.

Rebates – The Company will be 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 estimates the amount in rebates 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. Rebate estimates are recorded as other current liabilities in 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 other current liabilities in accrued expenses on the balance sheet.

The following table provides a summary of the Company's sales allowances and related accruals for the year ended December 31, 2022 which have been deducted in arriving at revenues, net.

	December 31, 2021	Allowances for current period sales	Payments & credits	December 31, 2022
Customer credits, discounts and allowances (contra accounts receivable)	$ 371	$ 5,891	$ (3,268)	$ 2,994
Rebates and co-pay assistance (accrued expenses)	669	4,434	(2,771)	2,332
Total	$ 1,040	$ 10,325	$ (6,039)	$ 5,326

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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 Company issued warrants to purchase 35,000 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 11,250 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. The Perceptive Warrants were subject to repricing in the event of an offering of securities at a price lower than the existing strike price before December 31, 2022. In connection with the Sixth Amendment, we amended and restated the Perceptive Warrants to reset the strike price of the Perceptive Warrants. See Notes 9 and 10 for additional information.

In connection with an underwritten public offering completed in October 2021, the Company issued warrants to purchase 333,333 shares of its common stock. 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 9 and 10 for additional information.

In connection with a registered direct offering completed in March 2022, the Company issued warrants to purchase 1,242,813 shares of its common stock. 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 9 and 10 for additional information.

In connection with a letter agreement and waiver entered into with an investor on April 2022, the Company issued warrants to purchase 212,188 shares of common stock. See Note 10 for additional information.

In connection with a public offering completed in July 2022, the Company issued warrants to purchase 54,666,665 shares of its common stock. 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.

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 uncertain tax positions as of December 31, 2022 that qualify for either recognition or disclosure in the financial statements under this guidance.

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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. Cost associated with performance-based restricted stock units with a performance condition which affects the vesting is recognized only if the performance condition is probable of being satisfied.

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, 2022, 2021 and 2020, respectively, because to do so would be anti-dilutive (in common equivalent shares):

	Year Ended December 31,		
	2022	2021	2020
Common stock warrants	56,501,249	379,583	35,000
Unvested restricted stock units	6,461	8,325	3,995
Common stock options	397,818	259,145	212,977
Total	56,905,528	647,053	251,972

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Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed below, the Company does not believe that the adoption of recently issued standards have or may have a material impact on our consolidated financial statements or disclosures.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"), which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses rather than incurred losses to estimate credit losses on certain types of financial instruments, including trade receivables. ASU 2016-13 was adopted by the Company on January 1, 2020 and had no current impact on the Company as the Company did not have any financial instruments covered by the topic on the date of adoption. Subsequent to the adoption date, the allowance for credit losses is immaterial.

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"). This guidance simplifies the accounting for income taxes by, among other things, reducing complexity in the interim-period accounting for year-to-date loss limitations and changes in tax laws. The adoption of this standard did not have a material impact on its financial statements.

In January 2021, the FASB issued ASU 2021-01, Reference Rate Reform (Topic 848), an expansion of ASU 2020-04: Facilitation of the Effects of Reference Rate Reform on Financial Reporting ("ASU 2021-01"). This guidance permits entities to elect certain optional expedients and exceptions when accounting for derivative contracts and certain hedging relationships affected by changes in the interest rates used for discounting cash flows, for computing variation margin settlements, and for calculating price alignment interest) in connection with reference rate reform activities under way in global financial markets (the "discounting transition"). The guidance was effective immediately and did not have an impact on our consolidated 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.

4. 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 and 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.

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- 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's level 3 liabilities consist of warrant liability. The Company has no level 3 assets.

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, 2022 and 2021:

	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

	Level 1	Level 2	Level 3 (Restated)
December 31, 2021			
Assets:			
Cash and cash equivalents	$ 19,143	$ —	$ —
Total assets at fair value	$ 19,143	$ —	$ —
Liabilities:			
Warrant Liability (Restated)	$ —	$ —	$ 5,356
Total assets at fair value	$ —	$ —	$ 5,356

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%, (iii) strike price for the common warrants $0.90, (iv) strike price for the preferred warrants (10.40), (v) fair value of common stock $0.23, and (vi) expected life 4.3 – 4.5 years. The significant assumptions used in preparing the option pricing model for valuing the Company's warrants as of December 31, 2021 include (i) volatility 136.4%, (ii) risk-free interest rate 1.1%, (iii) strike price for the common warrants $34.08, (iv) fair value of common stock $31.63, and (v) expected life 4.98 years.

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

Beginning balance at December 31, 2020	$ —
Warrants issued	9,183
Change in fair value	(3,827)
Ending balance at December 31, 2021 (Restated)	5,356
Warrants issued	26,098
Change in fair value	(25,520)
Ending balance at December 31, 2022	$ 5,934

There were no transfers between Level 1, 2 or 3 during 2022 or 2021.

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5. Prepaid Expenses

Prepaid expenses consist of the following:

	December 31, 2022	December 31, 2021
Prepaid insurance	$ 628	$ 775
Other	775	1,508
Total prepaid expenses and other current assets	$ 1,403	$ 2,283

6. 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, 2022	December 31, 2021	Estimated Life
Office equipment	$ 132	$ 7	5 years
Computer equipment	121	113	3 Years
Manufacturing equipment	—	14,477	7 years
	253	14,597	
Less: accumulated depreciation	(76)	(2,150)	
Property and equipment	$ 177	$ 12,447	

Upon successful completion of the validation of the commercial manufacturing process for Twirla by the Company's contract manufacturer, Corium, and the announcement of the commercial launch of Twirla in December 2020, manufacturing equipment with a cost of $14.3 million was placed into service and started being depreciated.

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.

7. Accrued Liabilities

Accrued liabilities consist of the following:

	December 31, 2022	December 31, 2021
Gross to net accruals	$ 2,332	$ 670
Accrued compensation	833	2,086
Accrued professional fees and other	743	807
Total accrued liabilities	$ 3,908	$ 3,563

8. Leases

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the statement of operations. The Company adopted ASU No. 2016-02 on January 1, 2019 for

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leases that existed on that date. The Company has elected to apply the provisions of ASC 842 modified retrospectively at January 1, 2019 through a cumulative-effect adjustment. Prior period results continue to be presented under ASC 840 based on the accounting standards originally in effect for such periods.

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.

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 and $180,000 for the years ended December 31, 2022 and 2021, respectively. Operating cash flows used for operating leases during the years ended December 31, 2022 and 2021 were $175,000 and $131,000 respectively. As of December 31, 2022, the weighted-average remaining lease term was 2.25 years and the weighted average discount rate was 11.8%.

Future minimum lease payments under non-cancellable leases as of December 31, 2022 were as follows:

2023	$	391
2024		397
2025		101
Total	$	889
Less: Interest		(104)
Present value of lease liability	$	785

9. Credit Agreement and Guaranty

On February 10, 2020 (the “Closing Date”), the Company entered into a Credit Agreement and Guaranty with 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. Another $15.0 million tranche was to be available to the Company based on the achievement of a revenue milestone by December 31, 2021, which was not achieved. The other tranches of debt under the Amended 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 Amended 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 under the Amended Perceptive Credit Agreement using the proceeds of recent sales under the Company’s ATM program with H.C. Wainwright & Co., LLC. Such payment was made on July 25, 2022.

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The facility will mature on February 10, 2024 ("Maturity Date"). Pursuant to the Fifth Amendment, beginning August 31, 2022, the Company began making monthly principal payments in an amount equal to $75,000, continuing until February 10, 2024, at which time all remaining principal amount outstanding is due.

Borrowings under the Fifth Amendment will accrue interest at an annual rate equal to the London Interbank Offered Rate for one-month deposits ("LIBOR") plus 10.25%, provided that LIBOR shall not be less than 1.5%. The rate of interest in effect as of July 25, 2022 was 11.97% and at December 31, 2022 was 14.38%. Upon the occurrence and during the continuance of any event of default under the Fifth Amendment, the interest rate automatically increases by 3.0% per annum.

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 4.0% if such prepayment occurs after February 10, 2022 and on or prior to February 10, 2023; and 2.0% if such prepayment occurs after February 10, 2023 and prior to the Maturity Date.

All of the Company's obligations under the Fifth Amendment 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 Amended Perceptive 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 Amended 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 Amended 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 Amended Perceptive Credit Agreement. In addition, the Company must (i) at all times prior 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 December 31, 2022, report revenues for the trailing 12-month period that exceed the amounts set forth in the Fifth Amendment which range from $62.6 million for the fiscal quarter ending March 31, 2023 to $87.1 million for the fiscal quarter ending December 31, 2023. Pursuant to the Waiver and Sixth Amendment to the Perceptive Credit Agreement (the "Sixth Amendment"), the Company has received a waiver of certain financial covenants through the second quarter of 2023. In the event the Company does not pay off the remainder of the outstanding principal under the facility, the Company will need to negotiate for a waiver of its obligations to comply with the covenants relating to revenue for Twirla in the second quarter of 2023.

In connection with the Perceptive Credit Agreement, the Company issued to Perceptive two warrants to purchase an aggregate of 35,000 shares of the Company's common stock (together, the "2020 Perceptive Warrants"). The first warrant is exercisable for 17,500 shares of common stock at an exercise price of $149.60 per share. The second warrant is exercisable for 17,500 shares of common stock at an exercise price of $186.80 per share. The 2020 Perceptive Warrants expire on February 10, 2027. In connection with the Amended Perceptive Credit Agreement, the Company issued to Perceptive a warrant to purchase 11,250 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 $114.80 per share. The 2021 Perceptive Warrant expires on February 26, 2028. The Perceptive Warrants contain anti-dilution provisions that expired on December 31, 2022 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 as a result of the exercise. In connection with the Sixth Amendment, we amended and restated the Perceptive Warrants to reset the strike price of the Perceptive Warrants.

As a result of the public offering of the Company's common stock completed in October 2021 (see Note 10), the antidilution provision of the Perceptive Warrants was triggered, resulting in a reduction of the strike price for the Perceptive Warrants. Warrants to purchase 17,500 shares of common stock that had an exercise price of $186.80 per

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share were reduced to $141.60 per share, warrants to purchase 17,500 shares of common stock that had an exercise price of $149.60 per share were reduced to $115.20 per share, and warrants to purchase 11,250 shares of common stock that had an exercise price of $114.80 per share were reduced to $90.80 per share.

As a result of the registered direct offering completed in March 2022 (see Note 10), 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 17,500 shares of common stock that had an adjusted exercise price of $141.60 per share were reduced to $105.52 per share, warrants to purchase 17,500 shares of common stock that had an adjusted exercise price of $115.20 per share were reduced to $86.61 per share, and warrants to purchase 11,250 shares of common stock that had an adjusted exercise price of $90.80 per share were reduced to $69.13 per share.

As a result of the public offering of the Company's common stock completed in July 2022 (see Note 10), 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 17,500 shares of common stock that had an exercise price of $105.52 per share were reduced to $14.90 per share, warrants to purchase 17,500 shares of common stock that had an exercise price of $86.61 per share were reduced to $12.37 per share, and warrants to purchase 11,250 shares of common stock that had an exercise price of $69.13 per share were reduced to $10.03 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 preparing 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 $149.60 and $186.80 for the common stock warrants, (iv) fair value of common stock ($160.40) 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 $114.80 for the common stock warrant, (iv) fair value of common stock ($114.80) 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, 2022	December 31, 2021
Notes payable	$ 2,625	$ 20,000
Debt issuance costs	(209)	(550)
Warrant discount	(990)	(2,617)
Total debt	$ 1,426	$ 16,833
Less, current portion	1,426	16,833
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 $1,969,000, $1,661,000 and $1,341,000 for the years ended December 31, 2022, 2021, and 2020 respectively.

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10. Stockholders' Equity

The Company's Certificate of Incorporation, as amended, among other things: (i) authorizes 300,000,000 shares of common stock; (ii) authorizes 10,000,000 shares of undesignated preferred stock that may be issued from time to time by the Board in one or more series; (iii) provides that the Board be divided into three classes with staggered three-year terms, with one class of directors to be elected at each annual meeting of the Company's stockholders; (iv) provides that directors may only be removed with cause and only upon the affirmative vote of holders of at least 75% of the voting power of all then-outstanding shares of capital stock of the Company entitled to vote generally in the election of directors; (v) provides that only the Board, the chairman of the Board or the chief executive officer may call a special meeting of stockholders; and (vi) requires that any action instituted against the Company's officers or directors in connection with their service to the Company be brought in the State of Delaware.

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.

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.

Public Offerings

In October 2021, the Company completed a public offering of 666,666 shares of its common stock and warrants to purchase 333,333 shares of its common stock at a combined price of $34.00 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 public offering of (1) 19,148,332 shares of its common stock and warrants to purchase 38,296,664 shares of its common stock at a combined price of $0.90 per share of common stock and warrants and (2) 7,518,334 pre-funded warrants to purchase 7,518,334 shares of its common stock and warrants to purchase 15,036,668 shares of its common stock at a combined price of $0.8999 per share of common stock and pre-funded warrant. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses were approximately $22.0 million.

ATM Sales Agreements

In March 2021, the Company entered into a common stock sales agreement (the "2021 ATM 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 2021 ATM Agreement. During the year ended December 31, 2021, the Company issued and sold 172,879 shares of common stock under the 2021 ATM Agreement resulting in net proceeds to the Company of approximately $9.3 million.

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On January 10, 2022, the Company filed a prospectus supplement to its 2020 Shelf Registration Statement registering an at-the-market offering program (the "January 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 January 2022 ATM. During the nine months ended September 30, 2022, the Company issued and sold 25,623 shares of common stock under the January 2022 ATM resulting in net proceeds to the Company of approximately $0.3 million. On April 26, 2022, the Company terminated the January 2022 ATM.

On April 27, 2022, the Company entered into a new at-the-market offering program ("April 2022 ATM") with H.C. Wainwright LLC and Co. (the "Sales Agent"), under which the Company may, from time to time in its sole discretion, issue and sell through or to the Sales Agent, acting as the Company's agent, up to $12,841,000 of shares of the Company's common stock (the "Placement Shares"). The Company agreed to pay the Sales Agent a commission of up to 3.0% of the gross sales proceeds of any Placement Shares sold under the April 2022 ATM. Through September 30, 2022, the Company issued and sold a total of 8,687,502 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 may now offer and sell, from time to time through the Sales Agent, shares of the Company's 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 3,942,648 shares of common stock under the August 2022 ATM resulting in net proceeds to the Company of approximately $0.9 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 606,250 shares of the common stock of the Company and Series B warrants (the "Series B Warrants") to purchase up to an aggregate of 606,250 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 $8.00 per share. The shares of preferred stock issued in the 2022 Preferred Stock Offering are convertible into an aggregate of 606,250 shares of common stock. The Series A Warrants have an exercise price of $10.40 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 $10.40 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 30,313 shares of the common stock of the Company at a strike price of $10.00 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 303,125 shares of the Company's common stock. On April 4, 2022, 2,425 shares of the Series B Preferred Stock were converted into 303,125 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

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conditions as the Series A Warrants, provided that such New Warrant shall be exercisable into 212,188 warrant shares. The Series A Warrants have an exercise price of $10.40 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.

On July 6, 2022, the Company completed a best efforts public offering (the "Offering") in which the Company raised net proceeds of $22.0 million through the sale of 19,148,332 shares of common stock and 7,518,334 pre-funded warrants ("Series B pre-funded warrants") to purchase 7,518,334 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 are exercisable immediately and will expire thirteen 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. The Company also issued to certain designees of H.C. Wainwright warrants to purchase up to 1,333,333 shares of commons stock with an exercise price of $1.125 per share.

Common Stock Warrants

In connection with the Perceptive Credit Agreement (see Note 9), the Company issued warrants to Perceptive to purchase 35,000 shares of its common stock. These warrants contain antidilution provisions that were triggered upon the Company's public offering that was completed in October 2021. As a result of the offering, warrants to purchase 17,500 shares of common stock that had an exercise price of $186.80 per share were reduced to $141.60 per share, warrants to purchase 17,500 shares of common stock that had an exercise price of $149.60 per share were reduced to $115.20 per share, and warrants to purchase 11,250 shares of common stock that had an exercise price of $114.80 per share were reduced to $90.80 per share. These repricing's resulted in an immaterial increase to additional paid-in-capital. In connection with the Sixth Amendment, we amended and restated the Perceptive Warrants to reset the strike price of the Perceptive Warrants.

As a result of the registered direct offering completed in March 2022, 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 17,500 shares of common stock that had an adjusted exercise price of $141.60 per share were reduced to $105.52 per share, warrants to purchase 17,500 shares of common stock that had an adjusted exercise price of $115.20 per share were reduced to $86.61 per share, and warrants to purchase 11,250 shares of common stock that had an adjusted exercise price of $90.80 per share were reduced to $69.13 per share.

As a result of the public offering of the Company's common stock completed in July 2022, 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 17,500 shares of common stock that had an exercise price of $105.52 per share were reduced to $14.90 per share, warrants to purchase 17,500 shares of common stock that had an exercise price of $86.61 per share were reduced to $12.37 per share, and warrants to purchase 11,250 shares of common stock that had an exercise price of $69.13 per share were reduced to $10.03 per share.

All Perceptive Warrants are accounted for in equity, whereas all warrants associated with our various 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.

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11. 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 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. As of December 31, 2022, there were 314,398 shares available for future grant under the Amended 2014 Plan.

Through December 31, 2022, the Company granted options to certain employees and non-employees to purchase shares of common stock at exercise prices ranging from $0.20 to $430.00 per share. The Company recorded noncash stock-based compensation expense for the years ended December 31, 2022, 2021 and 2020 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,		
	2022	2021	2020
Cost of goods sold	$ 133	$ 271	$ 14
Research and development	372	490	651
Selling and marketing	155	148	108
General and administrative	1,833	2,429	2,045
Total	$ 2,493	$ 3,338	$ 2,818

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

	2022	2021	2020
Risk-free interest rate	1.71% - 4.22 %	.66% - 1.51 %	.40% - 1.68 %
Expective volatility	107% - 118 %	105% - 106 %	65% - 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. The expected volatility assumption was based on volatilities of a peer group of similar companies whose share prices are publicly available until August 2020. The peer group was developed based on comparable companies in the biotechnology and pharmaceutical industries. In August 2020, the Company transitioned to its own expected volatility based on sufficient historical data.

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Expected term. The expected term represents the period of time that options are expected to be outstanding. Because the Company does not have historic 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, 2022, the unrecorded deferred stock-based compensation balance related to stock options was approximately $3.3 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, 2022 was $3.29.

The following table summarizes the options outstanding, options vested and the options exercisable as of December 31, 2022, 2021 and 2020:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2020	212,946	125.29	6.3	
Options granted	64,528	105.00		
Options exercised	(3,159)	23.80		
Options cancelled/forfeited	(15,170)	264.46		
Options outstanding at December 31, 2021	259,145	113.33	6.1	
Options granted	187,454	3.97		
Options exercised	—	—		
Options cancelled/forfeited	(48,781)	97.44		
Options outstanding at December 31, 2022	397,818	63.75	7.7	$ 6
Options exercisable at December 31, 2022	182,667	113.54	5.7	$ —
Vested and expected to vest at December 31, 2022	397,818			$ 6

Intrinsic value in the tables was calculated as the difference between the Company's stock price at December 31, 2022, of $0.23 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 1,774 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 5,659 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 4,690 RSUs to directors of the Company. These RSUs vest ratably over one year.

As of December 31, 2022, the unrecorded deferred stock-based compensation balance related to RSUs was approximately $68,000 and will be recognized over an estimated weighted-average amortization period of 0.7 years. The following table shows the Company's restricted stock unit activity during the years ended December 31, 2022, and 2021:

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	Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Restricted stock units outstanding at December 31, 2020	3,988		$ 458
Granted	7,433	67.27	
Vested	(3,096)	112.73	
Restricted stock units outstanding at December 31, 2021	8,325	—	$ 163
Granted	4,690	1.05	
Vested	(6,554)	76.30	
Restricted stock units outstanding at December 31, 2022	6,461		$ 2

12. 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, 2022, the Company had available net operating loss carryforwards ("NOLs") of approximately $390.6 million for federal and $79.9 million for state income tax reporting purposes. Under the TCJA, the federal NOLs generated after 2017, approximately $201.7 million, can be carried forward indefinitely, while the NOLs generated through taxable years ending December 31, 2017, approximately $188.9 million, are available to offset future federal taxable income, if any, through 2037. The Company also has research and development tax credit carryforwards of approximately $6.4 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 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.

As of December 31, 2022, the Company has not accrued interest or penalties related to uncertain tax positions. The Company's tax returns for the years ended December 31, 2019 through December 31, 2021 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, 2022, 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 in known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and 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.

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

	December 31, 2022	December 31, 2021
Deferred tax assets:		
Net operating loss carryforwards	$ 87,216	$ 81,102
Research credit carryforward	7,071	7,943
Stock options and other	2,297	2,114
Total gross deferred tax assets	96,584	91,159
Valuation allowance for deferred tax assets	(96,584)	(91,159)
Net deferred tax assets	$ —	$ —

The net change in the valuation allowance for the years ended December 31, 2022 and 2021 was an increase of $5.4 million and an increase of $14.4 million, respectively.

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

	December 31, 2022	December 31, 2021 (Restated)	December 31, 2020
Federal income tax at statutory rate	21.0 %	21.0 %	21.0 %
State income tax benefit, net of federal benefit	0.1 %	0.2 %	1.0 %
Unrealized gain on warrants	18.8 %	1.1 %	— %
Research and development tax credits	0.1 %	0.2 %	0.7 %
Other	(5.6)%	(2.2)%	(2.0)%
Increase to valuation allowance	(18.5)%	(20.3)%	(20.7)%
Effective income tax rate	15.9 %	0.0 %	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.

13. 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, total $238.2 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 2023 or termination amounts. Additionally, the Company purchases products and services as needed with no firm commitment.

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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 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 2022 is $5.3 million, for 2023 is $7.0 million, and is $22.5 million for 2024 and each year thereafter. 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 2022 and 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, 2022, the Company has not recorded a provision for any contingent losses.

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14. Quarterly Financial Information (Unaudited)

As further described in Note 2, the previously reported financial information for the three months ended March 31, 2022, the three and six months ended June 30, 2022 and the three and nine months ended September 30, 2022, have been restated. Relevant restated financial information for each relevant period is included in this Annual Report on Form 10-K in the tables that follow. As part of the restatement, the Company recorded adjustments to correct the misstatements in the impacted periods. Descriptions of the restatement can be found in Note 2. The unaudited interim financial statements reflect all adjustments which are, in the opinion of management, necessary for a fair statement of the results for the interim periods presented. Restated amounts are computed independently each quarter; therefore, the sum of the quarterly amounts may not equal the total amount for the respective year due to rounding.

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Balance Sheets

	March 31, 2022 (unaudited)			June 30, 2022 (unaudited)			September 30, 2022 (unaudited)		
	As Previously Reported	Adjustment	As Restated	As Previously Reported	Adjustment	As Restated	As Previously Reported	Adjustment	As Restated
Assets									
Current assets:									
Cash and cash equivalents	$ 3,743	$ —	$ 3,743	$ 13,027	$ —	$ 13,027	$ 6,145	$ —	$ 6,145
Accounts receivable, net	1,665	—	1,665	2,087	—	2,087	3,711	—	3,711
Income taxes receivable	4,675	—	4,675	—	—	—	—	—	—
Inventory, net	2,693	—	2,693	2,340	—	2,340	1,797	—	1,797
Prepaid expenses and other current assets	1,576	—	1,576	1,016	—	1,016	3,834	—	3,834
Total current assets	14,352	—	14,352	18,470	—	18,470	15,487	—	15,487
Property and equipment, net	12,047	—	12,047	11,524	—	11,524	203	—	203
Right of use asset	888	—	888	825	—	825	761	—	761
Other non-current assets	2,012	—	2,012	2,012	—	2,012	2,012	—	2,012
Total assets	$ 29,299	$ —	$ 29,299	$ 32,831	$ —	$ 32,831	$ 18,463	$ —	$ 18,463
Liabilities and stockholders' equity									
Current liabilities:									
Long-term debt, current portion	$ 12,252	—	$ 12,252	$ 12,630	—	$ 12,630	$ 1,318	—	$ 1,318
Accounts payable	9,537	—	9,537	12,036	—	12,036	4,906	—	4,906
Accrued expenses	3,828	—	3,828	3,877	—	3,877	5,152	—	5,152
Lease liability, current portion	231	—	231	239	—	239	277	—	277
Total current liabilities	25,848	—	25,848	28,782	—	28,782	11,653	—	11,653
Lease liabilities, long-term	708	—	708	630	—	630	550	—	550
Warrant liability	—	8,101	8,101	—	1,050	1,050	—	9,285	9,285
Total liabilities	26,556	8,101	34,657	29,412	1,050	30,462	12,203	9,285	21,488
Commitments and contingencies (Note 13)									
Stockholders' equity									
Preferred stock, $.0001 par value, 10,000,000 shares authorized, 4,850 issued and no shares outstanding at December 31, 2022 and no shares issued and outstanding at December 31, 2021	887	(887)	—	—	—	—	—	—	—
Common stock, $.0001 par value, 300,000,000 shares authorized, 42,970,134 and 3,034,901 issued and outstanding at December 31, 2022 and December 31, 2021, respectively *	—	—	—	1	—	1	4	—	4
Additional paid-in capital *	400,742	(12,425)	388,317	414,523	(13,312)	401,211	437,027	(35,283)	401,744
Accumulated deficit	(398,886)	5,211	(393,675)	(411,105)	12,262	(398,843)	(430,771)	25,998	(404,773)
Total stockholders' equity	2,743	(8,101)	(5,358)	3,419	(1,050)	2,369	6,260	(9,285)	(3,025)
Total liabilities and stockholders' equity	$ 29,299	$ —	$ 29,299	$ 32,831	$ —	$ 32,831	$ 18,463	$ —	$ 18,463

* Adjustment reflected as a result of the 1-for-40 reverse stock split effectuated on April 26, 2022.

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Quarterly and Year to Date Statements of Operations and Comprehensive Loss

	Three Months Ended March 31, 2022 (unaudited)			Three Months Ended June 30, 2022 (unaudited)			Three Months Ended September 30, 2022 (unaudited)		
	As Previously Reported	Adjustment	As Restated	As Previously Reported	Adjustment	As Restated	As Previously Reported	Adjustment	As Restated
Revenues, net	$ 1,761	$ —	$ 1,761	$ 2,126	$ —	$ 2,126	$ 3,002	$ —	$ 3,002
Cost of product revenues	1,527	—	1,527	2,231	—	2,231	1,425	—	1,425
Gross profit (loss)	234	—	234	(105)	—	(105)	1,577	—	1,577
Operating expenses:									
Research and development	$ 1,257	$ —	$ 1,257	$ 856	$ —	$ 856	$ 788	$ —	$ 788
Selling and marketing	10,553	—	10,553	7,411	—	7,411	5,560	—	5,560
General and administrative	3,997	—	3,997	3,026	—	3,026	2,815	—	2,815
Loss on disposition of assets	—	—	—	—	—	—	11,122	—	11,122
Total operating expenses	15,807	—	15,807	11,293	—	11,293	20,285	—	20,285
Loss from operations	(15,573)	—	(15,573)	(11,398)	—	(11,398)	(18,708)	—	(18,708)
Other income (expense)									
Interest income	1	—	1	2	—	2	46	—	46
Interest expense	(872)	—	(872)	(823)	—	(823)	(1,004)	—	(1,004)
Unrealized gain on warrant liability	—	1,384	1,384	—	7,051	7,051	—	13,736	13,736
Total other income (expense), net	(871)	1,384	513	(821)	7,051	6,230	(958)	13,736	12,778
Loss before benefit from income taxes	(16,444)	1,384	(15,060)	(12,219)	7,051	(5,168)	(19,666)	13,736	(5,930)
Benefit from income taxes	4,675	—	4,675	—	—	—	—	—	—
Net loss	$ (11,769)	$ 1,384	$ (10,385)	$ (12,219)	$ 7,051	$ (5,168)	$ (19,666)	$ 13,736	$ (5,930)
Net loss per share (basic and diluted)	$ (3.78)	$ 0.44	$ (3.33)	$ (2.71)	$ 1.56	$ (1.15)	$ (0.53)	$ 0.37	$ (0.16)
Weighted-average common shares (basic and diluted)	3,115,211	3,115,211	3,115,211	4,510,219	4,510,219	4,510,219	36,997,836	36,997,836	36,997,836
Comprehensive loss:									
Net loss	$ (11,769)	$ 1,384	$ (10,385)	$ (12,219)	$ 7,051	$ (5,168)	$ (19,666)	$ 13,736	$ (5,930)
Other comprehensive income:									
Unrealized (loss) gain on marketable securities	—	—	—	—	—	—	—	—	—
Comprehensive loss	$ (11,769)	$ 1,384	$ (10,385)	$ (12,219)	$ 7,051	$ (5,168)	$ (19,666)	$ 13,736	$ (5,930)

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	Six Months Ended June 30, 2022 (unaudited)			Nine Months Ended September 30, 2022 (unaudited)		
	As Previously Reported	Adjustment	As Restated	As Previously Reported	Adjustment	As Restated
Revenues, net	$ 3,887	$ —	$ 3,887	$ 6,888	$ —	$ 6,888
Cost of product revenues	3,758	—	3,758	5,183	—	5,183
Gross profit (loss)	129	—	129	1,705	—	1,705
Operating expenses:						
Research and development	$ 2,113	$ —	$ 2,113	$ 2,901	$ —	$ 2,901
Selling and marketing	17,964	—	17,964	23,523	—	23,523
General and administrative	7,023	—	7,023	9,837	—	9,837
Loss on disposition of assets	—	—	—	11,122	—	11,122
Total operating expenses	27,100	—	27,100	47,383	—	47,383
Loss from operations	(26,971)	—	(26,971)	(45,678)	—	(45,678)
Other income (expense)						
Interest income	3	—	3	50	—	50
Interest expense	(1,695)	—	(1,695)	(2,699)	—	(2,699)
Unrealized gain on warrant liability	—	8,435	8,435	—	22,171	22,171
Total other income (expense), net	(1,692)	8,435	6,743	(2,649)	22,171	19,522
Loss before benefit from income taxes	(28,663)	8,435	(20,228)	(48,327)	22,171	(26,156)
Benefit from income taxes	4,675	—	4,675	4,675	—	4,675
Net loss	$ (23,988)	$ 8,435	$ (15,553)	$ (43,652)	$ 22,171	$ (21,481)
Net loss per share (basic and diluted)	$ (6.29)	$ 2.21	$ (4.08)	$ (2.91)	$ 1.48	$ (1.43)
Weighted-average common shares (basic and diluted)	3,816,569	3,816,569	3,816,569	14,998,534	14,998,534	14,998,534
Comprehensive loss:						
Net loss	$ (23,988)	$ 8,435	$ (15,553)	$ (43,652)	$ 22,171	$ (21,481)
Other comprehensive income:						
Unrealized (loss) gain on marketable securities	—	—	—	—	—	—
Comprehensive loss	$ (23,988)	$ 8,435	$ (15,553)	$ (43,652)	$ 22,171	$ (21,481)

Agile Therapeutics, Inc.
Notes to Financial Statements (Continued)
December 31, 2022
(amounts in tables in thousands, except share and per share data)

Statements of Changes in Stockholders' Equity (Unaudited)

	Preferred Stock		Common Stock		Additional Paid-in Capital *	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount	Number of Shares *	Amount				
As Previously Reported								
Balance December 31, 2021	—	$ —	3,034,901	$ —	$ 396,388	$ —	$ (387,117)	$ 9,271
Share-based compensation - stock options and RSUs	—	—	—	—	764	—	—	764
Issuance of common stock pursuant to at-the market stock sales, net of expenses	—	—	25,623	—	348	—	—	348
Issuance of series A and B convertible preferred stock in a registered direct offering (Note 8)	4,850	4,850	—	—	—	—	—	4,850
Registered direct financing costs, inclusive of warrants	—	(965)	—	—	244	—	—	(721)
Conversion of series A convertible preferred stock	(2,425)	(897)	303,125	—	897	—	—	—
Vesting of RSUs	—	—	1,773	—	—	—	—	—
Warrants issued in connection with registered direct offering	—	(2,101)	—	—	2,101	—	—	—
Net loss	—	—	—	—	—	—	(11,769)	(11,769)
Balance March 31, 2022	2,425	$ 887	3,365,422	$ —	$ 400,742	$ —	$ (398,886)	$ 2,743
Adjustment								
Balance December 31, 2021	—	—	—	—	(9,183)	—	3,827	(5,356)
Share-based compensation - stock options and RSUs	—	—	—	—	—	—	—	—
Issuance of common stock pursuant to at-the market stock sales, net of expenses	—	—	—	—	—	—	—	—
Issuance of series A and B convertible preferred stock in a registered direct offering (Note 8)	—	(4,850)	—	—	—	—	—	(4,850)
Registered direct financing costs, inclusive of warrants	—	965	—	—	(244)	—	—	721
Conversion of series A convertible preferred stock	—	897	—	—	(897)	—	—	—
Vesting of RSUs	—	—	—	—	—	—	—	—
Warrants issued in connection with registered direct offering	—	2,101	—	—	(2,101)	—	—	—
Net loss	—	—	—	—	—	—	1,384	1,384
Total Adjustment March 31, 2022	—	$ (887)	—	$ —	$ (12,425)	$ —	$ 5,211	$ (8,101)
As Restated								
Balance December 31, 2021	—	$ —	3,034,901	$ —	$ 387,205	$ —	$ (383,290)	$ 3,915
Share-based compensation - stock options and RSUs	—	—	—	—	764	—	—	764
Issuance of common stock pursuant to at-the market stock sales, net of expenses	—	—	25,623	—	348	—	—	348
Issuance of series A and B convertible preferred stock in a registered direct offering (Note 8)	4,850	—	—	—	—	—	—	—
Registered direct financing costs, inclusive of warrants	—	—	—	—	—	—	—	—
Conversion of series A convertible preferred stock	(2,425)	—	303,125	—	—	—	—	—
Vesting of RSUs	—	—	1,773	—	—	—	—	—
Warrants issued in connection with registered direct offering	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	(10,385)	(10,385)
Balance March 31, 2022	2,425	$ —	3,365,422	$ —	$ 388,317	$ —	$ (393,675)	$ (5,358)

Agile Therapeutics, Inc.
Notes to Financial Statements (Continued)
December 31, 2022
(amounts in tables in thousands, except share and per share data)

Statements of Changes in Stockholders' Equity (Unaudited)

	Preferred Stock		Common Stock		Additional Paid-in Capital *	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount	Number of Shares *	Amount				
As Previously Reported								
Balance March 31, 2022	2,425	$ 887	3,365,422	$ —	$ 400,742	$ —	$ (398,886)	$ 2,743
Share-based compensation - stock options and RSUs	—	—	—	—	669	—	—	669
Fractional shares retired as a result of reverse split	—	—	(10)	—	—	—	—	—
Issuance of common stock pursuant to at-the market stock sales, net of expenses	—	—	8,687,502	1	12,225	—	—	12,226
Conversion of series B convertible preferred stock	(2,425)	(887)	303,125	—	887	—	—	—
Vesting of RSUs	—	—	4,118	—	—	—	—	—
Net loss	—	—	—	—	—	—	(12,219)	(12,219)
Balance June 30, 2022	—	$ —	12,360,157	$ 1	$ 414,523	$ —	$ (411,105)	$ 3,419
Adjustment								
Balance March 31, 2022	—	(887)	—	—	(12,425)	—	5,211	(8,101)
Share-based compensation - stock options and RSUs	—	—	—	—	—	—	—	—
Fractional shares retired as a result of reverse split	—	—	—	—	—	—	—	—
Issuance of common stock pursuant to at-the market stock sales, net of expenses	—	—	—	—	—	—	—	—
Conversion of series B convertible preferred stock	—	887	—	—	(887)	—	—	—
Vesting of RSUs	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	7,051	7,051
Balance June 30, 2022	—	$ —	—	$ —	$ (13,312)	$ —	$ 12,262	$ (1,050)
As Restated								
Balance March 31, 2022	2,425	$ —	3,365,422	$ —	$ 388,317	$ —	$ (393,675)	$ (5,358)
Share-based compensation - stock options and RSUs	—	—	—	—	669	—	—	669
Fractional shares retired as a result of reverse split	—	—	(10)	—	—	—	—	—
Issuance of common stock pursuant to at-the market stock sales, net of expenses	—	—	8,687,502	1	12,225	—	—	12,226
Conversion of series B convertible preferred stock	(2,425)	—	303,125	—	—	—	—	—
Vesting of RSUs	—	—	4,118	—	—	—	—	—
Net loss	—	—	—	—	—	—	(5,168)	(5,168)
Balance June 30, 2022	—	$ —	12,360,157	$ 1	$ 401,211	$ —	$ (398,843)	$ 2,369

* Adjustment reflected as a result of the 1-for-40 reverse stock split effectuated on April 26, 2022.

Agile Therapeutics, Inc.
Notes to Financial Statements (Continued)
December 31, 2022
(amounts in tables in thousands, except share and per share data)

Statements of Changes in Stockholders' Equity (Unaudited)

	Preferred Stock		Common Stock		Additional Paid-in Capital *	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount	Number of Shares *	Amount				
As Previously Reported								
Balance June 30, 2022	—	$ —	12,360,157	$ 1	$ 414,523	$ —	$ (411,105)	$ 3,419
Share-based compensation - stock options and RSUs	—	—	—	—	536	—	—	536
Issuance of common stock pursuant to a public offering, net of expenses	—	—	26,666,666	3	21,968	—	—	21,971
Net loss	—	—	—	—	—	—	(19,666)	(19,666)
Balance September 30, 2022	—	—	39,026,823	$ 4	$ 437,027	$ —	$ (430,771)	$ 6,260
Adjustment								
Balance June 30, 2022	—	—	—	—	(13,312)	—	12,262	(1,050)
Share-based compensation - stock options and RSUs	—	—	—	—	—	—	—	—
Issuance of common stock pursuant to a public offering, net of expenses	—	—	—	—	(21,971)	—	—	(21,971)
Net loss	—	—	—	—	—	—	13,736	13,736
Balance September 30, 2022	—	—	—	$ —	$ (35,283)	$ —	$ 25,998	$ (9,285)
As Restated								
Balance June 30, 2022	—	$ —	12,360,157	$ 1	$ 401,211	$ —	$ (398,843)	$ 2,369
Share-based compensation - stock options and RSUs	—	—	—	—	536	—	—	536
Issuance of common stock pursuant to a public offering, net of expenses	—	—	26,666,666	3	(3)	—	—	—
Net loss	—	—	—	—	—	—	(5,930)	(5,930)
Balance September 30, 2022	—	—	39,026,823	$ 4	$ 401,744	$ —	$ (404,773)	$ (3,025)

* Adjustment reflected as a result of the 1-for-40 reverse stock split effectuated on April 26, 2022.

Agile Therapeutics, Inc.
Notes to Financial Statements (Continued)
December 31, 2022
(amounts in tables in thousands, except share and per share data)

Statements of Cash Flows

	Three Months Ended March 31, 2022 (unaudited)			Six Months Ended June 30, 2022 (unaudited)			Nine Months Ended September 30, 2022 (unaudited)		
	As Previoulsy Reported	Adjustment	As Restated	As Previoulsy Reported	Adjustment	As Restated	As Previoulsy Reported	Adjustment	As Restated
Cash flows from operating activities:									
Net loss	$ (11,769)	$ 1,384	$ (10,385)	$ (23,988)	$ 8,435	$ (15,553)	$ (43,652)	$ 22,171	$ (21,481)
Adjustments to reconcile net loss to net cash used in operating activities:									
Noncash inventory reserve	—	—	—	—	—	—	—	—	—
Depreciation	527	—	527	1,057	—	1,057	1,255	—	1,255
Amortization	61	—	61	124	—	124	188	—	188
Loss on disposition of assets	—	—	—	—	—	—	11,122	—	11,122
Noncash stock-based compensation	764	—	764	1,433	—	1,433	1,969	—	1,969
Noncash amortization of deferred financing costs	419	—	419	797	—	797	1,635	—	1,635
Unrealized gain on warrants	—	(1,384)	(1,384)	—	(8,435)	(8,435)		(22,171)	(22,171)
Changes in operating assets and liabilities:			—						
Accounts receivable	(132)	—	(132)	(554)	—	(554)	(2,178)	—	(2,178)
Income taxes receivable	(4,675)		(4,675)	—		—	—		—
Inventory	(1,727)	—	(1,727)	(1,374)	—	(1,374)	(831)	—	(831)
Prepaid expenses and other assets	707	—	707	1,267	—	1,267	(1,551)	—	(1,551)
Accounts payable and accrued expenses	1,095	—	1,095	3,643	—	3,643	(2,213)	—	(2,213)
Lease liability	(21)	—	(21)	(90)	—	(90)	(132)	—	(132)
Net cash used in operating activities	(14,751)	—	(14,751)	(17,685)	—	(17,685)	(34,388)	—	(34,388)
Cash flows from investing activities:									
Purchases of marketable securities	—	—	—	—	—	—	—	—	—
Sales and maturities of marketable securities	—	—	—	—	—	—	—	—	—
Acquisition of property and equipment	(126)	—	(126)	(133)	—	(133)	(133)	—	(133)
Net cash (used in) provided by investing activities	(126)	—	(126)	(133)	—	(133)	(133)	—	(133)
Cash flows from financing activities:									
Proceeds from issuance of preferred stock in registered direct offering, net of offering costs	4,129	—	4,129	4,129	—	4,129	4,129	—	4,129
Proceeds from issuance of common stock in public offering, net of offering costs	—	—	—		—	—	21,971	—	21,971
Proceeds from At-the-Market sales of common stock, net of offering costs	348	—	348	12,573	—	12,573	12,573	—	12,573
Proceeds from issuance of long-term debt	—	—	—	—	—	—	—	—	—
Repayments of long-term debt	(5,000)	—	(5,000)	(5,000)	—	(5,000)	(17,150)	—	(17,150)
Debt financing costs paid	—	—	—	—	—	—	—	—	—
Proceeds from exercise of stock options	—	—	—	—	—	—	—	—	—
Net cash provided by financing activities	(523)	—	(523)	11,702	—	11,702	21,523	—	21,523
Net (decrease) increase in cash and cash equivalents	(15,400)	—	(15,400)	(6,116)	—	(6,116)	(12,998)	—	(12,998)
Cash and cash equivalents, beginning of period	19,143	—	19,143	19,143	—	19,143	19,143	—	19,143
Cash and cash equivalents, end of period	$ 3,743	$ —	$ 3,743	$ 13,027	$ —	$ 13,027	$ 6,145	$ —	$ 6,145
Supplemental cash flow information									
Interest paid	$ 452	$ —	$ 452	$ 898	$ —	$ 898	$ 1,078	$ —	$ 1,078

15. Subsequent Events

On January 25, 2023, the Board declared a dividend of one one-thousandth (1/1,000th) of a share of Series C Preferred Stock for each outstanding share of Company's common stock to stockholders of record as of February 6, 2023. At a special meeting of stockholders held on March 9, 2023 ("Special Meeting"), the holders of Series C Preferred Stock had 1,000,000 votes per whole share of Series C Preferred Stock and were entitled to vote with the Company's common stock, together as a single class, on the proposals to implement a reverse stock split ("Reverse Stock Split Proposal") and adjournment of the Special Meeting, if necessary, but were not otherwise entitled to vote on any other proposals to be presented to the stockholders.

All shares of Series C Preferred Stock that were not present in person or by proxy at the Special Meeting as of immediately prior to the opening of the polls at the Special Meeting were automatically redeemed (the "Initial Redemption"). The outstanding shares of Series C Preferred Stock that were not redeemed pursuant to the Initial Redemption were redeemed automatically upon the approval by the Company's stockholders of the Reverse Stock Split Proposal.

Agile Therapeutics, Inc.
Notes to Financial Statements (Continued)
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On March 9, 2023, we conducted the Special Meeting where the vote on the Reverse Stock Split Proposal was approved. We have been notified by Nasdaq that we have until June 30, 2023 to effectuate the reverse stock split and regain compliance.

On March 21, 2023, the Company and Perceptive entered into 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. In connection with the Sixth Amendment to the Perceptive Agreement, we amended and restated the Perceptive Warrants to reset the strike price of the Perceptive Warrants.

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, 2022, our chief executive officer and principal financial officer have concluded that our disclosure controls and procedures were not effective to ensure that the information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, due to the material weakness in our internal control over financial reporting described below.

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, 2022. 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. Management has concluded that there is a material weakness in the review procedures related to complex securities including the determination of liability versus equity treatment of certain warrants. Management has concluded that there is a material weakness in the design and operating effectiveness of the Company's review procedures related to complex securities. The reviewer had insufficient resources supporting the assessment of the complex securities accounting model and the

review procedures were not performed at a level of precision to prevent or detect a material misstatement on a timely basis in the normal course of the review. As a result, our previously issued financial statements as of and for the year ended December 31, 2021 have been restated. Based on this assessment, management believes that our internal control over financial reporting was not effective as of December 31, 2022.

Changes in Internal Control over Financial Reporting

Except for the material weakness noted above, 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, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Remediation Plan for Material Weakness

Management has actively initiated remediation efforts to address the material weakness. Specifically, we expanded and improved our review process for complex securities and related accounting standards. We plan to further improve this process by enhancing access to accounting literature and identification of third-party accounting professionals with whom to consult regarding complex accounting applications. The elements of our remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects.

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

None.

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	
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
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
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
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	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.)
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.)

Exhibit Number	
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.)
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.)

Exhibit Number	
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	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.)
10.19	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.)
10.20	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.)
10.21*	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.)
10.22*	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.)
10.23*	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.)
10.24*	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.)
10.25*	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.)
10.26*	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.)
10.27* **	Sixth Amendment to Project Agreement, dated January 3, 2023, by and between Agile Therapeutics, Inc. and inVentiv Commercial Services, LLC.
10.28*	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.)

Exhibit Number	
10.29*	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.)
10.30*	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.)
10.31	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.)
10.32+	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.)
10.33+ **	Amended and Restated Employment Agreement, dated November 22, 2022 by and between Agile Therapeutics, Inc. and Alfred Altomari.
10.34+ **	Amended and Restated Employment Agreement, dated November 1, 2022 by and between Agile Therapeutics, Inc. and Geoffrey P. Gilmore.
10.35+ **	Amended and Restated Employment Agreement, dated November 1, 2022 by and between Agile Therapeutics, Inc. and Paul Korner, MD.
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.
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 22, 2023.

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 22, 2023
/s/ JASON BUTCH Jason Butch	Chief Accounting Officer (Principal Accounting Officer)	March 22, 2023
/s/ SHARON BARBARI Sharon Barbari	Director	March 22, 2023
/s/ SANDRA CARSON Sandra Carson, M.D., FACOG	Director	March 22, 2023
/s/ SETH H.Z. FISCHER Seth H.Z. Fischer	Director	March 22, 2023
/s/ JOHN HUBBARD John Hubbard, Ph.D.	Director	March 22, 2023
/s/ AJIT S. SHETTY Ajit S. Shetty, Ph.D.	Director	March 22, 2023
/s/ JOSEPHINE TORRENTE Josephine Torrente	Director	March 22, 2023

NEITHER THIS SECURITY NOR THE SECURITIES FOR WHICH THIS SECURITY IS EXERCISABLE HAVE BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS AS MAY BE REQUIRED TO BE EVIDENCED BY A LEGAL OPINION OF COUNSEL TO THE TRANSFEROR TO SUCH EFFECT, THE SUBSTANCE OF WHICH SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY. THIS SECURITY AND THE SECURITIES ISSUABLE UPON EXERCISE OF THIS SECURITY MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT WITH A REGISTERED BROKER-DEALER OR OTHER LOAN WITH A FINANCIAL INSTITUTION THAT IS AN "ACCREDITED INVESTOR" AS DEFINED IN RULE 501(a) UNDER THE SECURITIES ACT.

AMENDED AND RESTATED COMMON STOCK PURCHASE WARRANT

(FIRST WARRANT)

AGILE THERAPEUTICS, INC.

Common Stock Warrant Shares: 17,500	Original Issue Date: February 10, 2020
	Amendment Date: March 21, 2023

THIS AMENDED AND RESTATED COMMON STOCK PURCHASE WARRANT (this "Warrant") is entered into as of the Amendment Date set forth above between Agile Therapeutics, Inc., a Delaware corporation (the "Company") and Perceptive Credit Holdings III, LP (or its assigns, the "Holder").

WHEREAS, this Warrant was originally issued on the Original Issue Date set forth above (the "Original Warrant") in connection with that certain Credit Agreement and Guaranty dated as of February 10, 2020 (the "Credit Agreement") by and among the Company, as borrower, the subsidiaries of the Company from time to time party thereto as guarantors, the lenders from time to time party thereto, and Holder, as administrative agent for the lenders. The Original Warrant was exercisable for 700,000 Warrant Shares at an exercise price of $3.74 per share.

WHEREAS, on July 25, 2022, the Company issued to the Holder a Certificate of Adjustment (the "Certificate of Adjustment") setting forth an adjustment to the number of Warrant Shares and the Exercise Price applicable to the Warrant reflecting that the Warrant was then exercisable for 17,500 Warrant Shares at an exercise price of $12.37 per share.

WHEREAS, in connection with that certain Sixth Amendment to Credit Agreement and Guaranty dated as of March 21, 2023, the Company and the Holder have agreed to amend and

restate the Original Warrant in its entirety as set forth herein to, among other things, reflect the adjustments previously acknowledged by the Certificate of Adjustment and to further adjust the Exercise Price as set forth herein.

NOW, THEREFORE, for good and valuable consideration, the sufficiency of which is hereby acknowledged, the Company and the Holder agree that the Original Warrant is hereby amended and restated in its entirety as set forth below.

This Warrant certifies that, for value received, the Holder is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after February 10, 2020 and on or prior to the close of business on February 10, 2027 (the "Expiration Date") but not thereafter, to subscribe for and purchase from the Company up to seventeen thousand five hundred (17,500) shares of Common Stock (as subject to adjustment hereunder, the "Warrant Shares"). The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

For the avoidance of doubt, this Warrant shall be treated for all purposes as having been issued on, and having been outstanding since, the Original Issue Date

Section 1. Definitions. For the purposes hereof, in addition to the terms defined elsewhere in this Warrant, (a) capitalized terms used and not otherwise defined herein shall have the meanings set forth in the Credit Agreement, and (b) the following terms shall have the following meanings:

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"Closing Bid Price" means for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the last reported closing bid price for Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg, L.P., (b) if the Common Stock is not then listed or quoted for trading on a Trading Market and if prices for the Common Stock are then reported in the "Pink Sheets" published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (c) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holder and reasonably acceptable to the Company, the reasonable, actual and documented fees and reasonable, actual and documented out-of-pocket expenses of which shall be paid by the Company.

"Commission" means the United States Securities and Exchange Commission.

"Common Stock" means the common stock of the Company, par value $0.0001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Deemed Outstanding" means, at any given time, the sum of (i) the number

of shares of Common Stock actually outstanding at such time, plus (ii) the number of shares of Common Stock issuable upon exercise of Options actually outstanding at such time, plus (iii) the number of shares of Common Stock issuable upon conversion or exchange of Convertible Securities actually outstanding at such time (treating as actually outstanding any Convertible Securities issuable upon exercise of Options actually outstanding at such time), in each case, regardless of whether the Options or Convertible Securities are actually exercisable at such time; *provided* that Common Stock Deemed Outstanding at any given time shall not include shares owned or held by or for the account of the Company or any of its wholly owned subsidiaries.

"Common Stock Equivalents" means any securities of the Company or its wholly owned subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Convertible Securities" means any debt, equity or other securities that are, directly or indirectly, convertible into or exchangeable for Common Stock.

"Excluded Issuance" means the issuance of (a) shares of Common Stock (or options with respect thereto) issued or issuable to employees or directors of, or consultants to, the Company or any of its subsidiaries pursuant to a plan, agreement or arrangement approved by the Board of Directors of the Company, (b) warrants issued pursuant to the Credit Agreement and/or other securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date of this Warrant, *provided* that such securities have not been amended since the date of this Warrant to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities (for purposes of clarity, any decrease in the exercise price, exchange price or conversion price of such securities shall not be deemed an amendment thereto, if such decrease is as a result of any price-based anti-dilution provision contained in such securities prior to the date hereof), (c) other securities issued to financial institutions, institutional investors or lessors in connection with credit arrangements, equipment financings or similar transactions approved by a majority of disinterested directors of the Company, (d) securities issued pursuant to acquisitions or strategic transactions approved by a majority of disinterested directors of the Company, *provided* that any such issuance shall only be to a Person which is, itself or through its subsidiaries, an operating company in a business synergistic with the business of the Company and in which the Company receives benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities, *provided further* that the exclusion in this clause (d) shall be limited to 12,500,000 shares of Common Stock (as such number of shares is equitably adjusted for subsequent stock splits, stock combinations, stock dividends and recapitalizations occurring after the date hereof), and (e) securities issuable under any at-the-market offering programs the Company may establish in accordance with Rule 415(a)(4) under the Securities Act. In addition, for the avoidance of doubt, "Excluded Issuances" also include the filing of any registration statement of the Company with the Commission registering securities of the Company, or the filing of any amendments or supplements thereto, provided that the determination of whether sales under any such registration statement is an Excluded Issuance will be determined based on the preceding clauses (a) to (e) hereof.

"Fundamental Transaction" means (a) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (b) the Company, directly or indirectly, effects any sale, lease, exclusive license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (c) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of fifty percent (50%) or more of the outstanding Common Stock, (d) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock (but, for the avoidance of doubt, excluding any transaction, event or occurrence covered by Section 3(a)) or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, (e) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person whereby such other Person acquires more than fifty percent (50%) of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or Affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination).

"Marketable Securities" means securities that (a) are tradable on an established national U.S. or non-U.S. stock exchange or reported through NASDAQ or a comparable established non-U.S. over-the-counter trading system and (b) are not subject to restrictions on transfer under the Securities Act or contractual restrictions on transfer.

"Options" means any warrants or other rights or options to subscribe for or purchase Common Stock or Convertible Securities.

"Person" means any individual, sole proprietorship, partnership, limited liability company, corporation, joint venture, trust, incorporated organization or government or department or agency thereof.

"Prospectus" means the prospectus or prospectuses included in any Registration Statement, as amended or supplemented by any prospectus supplement with respect to the terms of the offering of any portion of the Registrable Securities covered by such Registration Statement and by all other amendments and supplements to the prospectus, including post-effective amendments and all material incorporated by reference in such prospectus or prospectuses.

"Registrable Securities" means (x) any shares of Common Stock held by Holder or issuable upon conversion, exercise or exchange of any securities owned by Holder at any time (including Warrant Shares exercisable upon exercise of this Warrant), and (y) any shares of Common Stock issued or issuable with respect to any shares described in subsection (x) above by way of a stock dividend or stock split or in connection with a combination of shares, recapitalization, merger, consolidation or other reorganization (it being understood that for purposes of this Warrant, Holder shall be deemed to be a holder of Registrable Securities whenever Holder has the right to then acquire or obtain from the Company any Registrable Securities, whether or not such acquisition

has actually been effected). As to any particular Registrable Securities, such securities shall cease to be Registrable Securities when (i) a Registration Statement covering such securities has been declared effective by the SEC and such securities have been disposed of pursuant to such effective Registration Statement, (ii) such securities are sold under circumstances in which all of the applicable conditions of Rule 144 (or any similar provisions then in force) under the Securities Act are met, (iii) such securities are otherwise transferred and such securities may be resold without subsequent registration under the Securities Act, or (iv) such securities shall have ceased to be outstanding.

"Registration Statement" means any registration statement of the Company which covers any of the Registrable Securities pursuant to the provisions of this Warrant, including the Prospectus, amendments and supplements to such Registration Statement, including post-effective amendments, all exhibits and all materials incorporated by reference in such Registration Statement.

"Rule 144" means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same effect as such Rule.

"Trading Day" means a day on which the principal Trading Market is open for trading.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE MKT, the Nasdaq Global Market, the Nasdaq Capital Market, the New York Stock Exchange, the OTCQB, the OTCQX U.S. or the Nasdaq Global Select Market (or any successors to any of the foregoing).

"Transfer Agent" means Broadridge Corporate Issuer Solutions, the current transfer agent of the Company, with a mailing address of P.O. Box 1342, Brentwood, NY 11717, and any successor transfer agent of the Company. "VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (or an equivalent quotation service acceptable to the Holder and the Company) (based on a Trading Day from 9:30 a.m. (local time in New York City, New York) to 4:00 p.m. (local time in New York City, New York)) (b) if the Common Stock is not then listed or quoted for trading on a Trading Market and if prices for the Common Stock are then reported in the "Pink Sheets" published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (c) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holder and reasonably acceptable to the Company, the reasonable, actual and documented fees and reasonable, actual and documented out-of-pocket expenses of which shall be paid by the Company.

Section 2. Exercise.

(a) Exercise of Warrant. Exercise of the purchase rights represented by this

Warrant may be made, in whole or in part, at any time or times before the Expiration Date by delivery to the Company (or such other office or agency of the Company as it may designate by notice in writing to the registered Holder at the address of the Holder appearing on the books of the Company) of a duly executed facsimile or electronic copy of the Notice of Exercise in the form annexed hereto (the "Notice of Exercise") and within two (2) Trading Days of the date said Notice of Exercise is delivered to the Company, the Company shall have received payment of the aggregate Exercise Price of the Warrant Shares thereby purchased by wire transfer or cashier's check drawn on a United States bank or pursuant to the cashless exercise procedure specified in Section 2(c) below. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise form be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and this Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within two (2) Trading Days of the date the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

In the event that immediately prior to the close of business on the Expiration Date, the Closing Bid Price of one share of Common Stock is greater than the then applicable Exercise Price, this Warrant shall be deemed to be automatically exercised as a "cashless exercise" pursuant to Section 2(c) below, and the Company shall deliver the applicable number of shares of Common Stock to the Holder pursuant to the provisions of Section 2(d) below.

(b) Exercise Price. The exercise price per share of the Common Stock issuable under this Warrant (the "Exercise Price") shall be the lower of (i) $0.21 and (ii) the lowest price that one share of Common Stock is issued by the Company in the period between the Amendment Date and June 30, 2023 (the "Price Adjustment Period"), as such Exercise Price may be subject to further adjustment hereunder. In connection with the foregoing, promptly after June 30, 2023, the Company shall provide a certificate to the Holder signed by an officer of the Company specifying, and certifying, the lowest issue price for one share of Common Stock issued by the Company during the Price Adjustment Period and, if applicable, the adjusted Exercise Price of this Warrant.

(c) Cashless Exercise. This Warrant may be exercised, in whole or in part, at any time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A) (a "Cashless Exercise"), where:

(A) = the VWAP on the Trading Day immediately preceding the date on which Holder elects to exercise this Warrant by means of a "cashless exercise," as set forth in the applicable Notice of Exercise;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise or, if only a portion of this Warrant is being exercised, the portion of this Warrant being cancelled.

(d) Mechanics of Exercise.

(i) Delivery of Warrant Shares Upon Exercise. Warrant Shares purchased hereunder shall be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's prime broker with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and the Warrant Shares are eligible for resale by the Holder without volume or manner-of-sale limitations pursuant to Rule 144 or an available Registration Statement, and otherwise by physical delivery to the address specified by the Holder in the Notice of Exercise by the date that is two (2) Trading Days after the delivery to the Company, by 11 a.m. (local time in New York City, New York) on a Trading Day, of the Notice of Exercise and payment of the aggregate Exercise Price as set forth above (including by Cashless Exercise) (such date, the "Warrant Share Delivery Date"). The Warrant Shares shall be deemed to have been issued, and the Holder or any other person so designated to be named therein shall be deemed to have become a holder of record of such Warrant Shares for all purposes, as of the date this Warrant has been exercised, with payment to the Company of the Exercise Price (or by Cashless Exercise) and all taxes required to be paid by the Holder, if any, pursuant to Section 2(d)(v) prior to the issuance of such Warrant Shares, having been paid. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, other than a failure to deliver caused by the Holder's failure to pay the applicable Exercise Price for such Warrant Shares or to timely take such actions as are necessary to post such Warrant Shares in DWAC, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each $1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), an amount equal to the Exercise Price per Trading Day for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise.

(ii) Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase

the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

(iii) Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the third (3rd) Trading Day following the Warrant Share Delivery Date, other than a failure to deliver caused by the Holder's failure to pay the applicable Exercise Price for such Warrant Shares or to timely take such actions as are necessary to post such Warrant Shares in DWAC, then the Holder will have the right to rescind such exercise.

(iv) Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to an exercise on or before the second (2nd) Trading Day following the Warrant Share Delivery Date and such failure is not caused by any act or omission of the Holder, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased (*provided*, Holder exercises reasonable efforts to minimize the amount of such purchase price) exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue by (2) the actual sale price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted exercise to acquire Warrant Shares with an aggregate sale price giving rise to such purchase obligation of $10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder $1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity, including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver Warrant Shares upon exercise of the Warrant as required pursuant to the terms hereof.

(v) No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As

to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall round up to the next whole share.

(vi) Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; *provided*, *however*, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by a completed Assignment Form in the form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

(vii) Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

(e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to this Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates, and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates) and of which portion of this Warrant is exercisable shall be in the sole discretion

of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company, or (C) a more recent written notice from the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written request of a Holder, the Company shall within three (3) Trading Days confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 19.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the applicable issuance of shares of Common Stock issuable upon exercise of this Warrant, *provided* that the Holder may decrease such Beneficial Ownership Limitation upon written notice to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

(f) No Violation. The Company shall take all such actions as may be necessary to ensure that all such Warrant Shares are issued without violation by the Company of any applicable law or governmental regulation or of any requirements of any domestic securities exchange upon which shares of Common Stock or other securities constituting Warrant Shares may be listed at the time of such exercise (except for official notice of issuance which shall be immediately delivered by the Company upon each such issuance).

Section 3. Certain Adjustments. In order to prevent dilution of the purchase rights granted under this Warrant Certificate, the Exercise Price and the number of Warrant Shares issuable upon exercise of this Warrant Certificate shall be subject to adjustment from time to time as provided in this Section 3.

(a) *Intentionally Omitted.*

(b) *Intentionally Omitted*.

(c) *Intentionally Omitted*.

(d) Adjustment to Exercise Price and Warrant Shares Upon Dividend, Subdivision or Combination of Common Stock. If the Company shall, at any time or from time to time after the date hereof, (i) pay a dividend or make any other distribution upon the Common Stock or any other capital stock of the Company payable in shares of Common Stock or in Options or Convertible Securities, or (ii) subdivide (by any stock split, recapitalization or otherwise) its outstanding shares of Common Stock into a greater number of shares, the Exercise Price in effect immediately prior to any such dividend, distribution or subdivision shall be proportionately reduced and the number of Warrant Shares issuable upon exercise of this Warrant Certificate shall be proportionately increased. If the Company at any time combines (by combination, reverse stock split or otherwise) its outstanding shares of Common Stock into a smaller number of shares, the Exercise Price in effect immediately prior to such combination shall be proportionately increased and the number of Warrant Shares issuable upon exercise of this Warrant Certificate shall be proportionately decreased. Any adjustment under this Section 3(d) shall become effective at the close of business on the date the dividend, subdivision or combination becomes effective.

(e) Adjustment to Exercise Price and Warrant Shares Upon Reorganization, Reclassification, Consolidation or Merger. Unless the Holder otherwise consents (in its sole discretion), in the event of any (A) capital reorganization of the Company, (B) reclassification of the stock of the Company (other than a change in par value or from par value to no par value or from no par value to par value or as a result of a stock dividend or subdivision, split-up or combination of shares), (C) Fundamental Transaction or (D) other similar transaction (other than any such transaction covered by Section 3(d)), in each case which entitles the holders of Common Stock to receive (either directly or upon subsequent liquidation) stock, securities or assets with respect to or in exchange for Common Stock:

(i) this Warrant Certificate shall, immediately after such transaction, remain outstanding and shall thereafter, in lieu of or in addition to (as the case may be) the number of Warrant Shares then exercisable under this Warrant Certificate, be exercisable for the kind and number of shares of stock or other securities or assets of the Company or of the successor Person resulting from such transaction to which the Holder would have been entitled upon such transaction if the Holder had exercised this Warrant Certificate in full immediately prior to the time of such transaction and acquired the applicable number of Warrant Shares then issuable hereunder as a result of such exercise (without taking into account any limitations or restrictions on the exercisability of this Warrant Certificate); and

(ii) appropriate adjustment (in form and substance satisfactory to the Holder) shall be made with respect to the Holder's rights under this Warrant Certificate to insure that the provisions of this Section 3 shall thereafter be applicable, as nearly as possible, to this Warrant Certificate in relation to any shares of stock, securities or assets thereafter acquirable upon exercise of this Warrant Certificate (including, in the case of any transaction in which the successor or purchasing Person is other than the Company, an immediate adjustment in the Exercise Price to the value per share for the Common Stock reflected by the terms

of such transaction, and a corresponding adjustment immediately shall be made to the number of Warrant Shares acquirable upon exercise of this Warrant Certificate, without regard to any limitations or restrictions on exercise, if the value so reflected is less than the Exercise Price in effect immediately prior to such transaction).

The provisions of this Section 3(e) shall similarly apply to successive reorganizations, reclassifications, Fundamental Transactions or similar transactions.

Notwithstanding anything to the contrary contained herein, with respect to any corporate event or other transaction contemplated by this Section 3(e), the Holder shall have the right to elect, prior to the consummation of such event or transaction, to exercise this Warrant instead of giving effect to Section 3(e).

(f) Other Dividends and Distributions. If the Company shall, at any time or from time to time after the date hereof, make or declare, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or any other distribution payable in cash, securities of the Company (other than a dividend or distribution of shares of Common Stock, Options or Convertible Securities in respect of outstanding shares of Common Stock) or other property, then, and in each such event, the Company shall ensure that provisions are made so that the Holder shall receive upon exercise of this Warrant Certificate, in addition to the number of Warrant Shares receivable thereupon, the kind and amount of cash, securities of the Company or other property which the Holder would have been entitled to receive had this Warrant Certificate been exercised in full into Warrant Shares on the date of such event and had the Holder thereafter, during the period from the date of such event to and including the date of exercise, retained such cash, securities or other property receivable by them as aforesaid during such period, giving application to all adjustments called for during such period under this Section 3 with respect to the rights of the Holder; *provided* that no such provision shall be made if the Holder receives, simultaneously with the distribution to the holders of Common Stock, a dividend or other distribution of such securities, cash or other property in an amount equal to the amount of such securities, cash or other property as the Holder would have received if this Warrant Certificate had been exercised in full into Warrant Shares on the date of such event.

(g) Certain Events. If any event of the type contemplated by the provisions of this Section 3 but not expressly provided for by such provisions (including, without limitation, the granting of stock appreciation rights, phantom stock rights or other rights with equity features in each case, other than with respect to any Excluded Issuance) occurs, then the Board of Directors of the Company shall make an appropriate adjustment in the Exercise Price of this Warrant Certificate so as to protect the rights of the Holder in a manner consistent with the provisions of this Section 3; provided that (i) no such adjustment pursuant to this Section 3(g) shall increase the Exercise Price or decrease the number of Warrant Shares issuable as otherwise determined pursuant to this Section 3 and (ii) for the avoidance of doubt, no adjustment pursuant to this Section 3(g) shall be made in connection with an Excluded Issuance.

(h) Certificate as to Adjustment. As promptly as reasonably practicable

following any adjustment of the Exercise Price, but in any event not later than three business days thereafter, the Company shall furnish to the Holder a certificate of an executive officer setting forth in reasonable detail such adjustment and the facts upon which it is based and certifying the calculation thereof. As promptly as reasonably practicable following the receipt by the Company of a written request by the Holder, but in any event not later than three business days thereafter, the Company shall furnish to the Holder a certificate of an executive officer certifying the Exercise Price then in effect and the number of Warrant Shares or the amount, if any, of other shares of stock, securities or assets then issuable upon exercise of this Warrant Certificate.

(i) Fundamental Transaction. If, at any time while this Warrant is outstanding, the Company effects a Fundamental Transaction, then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one (1) share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the Exercise Price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such Exercise Price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the

occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant and the other Loan Documents referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant and the other Loan Documents with the same effect as if such Successor Entity had been named as the Company herein.

(j) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

(k) Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, or (F) the Company seeks to engage in a Fundamental Transaction, then, in each case, the Company shall cause to be mailed to the Holder at its last address as it shall appear upon the Warrant Register (as defined below) of the Company, at least twenty (20) calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such Fundamental Transaction, reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such Fundamental Transaction, reclassification, consolidation, merger, sale, transfer or share exchange; *provided* that the failure to mail such notice or any defect therein or in the mailing thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice required to be provided hereunder may contain information that constitutes material, non-public information regarding the Company or any of its subsidiaries, the Company shall obtain the Holder's prior consent to receipt of such notice. If the Holder declines to receive any such notice pursuant to the immediately preceding sentence, the Company shall not be deemed to have breached its obligation to deliver such notice hereunder. The Holder shall remain entitled to exercise this Warrant during the 20-day period commencing on the date of such notice through the effective date of the event

triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Intentionally Omitted.

Section 5. Transfer of Warrant.

(a) Transferability. Subject to compliance with any applicable securities laws, this Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within two (2) Trading Days of the date the Holder delivers to the Company a completed Assignment Form in the form attached hereto duly executed by the Holder assigning all or any portion of this Warrant. This Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

(b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 5(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated as of February 10, 2020 and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

(c) Transferee Representations. If, at the time of the surrender of this Warrant in connection with any transfer of this Warrant, the transfer of this Warrant shall not be eligible for resale without volume or manner-of-sale restrictions or current public information requirements pursuant to Rule 144, the Company may require, as a condition of allowing such transfer, that the Holder or transferee of this Warrant, as the case may be, deliver a written statement from the transferee to the Company certifying that the transferee is an “accredited investor” as defined in Rule 501(a) under the Securities Act, making the representations and certifications set forth in Section 5(e) of this Warrant and making such additional representations as the Company may, after consultation with its counsel, require in order to confirm compliance with applicable securities laws.

(d) Warrant Register. The Company shall register this Warrant, upon records

to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

(e) Representation by the Holder. The Holder, by the acceptance hereof, represents and warrants that it is acquiring this Warrant and, upon any exercise hereof, will acquire the Warrant Shares issuable upon such exercise, for its own account and not with a view to or for distributing or reselling such Warrant Shares or any part thereof in violation of the Securities Act or any applicable state securities law, except pursuant to sales registered or exempted under the Securities Act.

Section 6. Miscellaneous.

(a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting the rights of a Holder to receive Warrant Shares on a "cashless exercise," in no event will the Company be required to net cash settle an exercise of this Warrant.

(b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of this Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

(c) Removal of Restrictive Legends. Neither this Warrant nor any certificates evidencing Warrant Shares shall contain any legend restricting the transfer thereof in any of the following circumstances: (A) following any sale of this Warrant or such Warrant Shares issued or delivered to the Holder under or in connection herewith pursuant to Rule 144, (B) if this Warrant or such Warrant Shares are eligible for sale under Rule 144(b)(1), or (C) if such legend is not required under applicable requirements of the Securities Act (including judicial interpretations and pronouncements issued by the staff of the Commission) (collectively, the "Unrestricted Conditions"). In such circumstances, the Company shall seek to cause its counsel to issue a legal opinion to the Transfer Agent if required by such Transfer Agent to effect the issuance of Warrant Shares, without a restrictive legend or removal of the legend hereunder. If the Unrestricted Conditions are met at the time of issuance of this Warrant, the Warrant Shares or such other shares of Common Stock, then this Warrant, Warrant Shares or other Common Stock, as the case may be, shall be issued free of all legends.

(d) Replacement Warrant. The Company agrees that at such time as the

Unrestricted Conditions have been satisfied it shall promptly (but in any event within ten (10) Business Days) following written request from the Holder issue a replacement Warrant or replacement Warrant Shares or replacement shares in respect of such other Common Stock, as the case may be, free of all restrictive legends ("Unlegended Shares").

(e) Authorized Shares; No Other Adjustments. The Company covenants that, during the period this Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock is listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue). The Company represents and warrants that, during the period commencing on the Original Issue Date through the Amendment Date, there were no events, actions, or circumstances that would have resulted in an adjustment under Section 3 of the Warrant (as such Section 3 existed prior to the Amendment Date), other than the cumulative adjustments reflected in the July 25, 2022 Certificate of Adjustment and incorporated herein.

(f) No Impairment. Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue unrestricted, fully paid and nonassessable Warrant Shares upon the exercise of this Warrant, and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant. Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

(g) Rule 144 Compliance. With a view to making available to the Holder the benefits of Rule 144 under the Securities Act and any other rule or regulation of the SEC that may at any time permit a holder to sell securities of the Company to the public without registration or pursuant to a Registration Statement, the Company shall:

(i) make and keep public information available, as those terms are understood and defined in Rule 144 under the Securities Act;

(ii) use reasonable best efforts to file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act; and

(iii) furnish to the Holder, promptly upon request, a written statement by the Company as to its compliance with the reporting requirements of Rule 144 under the Securities Act and of the Securities Act and the Exchange Act, a copy of the most recent annual or quarterly report of the Company, and such other reports and documents so filed or furnished by the Company as such holder may reasonably request in connection with the sale of Warrant Shares without registration.

(h) Governing Law. This Warrant and the rights and obligations of the parties hereunder shall be governed by, and construed in accordance with, the law of the State of New York, without regard to principles of conflicts of laws that would result in the application of the laws of any other jurisdiction.

(i) Submission to Jurisdiction. The Company agrees that any suit, action or proceeding with respect to this Warrant or any judgment entered by any court in respect thereof may be brought initially in the federal or state courts in New York, New York or in the courts of its own corporate domicile and irrevocably submits to the exclusive jurisdiction of each such court for the purpose of any such suit, action, proceeding or judgment. This Section is for the benefit of the Holder only and, as a result, the Holder shall not be prevented from taking proceedings in any other courts with jurisdiction. To the extent allowed by any applicable law, the Holder may take concurrent proceedings in any number of jurisdictions.

(j) Waiver of Venue, Etc. The Company irrevocably waives to the fullest extent permitted by law any objection that it may now or hereafter have to the laying of the venue of any suit, action or proceeding arising out of or relating to this Warrant and hereby further irrevocably waives to the fullest extent permitted by law any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. A final judgment (in respect of which time for all appeals has elapsed) in any such suit, action or proceeding shall be conclusive and may be enforced in any court to the jurisdiction of which the Company is or may be subject, by suit upon judgment.

(k) Waiver of Jury Trial. THE COMPANY AND THE HOLDER HEREBY IRREVOCABLY WAIVE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS WARRANT

OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.

(l) No Waiver. No failure on the part of the Holder to exercise and no delay in exercising, and no course of dealing with respect to, any right, power or privilege under this Warrant shall operate as a waiver thereof, nor shall any single or partial exercise of any right, power or privilege under this Warrant preclude any other or further exercise thereof or the exercise of any other right, power or privilege. The remedies provided herein are cumulative and not exclusive of any remedies provided by law.

(m) Expenses. If the Company fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any actual, reasonable and documented attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

(n) Notices. All notices, requests, instructions, directions and other communications provided for herein (including any modifications of, or waivers, requests or consents under, this Warrant) shall be given or made in writing (including by telecopy or email) delivered, if to the Company or the Holder, to its address specified on the signature pages hereto, or at such other address as shall be designated by such party in a written notice to the other party. Except as otherwise provided in this Warrant, all such communications shall be deemed to have been duly given upon receipt of a legible copy thereof, in each case given or addressed as aforesaid. All such communications provided for herein by telecopy shall be confirmed in writing promptly after the delivery of such communication (it being understood that non-receipt of written confirmation of such communication shall not invalidate such communication).

(o) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

(p) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to seek specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

(q) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall be binding upon and inure to the benefit of the successors and permitted assigns of the Company and the successors and permitted assigns of the Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the

Holder or any holder of Warrant Shares.

(r) Amendments, Etc. Except as otherwise expressly provided in this Warrant, any provision of this Warrant may be modified or supplemented only by an instrument in writing signed by the Company and the Holder.

(s) Severability. If any provision hereof is found by a court to be invalid or unenforceable, to the fullest extent permitted by any applicable Law the parties agree that such invalidity or unenforceability shall not impair the validity or enforceability of any other provision hereof.

(t) Captions. The captions and section headings appearing herein are included solely for convenience of reference and are not intended to affect the interpretation of any provision of this Warrant.

(u) Counterparts. This Warrant may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument and any of the parties hereto may execute this Warrant by signing any such counterpart.

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

AGILE THERAPEUTICS, INC.

By: /s/ Al Altomari
Name: Al Altomari
Title: Chairman and CEO

Address for Notices:

Agile Therapeutics, Inc.
500 College Road East
Suite 310
Princeton, New Jersey 08540
Attention: Chief Executive Officer

With a copy to (which shall not constitute notice):

Morgan, Lewis & Bockius LLP
170 Market Street
Philadelphia, PA 19103
Attention: Andrew Budreika

Accepted and Agreed,

Perceptive Credit Holdings III, LP

By: Perceptive Credit Opportunities GP, LLC, its general partner

By: /s/ Sandeep Dixit
Name: Sandeep Dixit
Title: Chief Credit Officer

By: /s/ Sam Chawla
Name: Sam Chawla
Title: Portfolio Manager

Address for Notices:

Perceptive Credit Holdings III, LP
c/o Perceptive Advisors LLC
51 Astor Place, 10th Floor
New York, NY 10003
Attn: Sandeep Dixit
Email: Sandeep@perceptivelife.com

NOTICE OF EXERCISE

TO: AGILE THERAPEUTICS, INC.

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

[ ] in lawful money of the United States; or

[ ] the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

Check applicable box and fill in information:

[ ] The Warrant Shares shall be delivered to the following DWAC Account Number:

_____

_____

_____

[ ] The Warrant Shares shall be delivered by physical delivery of a certificate to:

_____

_____

_____

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____
Signature of Authorized Signatory of Investing Entity: _____
Name of Authorized Signatory: _____
Title of Authorized Signatory: _____
Date: _____

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name of Person to Whom Warrant is being Transferred: _____

Address of Person to Whom Warrant is being Transferred: _____

_____

_____

Number of Shares Subject to Warrant being Transferred: _____

Dated: _____ __, _____

Holder's Name: _____

Holder's Signature:

_____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Holder's Address: _____

_____

NEITHER THIS SECURITY NOR THE SECURITIES FOR WHICH THIS SECURITY IS EXERCISABLE HAVE BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS AS MAY BE REQUIRED TO BE EVIDENCED BY A LEGAL OPINION OF COUNSEL TO THE TRANSFEROR TO SUCH EFFECT, THE SUBSTANCE OF WHICH SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY. THIS SECURITY AND THE SECURITIES ISSUABLE UPON EXERCISE OF THIS SECURITY MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT WITH A REGISTERED BROKER-DEALER OR OTHER LOAN WITH A FINANCIAL INSTITUTION THAT IS AN "ACCREDITED INVESTOR" AS DEFINED IN RULE 501(a) UNDER THE SECURITIES ACT.

AMENDED AND RESTATED COMMON STOCK PURCHASE WARRANT

(SECOND WARRANT)

AGILE THERAPEUTICS, INC.

Common Stock Warrant Shares: 17,500 Original Issue Date: February 10, 2020

Amendment Date: March 21, 2023

THIS AMENDED AND RESTATED COMMON STOCK PURCHASE WARRANT (this "Warrant") is entered into as of the Amendment Date set forth above between Agile Therapeutics, Inc., a Delaware corporation (the "Company") and Perceptive Credit Holdings III, LP (or its assigns, the "Holder").

WHEREAS, this Warrant was originally issued on the Original Issue Date set forth above (the "Original Warrant") in connection with that certain Credit Agreement and Guaranty dated as of February 10, 2020 (the "Credit Agreement") by and among the Company, as borrower, the subsidiaries of the Company from time to time party thereto as guarantors, the lenders from time to time party thereto, and Holder, as administrative agent for the lenders. The Original Warrant was exercisable for 700,000 Warrant Shares at an exercise price of $4.67 per share.

WHEREAS, on July 25, 2022, the Company issued to the Holder a Certificate of Adjustment (the "Certificate of Adjustment") setting forth an adjustment to the number of Warrant Shares and the Exercise Price applicable to the Warrant reflecting that the Warrant was then exercisable for 17,500 Warrant Shares at an exercise price of $14.90 per share.

WHEREAS, in connection with that certain Sixth Amendment to Credit Agreement and Guaranty dated as of March 21, 2023, the Company and the Holder have agreed to amend and restate the Original Warrant in its entirety as set forth herein to, among other things, reflect the

adjustments previously acknowledged by the Certificate of Adjustment and to further adjust the Exercise Price as set forth herein.

NOW, THEREFORE, for good and valuable consideration, the sufficiency of which is hereby acknowledged, the Company and the Holder agree that the Original Warrant is hereby amended and restated in its entirety as set forth below.

This Warrant certifies that, for value received, the Holder is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after February 10, 2020, and on or prior to the close of business on February 10, 2027 (the "Expiration Date") but not thereafter, to subscribe for and purchase from the Company up to seventeen thousand five hundred (17,500) shares of Common Stock (as subject to adjustment hereunder, the "Warrant Shares"). The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

For the avoidance of doubt, this Warrant shall be treated for all purposes as having been issued on, and having been outstanding since, the Original Issue Date

Section 1. Definitions. For the purposes hereof, in addition to the terms defined elsewhere in this Warrant, (a) capitalized terms used and not otherwise defined herein shall have the meanings set forth in the Credit Agreement, and (b) the following terms shall have the following meanings:

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"Closing Bid Price" means for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the last reported closing bid price for Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg, L.P., (b) if the Common Stock is not then listed or quoted for trading on a Trading Market and if prices for the Common Stock are then reported in the "Pink Sheets" published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (c) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holder and reasonably acceptable to the Company, the reasonable, actual and documented fees and reasonable, actual and documented out-of-pocket expenses of which shall be paid by the Company.

"Commission" means the United States Securities and Exchange Commission.

"Common Stock" means the common stock of the Company, par value $0.0001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Deemed Outstanding" means, at any given time, the sum of (i) the number of shares of Common Stock actually outstanding at such time, plus (ii) the number of shares of

Common Stock issuable upon exercise of Options actually outstanding at such time, plus (iii) the number of shares of Common Stock issuable upon conversion or exchange of Convertible Securities actually outstanding at such time (treating as actually outstanding any Convertible Securities issuable upon exercise of Options actually outstanding at such time), in each case, regardless of whether the Options or Convertible Securities are actually exercisable at such time; *provided* that Common Stock Deemed Outstanding at any given time shall not include shares owned or held by or for the account of the Company or any of its wholly owned subsidiaries.

"Common Stock Equivalents" means any securities of the Company or its wholly owned subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Convertible Securities" means any debt, equity or other securities that are, directly or indirectly, convertible into or exchangeable for Common Stock.

"Excluded Issuance" means the issuance of (a) shares of Common Stock (or options with respect thereto) issued or issuable to employees or directors of, or consultants to, the Company or any of its subsidiaries pursuant to a plan, agreement or arrangement approved by the Board of Directors of the Company, (b) warrants issued pursuant to the Credit Agreement and/or other securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date of this Warrant, *provided* that such securities have not been amended since the date of this Warrant to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities (for purposes of clarity, any decrease in the exercise price, exchange price or conversion price of such securities shall not be deemed an amendment thereto, if such decrease is as a result of any price-based anti-dilution provision contained in such securities prior to the date hereof), (c) other securities issued to financial institutions, institutional investors or lessors in connection with credit arrangements, equipment financings or similar transactions approved by a majority of disinterested directors of the Company, (d) securities issued pursuant to acquisitions or strategic transactions approved by a majority of disinterested directors of the Company, *provided* that any such issuance shall only be to a Person which is, itself or through its subsidiaries, an operating company in a business synergistic with the business of the Company and in which the Company receives benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities, *provided further* that the exclusion in this clause (d) shall be limited to 12,500,000 shares of Common Stock (as such number of shares is equitably adjusted for subsequent stock splits, stock combinations, stock dividends and recapitalizations occurring after the date hereof), and (e) securities issuable under any at-the-market offering programs the Company may establish in accordance with Rule 415(a)(4) under the Securities Act. In addition, for the avoidance of doubt, "Excluded Issuances" also include the filing of any registration statement of the Company with the Commission registering securities of the Company, or the filing of any amendments or supplements thereto, provided that the determination of whether sales under any such registration statement is an Excluded Issuance will be determined based on the preceding clauses (a) to (e) hereof.

"Fundamental Transaction" means (a) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (b) the Company, directly or indirectly, effects any sale, lease, exclusive license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (c) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of fifty percent (50%) or more of the outstanding Common Stock, (d) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock (but, for the avoidance of doubt, excluding any transaction, event or occurrence covered by Section 3(a)) or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, (e) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person whereby such other Person acquires more than fifty percent (50%) of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or Affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination).

"Marketable Securities" means securities that (a) are tradable on an established national U.S. or non-U.S. stock exchange or reported through NASDAQ or a comparable established non-U.S. over-the-counter trading system and (b) are not subject to restrictions on transfer under the Securities Act or contractual restrictions on transfer.

"Options" means any warrants or other rights or options to subscribe for or purchase Common Stock or Convertible Securities.

"Person" means any individual, sole proprietorship, partnership, limited liability company, corporation, joint venture, trust, incorporated organization or government or department or agency thereof.

"Prospectus" means the prospectus or prospectuses included in any Registration Statement, as amended or supplemented by any prospectus supplement with respect to the terms of the offering of any portion of the Registrable Securities covered by such Registration Statement and by all other amendments and supplements to the prospectus, including post-effective amendments and all material incorporated by reference in such prospectus or prospectuses.

"Registrable Securities" means (x) any shares of Common Stock held by Holder or issuable upon conversion, exercise or exchange of any securities owned by Holder at any time (including Warrant Shares exercisable upon exercise of this Warrant), and (y) any shares of Common Stock issued or issuable with respect to any shares described in subsection (x) above by way of a stock dividend or stock split or in connection with a combination of shares, recapitalization, merger, consolidation or other reorganization (it being understood that for purposes of this Warrant, Holder shall be deemed to be a holder of Registrable Securities whenever Holder has the right to then acquire or obtain from the Company any Registrable Securities, whether or not such acquisition

has actually been effected). As to any particular Registrable Securities, such securities shall cease to be Registrable Securities when (i) a Registration Statement covering such securities has been declared effective by the SEC and such securities have been disposed of pursuant to such effective Registration Statement, (ii) such securities are sold under circumstances in which all of the applicable conditions of Rule 144 (or any similar provisions then in force) under the Securities Act are met, (iii) such securities are otherwise transferred and such securities may be resold without subsequent registration under the Securities Act, or (iv) such securities shall have ceased to be outstanding.

"Registration Statement" means any registration statement of the Company which covers any of the Registrable Securities pursuant to the provisions of this Warrant, including the Prospectus, amendments and supplements to such Registration Statement, including post-effective amendments, all exhibits and all materials incorporated by reference in such Registration Statement.

"Rule 144" means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same effect as such Rule.

"Trading Day" means a day on which the principal Trading Market is open for trading.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE MKT, the Nasdaq Global Market, the Nasdaq Capital Market, the New York Stock Exchange, the OTCQB, the OTCQX U.S. or the Nasdaq Global Select Market (or any successors to any of the foregoing).

"Transfer Agent" means Broadridge Corporate Issuer Solutions, the current transfer agent of the Company, with a mailing address of P.O. Box 1342, Brentwood, NY 11717, and any successor transfer agent of the Company."VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (or an equivalent quotation service acceptable to the Holder and the Company) (based on a Trading Day from 9:30 a.m. (local time in New York City, New York) to 4:00 p.m. (local time in New York City, New York)) (b) if the Common Stock is not then listed or quoted for trading on a Trading Market and if prices for the Common Stock are then reported in the "Pink Sheets" published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (c) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holder and reasonably acceptable to the Company, the reasonable, actual and documented fees and reasonable, actual and documented out-of-pocket expenses of which shall be paid by the Company.

Section 2. Exercise.

(a) Exercise of Warrant. Exercise of the purchase rights represented by this

Warrant may be made, in whole or in part, at any time or times before the Expiration Date by delivery to the Company (or such other office or agency of the Company as it may designate by notice in writing to the registered Holder at the address of the Holder appearing on the books of the Company) of a duly executed facsimile or electronic copy of the Notice of Exercise in the form annexed hereto (the "Notice of Exercise") and within two (2) Trading Days of the date said Notice of Exercise is delivered to the Company, the Company shall have received payment of the aggregate Exercise Price of the Warrant Shares thereby purchased by wire transfer or cashier's check drawn on a United States bank or pursuant to the cashless exercise procedure specified in Section 2(c) below. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise form be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and this Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within two (2) Trading Days of the date the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

In the event that immediately prior to the close of business on the Expiration Date, the Closing Bid Price of one share of Common Stock is greater than the then applicable Exercise Price, this Warrant shall be deemed to be automatically exercised as a "cashless exercise" pursuant to Section 2(c) below, and the Company shall deliver the applicable number of shares of Common Stock to the Holder pursuant to the provisions of Section 2(d) below.

(b) Exercise Price. The exercise price per share of the Common Stock issuable under this Warrant (the "Exercise Price") shall be the lower of (i) $0.21 and (ii) the lowest price that one share of Common Stock is issued by the Company in the period between the Amendment Date and June 30, 2023 (the "Price Adjustment Period"), as such Exercise Price may be subject to further adjustment hereunder. In connection with the foregoing, promptly after June 30, 2023, the Company shall provide a certificate to the Holder signed by an officer of the Company specifying, and certifying, the lowest issue price for one share of Common Stock issued by the Company during the Price Adjustment Period and, if applicable, the adjusted Exercise Price of this Warrant.

(c) Cashless Exercise. This Warrant may be exercised, in whole or in part, at any time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A) (a "Cashless Exercise"), where:

(A) = the VWAP on the Trading Day immediately preceding the date on which Holder elects to exercise this Warrant by means of a "cashless exercise," as set forth in the applicable Notice of Exercise;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise or, if only a portion of this Warrant is being exercised, the portion of this Warrant being cancelled.

(d) Mechanics of Exercise.

(i) Delivery of Warrant Shares Upon Exercise. Warrant Shares purchased hereunder shall be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's prime broker with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and the Warrant Shares are eligible for resale by the Holder without volume or manner-of-sale limitations pursuant to Rule 144 or an available Registration Statement, and otherwise by physical delivery to the address specified by the Holder in the Notice of Exercise by the date that is two (2) Trading Days after the delivery to the Company, by 11 a.m. (local time in New York City, New York) on a Trading Day, of the Notice of Exercise and payment of the aggregate Exercise Price as set forth above (including by Cashless Exercise) (such date, the "Warrant Share Delivery Date"). The Warrant Shares shall be deemed to have been issued, and the Holder or any other person so designated to be named therein shall be deemed to have become a holder of record of such Warrant Shares for all purposes, as of the date this Warrant has been exercised, with payment to the Company of the Exercise Price (or by Cashless Exercise) and all taxes required to be paid by the Holder, if any, pursuant to Section 2(d)(v) prior to the issuance of such Warrant Shares, having been paid. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, other than a failure to deliver caused by the Holder's failure to pay the applicable Exercise Price for such Warrant Shares or to timely take such actions as are necessary to post such Warrant Shares in DWAC, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each $1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), an amount equal to the Exercise Price per Trading Day for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise.

(ii) Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase

the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

(iii) Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the third (3rd) Trading Day following the Warrant Share Delivery Date, other than a failure to deliver caused by the Holder's failure to pay the applicable Exercise Price for such Warrant Shares or to timely take such actions as are necessary to post such Warrant Shares in DWAC, then the Holder will have the right to rescind such exercise.

(iv) Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to an exercise on or before the second (2nd) Trading Day following the Warrant Share Delivery Date and such failure is not caused by any act or omission of the Holder, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased (*provided*, Holder exercises reasonable efforts to minimize the amount of such purchase price) exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue by (2) the actual sale price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted exercise to acquire Warrant Shares with an aggregate sale price giving rise to such purchase obligation of $10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder $1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity, including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver Warrant Shares upon exercise of the Warrant as required pursuant to the terms hereof.

(v) No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As

to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall round up to the next whole share.

(vi) Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; *provided*, *however*, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by a completed Assignment Form in the form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

(vii) Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

(e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to this Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates, and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates) and of which portion of this Warrant is exercisable shall be in the sole discretion

of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company, or (C) a more recent written notice from the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written request of a Holder, the Company shall within three (3) Trading Days confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 19.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the applicable issuance of shares of Common Stock issuable upon exercise of this Warrant, *provided* that the Holder may decrease such Beneficial Ownership Limitation upon written notice to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

(f) No Violation. The Company shall take all such actions as may be necessary to ensure that all such Warrant Shares are issued without violation by the Company of any applicable law or governmental regulation or of any requirements of any domestic securities exchange upon which shares of Common Stock or other securities constituting Warrant Shares may be listed at the time of such exercise (except for official notice of issuance which shall be immediately delivered by the Company upon each such issuance).

Section 3. Certain Adjustments. In order to prevent dilution of the purchase rights granted under this Warrant Certificate, the Exercise Price and the number of Warrant Shares issuable upon exercise of this Warrant Certificate shall be subject to adjustment from time to time as provided in this Section 3.

(a) *Intentionally Omitted.*

(b) *Intentionally Omitted*.

(c) *Intentionally Omitted.*

(d) Adjustment to Exercise Price and Warrant Shares Upon Dividend, Subdivision or Combination of Common Stock. If the Company shall, at any time or from time to time after the date hereof, (i) pay a dividend or make any other distribution upon the Common Stock or any other capital stock of the Company payable in shares of Common Stock or in Options or Convertible Securities, or (ii) subdivide (by any stock split, recapitalization or otherwise) its outstanding shares of Common Stock into a greater number of shares, the Exercise Price in effect immediately prior to any such dividend, distribution or subdivision shall be proportionately reduced and the number of Warrant Shares issuable upon exercise of this Warrant Certificate shall be proportionately increased. If the Company at any time combines (by combination, reverse stock split or otherwise) its outstanding shares of Common Stock into a smaller number of shares, the Exercise Price in effect immediately prior to such combination shall be proportionately increased and the number of Warrant Shares issuable upon exercise of this Warrant Certificate shall be proportionately decreased. Any adjustment under this Section 3(d) shall become effective at the close of business on the date the dividend, subdivision or combination becomes effective.

(e) Adjustment to Exercise Price and Warrant Shares Upon Reorganization, Reclassification, Consolidation or Merger. Unless the Holder otherwise consents (in its sole discretion), in the event of any (A) capital reorganization of the Company, (B) reclassification of the stock of the Company (other than a change in par value or from par value to no par value or from no par value to par value or as a result of a stock dividend or subdivision, split-up or combination of shares), (C) Fundamental Transaction or (D) other similar transaction (other than any such transaction covered by Section 3(d)), in each case which entitles the holders of Common Stock to receive (either directly or upon subsequent liquidation) stock, securities or assets with respect to or in exchange for Common Stock:

(i) this Warrant Certificate shall, immediately after such transaction, remain outstanding and shall thereafter, in lieu of or in addition to (as the case may be) the number of Warrant Shares then exercisable under this Warrant Certificate, be exercisable for the kind and number of shares of stock or other securities or assets of the Company or of the successor Person resulting from such transaction to which the Holder would have been entitled upon such transaction if the Holder had exercised this Warrant Certificate in full immediately prior to the time of such transaction and acquired the applicable number of Warrant Shares then issuable hereunder as a result of such exercise (without taking into account any limitations or restrictions on the exercisability of this Warrant Certificate); and

(ii) appropriate adjustment (in form and substance satisfactory to the Holder) shall be made with respect to the Holder's rights under this Warrant Certificate to insure that the provisions of this Section 3 shall thereafter be applicable, as nearly as possible, to this Warrant Certificate in relation to any shares of stock, securities or assets thereafter acquirable upon exercise of this Warrant Certificate (including, in the case of any transaction in which the successor or purchasing Person is other than the Company, an immediate adjustment in the Exercise Price to the value per share for the Common Stock reflected by the terms

of such transaction, and a corresponding adjustment immediately shall be made to the number of Warrant Shares acquirable upon exercise of this Warrant Certificate, without regard to any limitations or restrictions on exercise, if the value so reflected is less than the Exercise Price in effect immediately prior to such transaction).

The provisions of this Section 3(e) shall similarly apply to successive reorganizations, reclassifications, Fundamental Transactions or similar transactions.

Notwithstanding anything to the contrary contained herein, with respect to any corporate event or other transaction contemplated by this Section 3(e), the Holder shall have the right to elect, prior to the consummation of such event or transaction, to exercise this Warrant instead of giving effect to Section 3(e).

(f) Other Dividends and Distributions. If the Company shall, at any time or from time to time after the date hereof, make or declare, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or any other distribution payable in cash, securities of the Company (other than a dividend or distribution of shares of Common Stock, Options or Convertible Securities in respect of outstanding shares of Common Stock) or other property, then, and in each such event, the Company shall ensure that provisions are made so that the Holder shall receive upon exercise of this Warrant Certificate, in addition to the number of Warrant Shares receivable thereupon, the kind and amount of cash, securities of the Company or other property which the Holder would have been entitled to receive had this Warrant Certificate been exercised in full into Warrant Shares on the date of such event and had the Holder thereafter, during the period from the date of such event to and including the date of exercise, retained such cash, securities or other property receivable by them as aforesaid during such period, giving application to all adjustments called for during such period under this Section 3 with respect to the rights of the Holder; *provided* that no such provision shall be made if the Holder receives, simultaneously with the distribution to the holders of Common Stock, a dividend or other distribution of such securities, cash or other property in an amount equal to the amount of such securities, cash or other property as the Holder would have received if this Warrant Certificate had been exercised in full into Warrant Shares on the date of such event.

(g) Certain Events. If any event of the type contemplated by the provisions of this Section 3 but not expressly provided for by such provisions (including, without limitation, the granting of stock appreciation rights, phantom stock rights or other rights with equity features in each case, other than with respect to any Excluded Issuance) occurs, then the Board of Directors of the Company shall make an appropriate adjustment in the Exercise Price of this Warrant Certificate so as to protect the rights of the Holder in a manner consistent with the provisions of this Section 3; *provided* that (i) no such adjustment pursuant to this Section 3(g) shall increase the Exercise Price or decrease the number of Warrant Shares issuable as otherwise determined pursuant to this Section 3 and (ii) for the avoidance of doubt, no adjustment pursuant to this Section 3(g) shall be made in connection with an Excluded Issuance.

(h) Certificate as to Adjustment. As promptly as reasonably practicable

following any adjustment of the Exercise Price, but in any event not later than three business days thereafter, the Company shall furnish to the Holder a certificate of an executive officer setting forth in reasonable detail such adjustment and the facts upon which it is based and certifying the calculation thereof. As promptly as reasonably practicable following the receipt by the Company of a written request by the Holder, but in any event not later than three business days thereafter, the Company shall furnish to the Holder a certificate of an executive officer certifying the Exercise Price then in effect and the number of Warrant Shares or the amount, if any, of other shares of stock, securities or assets then issuable upon exercise of this Warrant Certificate.

(i) Fundamental Transaction. If, at any time while this Warrant is outstanding, the Company effects a Fundamental Transaction, then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one (1) share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the Exercise Price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such Exercise Price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the

occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant and the other Loan Documents referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant and the other Loan Documents with the same effect as if such Successor Entity had been named as the Company herein.

(j) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

(k) Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, or (F) the Company seeks to engage in a Fundamental Transaction, then, in each case, the Company shall cause to be mailed to the Holder at its last address as it shall appear upon the Warrant Register (as defined below) of the Company, at least twenty (20) calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such Fundamental Transaction, reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such Fundamental Transaction, reclassification, consolidation, merger, sale, transfer or share exchange; *provided* that the failure to mail such notice or any defect therein or in the mailing thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice required to be provided hereunder may contain information that constitutes material, non-public information regarding the Company or any of its subsidiaries, the Company shall obtain the Holder's prior consent to receipt of such notice. If the Holder declines to receive any such notice pursuant to the immediately preceding sentence, the Company shall not be deemed to have breached its obligation to deliver such notice hereunder. The Holder shall remain entitled to exercise this Warrant during the 20-day period commencing on the date of such notice through the effective date of the event

triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Intentionally Omitted.

Section 5. Transfer of Warrant.

(a) Transferability. Subject to compliance with any applicable securities laws, this Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within two (2) Trading Days of the date the Holder delivers to the Company a completed Assignment Form in the form attached hereto duly executed by the Holder assigning all or any portion of this Warrant. This Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

(b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 5(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated as of February 10, 2020 and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

(c) Transferee Representations. If, at the time of the surrender of this Warrant in connection with any transfer of this Warrant, the transfer of this Warrant shall not be eligible for resale without volume or manner-of-sale restrictions or current public information requirements pursuant to Rule 144, the Company may require, as a condition of allowing such transfer, that the Holder or transferee of this Warrant, as the case may be, deliver a written statement from the transferee to the Company certifying that the transferee is an "accredited investor" as defined in Rule 501(a) under the Securities Act, making the representations and certifications set forth in Section 5(e) of this Warrant and making such additional representations as the Company may, after consultation with its counsel, require in order to confirm compliance with applicable securities laws.

(d) Warrant Register. The Company shall register this Warrant, upon records

to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

(e) Representation by the Holder. The Holder, by the acceptance hereof, represents and warrants that it is acquiring this Warrant and, upon any exercise hereof, will acquire the Warrant Shares issuable upon such exercise, for its own account and not with a view to or for distributing or reselling such Warrant Shares or any part thereof in violation of the Securities Act or any applicable state securities law, except pursuant to sales registered or exempted under the Securities Act.

Section 6. Miscellaneous.

(a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting the rights of a Holder to receive Warrant Shares on a "cashless exercise," in no event will the Company be required to net cash settle an exercise of this Warrant.

(b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of this Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

(c) Removal of Restrictive Legends. Neither this Warrant nor any certificates evidencing Warrant Shares shall contain any legend restricting the transfer thereof in any of the following circumstances: (A) following any sale of this Warrant or such Warrant Shares issued or delivered to the Holder under or in connection herewith pursuant to Rule 144, (B) if this Warrant or such Warrant Shares are eligible for sale under Rule 144(b)(1), or (C) if such legend is not required under applicable requirements of the Securities Act (including judicial interpretations and pronouncements issued by the staff of the Commission) (collectively, the "Unrestricted Conditions"). In such circumstances, the Company shall seek to cause its counsel to issue a legal opinion to the Transfer Agent if required by such Transfer Agent to effect the issuance of Warrant Shares, without a restrictive legend or removal of the legend hereunder. If the Unrestricted Conditions are met at the time of issuance of this Warrant, the Warrant Shares or such other shares of Common Stock, then this Warrant, Warrant Shares or other Common Stock, as the case may be, shall be issued free of all legends.

(d) Replacement Warrant. The Company agrees that at such time as the

Unrestricted Conditions have been satisfied it shall promptly (but in any event within ten (10) Business Days) following written request from the Holder issue a replacement Warrant or replacement Warrant Shares or replacement shares in respect of such other Common Stock, as the case may be, free of all restrictive legends ("Unlegended Shares").

(e) Authorized Shares; No Other Adjustments. The Company covenants that, during the period this Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock is listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue). The Company represents and warrants that, during the period commencing on the Original Issue Date through the Amendment Date, there were no events, actions, or circumstances that would have resulted in an adjustment under Section 3 of the Warrant (as such Section 3 existed prior to the Amendment Date), other than the cumulative adjustments reflected in the July 25, 2022 Certificate of Adjustment and incorporated herein.

(f) No Impairment. Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue unrestricted, fully paid and nonassessable Warrant Shares upon the exercise of this Warrant, and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant. Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

(g) Rule 144 Compliance. With a view to making available to the Holder the benefits of Rule 144 under the Securities Act and any other rule or regulation of the SEC that may at any time permit a holder to sell securities of the Company to the public without registration or pursuant to a Registration Statement, the Company shall:

(i) make and keep public information available, as those terms are understood and defined in Rule 144 under the Securities Act;

(ii) use reasonable best efforts to file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act; and

(iii) furnish to the Holder, promptly upon request, a written statement by the Company as to its compliance with the reporting requirements of Rule 144 under the Securities Act and of the Securities Act and the Exchange Act, a copy of the most recent annual or quarterly report of the Company, and such other reports and documents so filed or furnished by the Company as such holder may reasonably request in connection with the sale of Warrant Shares without registration.

(h) Governing Law. This Warrant and the rights and obligations of the parties hereunder shall be governed by, and construed in accordance with, the law of the State of New York, without regard to principles of conflicts of laws that would result in the application of the laws of any other jurisdiction.

(i) Submission to Jurisdiction. The Company agrees that any suit, action or proceeding with respect to this Warrant or any judgment entered by any court in respect thereof may be brought initially in the federal or state courts in New York, New York or in the courts of its own corporate domicile and irrevocably submits to the exclusive jurisdiction of each such court for the purpose of any such suit, action, proceeding or judgment. This Section is for the benefit of the Holder only and, as a result, the Holder shall not be prevented from taking proceedings in any other courts with jurisdiction. To the extent allowed by any applicable law, the Holder may take concurrent proceedings in any number of jurisdictions.

(j) Waiver of Venue, Etc. The Company irrevocably waives to the fullest extent permitted by law any objection that it may now or hereafter have to the laying of the venue of any suit, action or proceeding arising out of or relating to this Warrant and hereby further irrevocably waives to the fullest extent permitted by law any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. A final judgment (in respect of which time for all appeals has elapsed) in any such suit, action or proceeding shall be conclusive and may be enforced in any court to the jurisdiction of which the Company is or may be subject, by suit upon judgment.

(k) Waiver of Jury Trial. THE COMPANY AND THE HOLDER HEREBY IRREVOCABLY WAIVE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS WARRANT

OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.

(l) No Waiver. No failure on the part of the Holder to exercise and no delay in exercising, and no course of dealing with respect to, any right, power or privilege under this Warrant shall operate as a waiver thereof, nor shall any single or partial exercise of any right, power or privilege under this Warrant preclude any other or further exercise thereof or the exercise of any other right, power or privilege. The remedies provided herein are cumulative and not exclusive of any remedies provided by law.

(m) Expenses. If the Company fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any actual, reasonable and documented attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

(n) Notices. All notices, requests, instructions, directions and other communications provided for herein (including any modifications of, or waivers, requests or consents under, this Warrant) shall be given or made in writing (including by telecopy or email) delivered, if to the Company or the Holder, to its address specified on the signature pages hereto, or at such other address as shall be designated by such party in a written notice to the other party. Except as otherwise provided in this Warrant, all such communications shall be deemed to have been duly given upon receipt of a legible copy thereof, in each case given or addressed as aforesaid. All such communications provided for herein by telecopy shall be confirmed in writing promptly after the delivery of such communication (it being understood that non-receipt of written confirmation of such communication shall not invalidate such communication).

(o) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

(p) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to seek specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

(q) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall be binding upon and inure to the benefit of the successors and permitted assigns of the Company and the successors and permitted assigns of the Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the

Holder or any holder of Warrant Shares.

(r) Amendments, Etc. Except as otherwise expressly provided in this Warrant, any provision of this Warrant may be modified or supplemented only by an instrument in writing signed by the Company and the Holder.

(s) Severability. If any provision hereof is found by a court to be invalid or unenforceable, to the fullest extent permitted by any applicable Law the parties agree that such invalidity or unenforceability shall not impair the validity or enforceability of any other provision hereof.

(t) Captions. The captions and section headings appearing herein are included solely for convenience of reference and are not intended to affect the interpretation of any provision of this Warrant.

(u) Counterparts. This Warrant may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument and any of the parties hereto may execute this Warrant by signing any such counterpart.

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

AGILE THERAPEUTICS, INC.

By: /s/ Al Altomari
Name: Al Altomari
Title: Chairman and CEO

Address for Notices:

Agile Therapeutics, Inc.
500 College Road East
Suite 310
Princeton, New Jersey 08540
Attention: Chief Executive Officer

With a copy to (which shall not constitute notice):

Morgan, Lewis & Bockius LLP
170 Market Street
Philadelphia, PA 19103
Attention: Andrew Budreika

Accepted and Agreed,

Perceptive Credit Holdings III, LP
By: Perceptive Credit Opportunities GP, LLC, its general partner

By: /s/ Sandeep Dixit
Name: Sandeep Dixit
Title: Chief Credit Officer

By: /s/ Sam Chawla
Name: Sam Chawla
Title: Portfolio Manager

Address for Notices:

Perceptive Credit Holdings III, LP
c/o Perceptive Advisors LLC
51 Astor Place, 10th Floor
New York, NY 10003
Attn: Sandeep Dixit
Email: Sandeep@perceptivelife.com

NOTICE OF EXERCISE

TO: AGILE THERAPEUTICS, INC.

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

[ ] in lawful money of the United States; or

[ ] the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

Check applicable box and fill in information:

[ ] The Warrant Shares shall be delivered to the following DWAC Account Number:

_____

_____

_____

[ ] The Warrant Shares shall be delivered by physical delivery of a certificate to:

_____

_____

_____

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____
Signature of Authorized Signatory of Investing Entity: _____
Name of Authorized Signatory: _____
Title of Authorized Signatory: _____
Date: _____

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name of Person to Whom Warrant is being Transferred: _____

Address of Person to Whom Warrant is being Transferred: _____

_____

_____

Number of Shares Subject to Warrant being Transferred: _____

Dated: _____ __, _____

Holder's Name: _____

Holder's Signature: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Holder's Address:

_____

NEITHER THIS SECURITY NOR THE SECURITIES FOR WHICH THIS SECURITY IS EXERCISABLE HAVE BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS AS MAY BE REQUIRED TO BE EVIDENCED BY A LEGAL OPINION OF COUNSEL TO THE TRANSFEROR TO SUCH EFFECT, THE SUBSTANCE OF WHICH SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY. THIS SECURITY AND THE SECURITIES ISSUABLE UPON EXERCISE OF THIS SECURITY MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT WITH A REGISTERED BROKER-DEALER OR OTHER LOAN WITH A FINANCIAL INSTITUTION THAT IS AN "ACCREDITED INVESTOR" AS DEFINED IN RULE 501(a) UNDER THE SECURITIES ACT.

AMENDED AND RESTATED COMMON STOCK PURCHASE WARRANT

(THIRD WARRANT)

AGILE THERAPEUTICS, INC.

Common Stock Warrant Shares: 11,250 Original Issue Date: February 26, 2021

Amendment Date: March 21, 2023

THIS AMENDED AND RESTATED COMMON STOCK PURCHASE WARRANT (this "Warrant") is entered into as of the Amendment Date set forth above between Agile Therapeutics, Inc., a Delaware corporation (the "Company") and Perceptive Credit Holdings III, LP (or its assigns, the "Holder").

WHEREAS, this Warrant was originally issued on the Original Issue Date set forth above (the "Original Warrant") in connection with that certain Credit Agreement and Guaranty dated as of February 10, 2020 (the "Credit Agreement") by and among the Company, as borrower, the subsidiaries of the Company from time to time party thereto as guarantors, the lenders from time to time party thereto, and Holder, as administrative agent for the lenders, as amended by the First Amendment to Credit Agreement and Guaranty dated as of February 26, 2021. The Original Warrant was exercisable for 450,000 Warrant Shares at an exercise price of $2.87 per share.

WHEREAS, on July 25, 2022, the Company issued to the Holder a Certificate of Adjustment (the "Certificate of Adjustment") setting forth an adjustment to the number of Warrant Shares and the Exercise Price applicable to the Warrant reflecting that the Warrant was then exercisable for 11,250 Warrant Shares at an exercise price of $10.03 per share.

WHEREAS, in connection with that certain Sixth Amendment to Credit Agreement and Guaranty dated as of March 21, 2023, the Company and the Holder have agreed to amend and

restate the Original Warrant in its entirety as set forth herein to, among other things, reflect the adjustments previously acknowledged by the Certificate of Adjustment and to further adjust the Exercise Price as set forth herein.

NOW, THEREFORE, for good and valuable consideration, the sufficiency of which is hereby acknowledged, the Company and the Holder agree that the Original Warrant is hereby amended and restated in its entirety as set forth below.

This Warrant certifies that, for value received, the Holder is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after February 26, 2021, and on or prior to the close of business on February 26, 2028 (the "Expiration Date") but not thereafter, to subscribe for and purchase from the Company up to eleven thousand two hundred and fifty (11,250) shares of Common Stock (as subject to adjustment hereunder, the "Warrant Shares"). The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

For the avoidance of doubt, this Warrant shall be treated for all purposes as having been issued on, and having been outstanding since, the Original Issue Date

Section 1. Definitions. For the purposes hereof, in addition to the terms defined elsewhere in this Warrant, (a) capitalized terms used and not otherwise defined herein shall have the meanings set forth in the Credit Agreement, and (b) the following terms shall have the following meanings:

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"Closing Bid Price" means for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the last reported closing bid price for Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg, L.P., (b) if the Common Stock is not then listed or quoted for trading on a Trading Market and if prices for the Common Stock are then reported in the "Pink Sheets" published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (c) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holder and reasonably acceptable to the Company, the reasonable, actual and documented fees and reasonable, actual and documented out-of-pocket expenses of which shall be paid by the Company.

"Commission" means the United States Securities and Exchange Commission.

"Common Stock" means the common stock of the Company, par value $0.0001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Deemed Outstanding" means, at any given time, the sum of (i) the number

of shares of Common Stock actually outstanding at such time, plus (ii) the number of shares of Common Stock issuable upon exercise of Options actually outstanding at such time, plus (iii) the number of shares of Common Stock issuable upon conversion or exchange of Convertible Securities actually outstanding at such time (treating as actually outstanding any Convertible Securities issuable upon exercise of Options actually outstanding at such time), in each case, regardless of whether the Options or Convertible Securities are actually exercisable at such time; *provided* that Common Stock Deemed Outstanding at any given time shall not include shares owned or held by or for the account of the Company or any of its wholly owned subsidiaries.

"Common Stock Equivalents" means any securities of the Company or its wholly owned subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Convertible Securities" means any debt, equity or other securities that are, directly or indirectly, convertible into or exchangeable for Common Stock.

"Excluded Issuance" means the issuance of (a) shares of Common Stock (or options with respect thereto) issued or issuable to employees or directors of, or consultants to, the Company or any of its subsidiaries pursuant to a plan, agreement or arrangement approved by the Board of Directors of the Company, (b) warrants issued pursuant to the Credit Agreement and/or other securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date of this Warrant, *provided* that such securities have not been amended since the date of this Warrant to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities (for purposes of clarity, any decrease in the exercise price, exchange price or conversion price of such securities shall not be deemed an amendment thereto, if such decrease is as a result of any price-based anti-dilution provision contained in such securities prior to the date hereof), (c) other securities issued to financial institutions, institutional investors or lessors in connection with credit arrangements, equipment financings or similar transactions approved by a majority of disinterested directors of the Company, (d) securities issued pursuant to acquisitions or strategic transactions approved by a majority of disinterested directors of the Company, *provided* that any such issuance shall only be to a Person which is, itself or through its subsidiaries, an operating company in a business synergistic with the business of the Company and in which the Company receives benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities, *provided further* that the exclusion in this clause (d) shall be limited to 12,500,000 shares of Common Stock (as such number of shares is equitably adjusted for subsequent stock splits, stock combinations, stock dividends and recapitalizations occurring after the date hereof), and (e) securities issuable under any at-the-market offering programs the Company may establish in accordance with Rule 415(a)(4) under the Securities Act. In addition, for the avoidance of doubt, "Excluded Issuances" also include the filing of any registration statement of the Company with the Commission registering securities of the Company, or the filing of any amendments or supplements thereto, provided that the determination of whether sales under any such registration statement is an Excluded Issuance will be determined based on the preceding clauses (a) to (e) hereof.

"Fundamental Transaction" means (a) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (b) the Company, directly or indirectly, effects any sale, lease, exclusive license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (c) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of fifty percent (50%) or more of the outstanding Common Stock, (d) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock (but, for the avoidance of doubt, excluding any transaction, event or occurrence covered by Section 3(a)) or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, (e) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person whereby such other Person acquires more than fifty percent (50%) of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or Affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination).

"Marketable Securities" means securities that (a) are tradable on an established national U.S. or non-U.S. stock exchange or reported through NASDAQ or a comparable established non-U.S. over-the-counter trading system and (b) are not subject to restrictions on transfer under the Securities Act or contractual restrictions on transfer.

"Options" means any warrants or other rights or options to subscribe for or purchase Common Stock or Convertible Securities.

"Person" means any individual, sole proprietorship, partnership, limited liability company, corporation, joint venture, trust, incorporated organization or government or department or agency thereof.

"Prospectus" means the prospectus or prospectuses included in any Registration Statement, as amended or supplemented by any prospectus supplement with respect to the terms of the offering of any portion of the Registrable Securities covered by such Registration Statement and by all other amendments and supplements to the prospectus, including post-effective amendments and all material incorporated by reference in such prospectus or prospectuses.

"Registrable Securities" means (x) any shares of Common Stock held by Holder or issuable upon conversion, exercise or exchange of any securities owned by Holder at any time (including Warrant Shares exercisable upon exercise of this Warrant), and (y) any shares of Common Stock issued or issuable with respect to any shares described in subsection (x) above by way of a stock dividend or stock split or in connection with a combination of shares, recapitalization, merger, consolidation or other reorganization (it being understood that for purposes of this Warrant, Holder shall be deemed to be a holder of Registrable Securities whenever Holder has the right to then acquire or obtain from the Company any Registrable Securities, whether or not such acquisition

has actually been effected). As to any particular Registrable Securities, such securities shall cease to be Registrable Securities when (i) a Registration Statement covering such securities has been declared effective by the SEC and such securities have been disposed of pursuant to such effective Registration Statement, (ii) such securities are sold under circumstances in which all of the applicable conditions of Rule 144 (or any similar provisions then in force) under the Securities Act are met, (iii) such securities are otherwise transferred and such securities may be resold without subsequent registration under the Securities Act, or (iv) such securities shall have ceased to be outstanding.

"Registration Statement" means any registration statement of the Company which covers any of the Registrable Securities pursuant to the provisions of this Warrant, including the Prospectus, amendments and supplements to such Registration Statement, including post-effective amendments, all exhibits and all materials incorporated by reference in such Registration Statement.

"Rule 144" means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same effect as such Rule.

"Trading Day" means a day on which the principal Trading Market is open for trading.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE MKT, the Nasdaq Global Market, the Nasdaq Capital Market, the New York Stock Exchange, the OTCQB, the OTCQX U.S. or the Nasdaq Global Select Market (or any successors to any of the foregoing).

"Transfer Agent" means Broadridge Corporate Issuer Solutions, the current transfer agent of the Company, with a mailing address of P.O. Box 1342, Brentwood, NY 11717, and any successor transfer agent of the Company. "VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (or an equivalent quotation service acceptable to the Holder and the Company) (based on a Trading Day from 9:30 a.m. (local time in New York City, New York) to 4:00 p.m. (local time in New York City, New York)) (b) if the Common Stock is not then listed or quoted for trading on a Trading Market and if prices for the Common Stock are then reported in the "Pink Sheets" published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (c) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holder and reasonably acceptable to the Company, the reasonable, actual and documented fees and reasonable, actual and documented out-of-pocket expenses of which shall be paid by the Company.

Section 2. Exercise.

(a) Exercise of Warrant. Exercise of the purchase rights represented by this

Warrant may be made, in whole or in part, at any time or times before the Expiration Date by delivery to the Company (or such other office or agency of the Company as it may designate by notice in writing to the registered Holder at the address of the Holder appearing on the books of the Company) of a duly executed facsimile or electronic copy of the Notice of Exercise in the form annexed hereto (the "Notice of Exercise") and within two (2) Trading Days of the date said Notice of Exercise is delivered to the Company, the Company shall have received payment of the aggregate Exercise Price of the Warrant Shares thereby purchased by wire transfer or cashier's check drawn on a United States bank or pursuant to the cashless exercise procedure specified in Section 2(c) below. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise form be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and this Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within two (2) Trading Days of the date the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be different than the amount stated on the face hereof. For the avoidance of doubt, the Holder may request a new Warrant upon the partial exercise of this Warrant.**

In the event that immediately prior to the close of business on the Expiration Date, the Closing Bid Price of one share of Common Stock is greater than the then applicable Exercise Price, this Warrant shall be deemed to be automatically exercised as a "cashless exercise" pursuant to Section 2(c) below, and the Company shall deliver the applicable number of shares of Common Stock to the Holder pursuant to the provisions of Section 2(d) below.

(b) Exercise Price. The exercise price per share of the Common Stock issuable under this Warrant (the "Exercise Price") shall be the lower of (i) $0.21 and (ii) the lowest price that one share of Common Stock is issued by the Company in the period between the Amendment Date and June 30, 2023 (the "Price Adjustment Period"), as such Exercise Price may be subject to further adjustment hereunder. In connection with the foregoing, promptly after June 30, 2023, the Company shall provide a certificate to the Holder signed by an officer of the Company specifying, and certifying, the lowest issue price for one share of Common Stock issued by the Company during the Price Adjustment Period and, if applicable, the adjusted Exercise Price of this Warrant.

(c) Cashless Exercise. This Warrant may be exercised, in whole or in part, at any time by means of a "cashless exercise" in which the Holder shall be entitled to receive

a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A) (a "Cashless Exercise"), where:

(A) = the VWAP on the Trading Day immediately preceding the date on which Holder elects to exercise this Warrant by means of a "cashless exercise," as set forth in the applicable Notice of Exercise;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise or, if only a portion of this Warrant is being exercised, the portion of this Warrant being cancelled.

(d) Mechanics of Exercise.

(i) Delivery of Warrant Shares Upon Exercise. Warrant Shares purchased hereunder shall be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's prime broker with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and the Warrant Shares are eligible for resale by the Holder without volume or manner-of-sale limitations pursuant to Rule 144 or an available Registration Statement, and otherwise by physical delivery to the address specified by the Holder in the Notice of Exercise by the date that is two (2) Trading Days after the delivery to the Company, by 11 a.m. (local time in New York City, New York) on a Trading Day, of the Notice of Exercise and payment of the aggregate Exercise Price as set forth above (including by Cashless Exercise) (such date, the "Warrant Share Delivery Date"). The Warrant Shares shall be deemed to have been issued, and the Holder or any other person so designated to be named therein shall be deemed to have become a holder of record of such Warrant Shares for all purposes, as of the date this Warrant has been exercised, with payment to the Company of the Exercise Price (or by Cashless Exercise) and all taxes required to be paid by the Holder, if any, pursuant to Section 2(d)(v) prior to the issuance of such Warrant Shares, having been paid. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, other than a failure to deliver caused by the Holder's failure to pay the applicable Exercise Price for such Warrant Shares or to timely take such actions as are necessary to post such Warrant Shares in DWAC, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each $1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), an amount equal to the Exercise Price per Trading Day for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise.

(ii) Delivery of New Warrants Upon Exercise. If this Warrant shall

have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

(iii) Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the third (3rd) Trading Day following the Warrant Share Delivery Date, other than a failure to deliver caused by the Holder's failure to pay the applicable Exercise Price for such Warrant Shares or to timely take such actions as are necessary to post such Warrant Shares in DWAC, then the Holder will have the right to rescind such exercise.

(iv) Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to an exercise on or before the second (2nd) Trading Day following the Warrant Share Delivery Date and such failure is not caused by any act or omission of the Holder, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased (*provided*, Holder exercises reasonable efforts to minimize the amount of such purchase price) exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue by (2) the actual sale price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted exercise to acquire Warrant Shares with an aggregate sale price giving rise to such purchase obligation of $10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder $1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity, including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver Warrant Shares upon exercise of the Warrant as required pursuant to the terms hereof.

(v) No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall round up to the next whole share.

(vi) Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; *provided*, *however*, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by a completed Assignment Form in the form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

(vii) Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

(e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to this Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates, and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant

is exercisable (in relation to other securities owned by the Holder together with any Affiliates) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company, or (C) a more recent written notice from the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written request of a Holder, the Company shall within three (3) Trading Days confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 19.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the applicable issuance of shares of Common Stock issuable upon exercise of this Warrant, *provided* that the Holder may decrease such Beneficial Ownership Limitation upon written notice to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

(f) No Violation. The Company shall take all such actions as may be necessary to ensure that all such Warrant Shares are issued without violation by the Company of any applicable law or governmental regulation or of any requirements of any domestic securities exchange upon which shares of Common Stock or other securities constituting Warrant Shares may be listed at the time of such exercise (except for official notice of issuance which shall be immediately delivered by the Company upon each such issuance).

Section 3. Certain Adjustments. In order to prevent dilution of the purchase rights granted under this Warrant Certificate, the Exercise Price and the number of Warrant Shares issuable upon exercise of this Warrant Certificate shall be subject to adjustment from time to time as provided in this Section 3.

(a) *Intentionally Omitted*.

(b) *Intentionally Omitted*.

(c) *Intentionally Omitted*.

(d) Adjustment to Exercise Price and Warrant Shares Upon Dividend, Subdivision or Combination of Common Stock. If the Company shall, at any time or from time to time after the date hereof, (i) pay a dividend or make any other distribution upon the Common Stock or any other capital stock of the Company payable in shares of Common Stock or in Options or Convertible Securities, or (ii) subdivide (by any stock split, recapitalization or otherwise) its outstanding shares of Common Stock into a greater number of shares, the Exercise Price in effect immediately prior to any such dividend, distribution or subdivision shall be proportionately reduced and the number of Warrant Shares issuable upon exercise of this Warrant Certificate shall be proportionately increased. If the Company at any time combines (by combination, reverse stock split or otherwise) its outstanding shares of Common Stock into a smaller number of shares, the Exercise Price in effect immediately prior to such combination shall be proportionately increased and the number of Warrant Shares issuable upon exercise of this Warrant Certificate shall be proportionately decreased. Any adjustment under this Section 3(d) shall become effective at the close of business on the date the dividend, subdivision or combination becomes effective.

(e) Adjustment to Exercise Price and Warrant Shares Upon Reorganization, Reclassification, Consolidation or Merger. Unless the Holder otherwise consents (in its sole discretion), in the event of any (A) capital reorganization of the Company, (B) reclassification of the stock of the Company (other than a change in par value or from par value to no par value or from no par value to par value or as a result of a stock dividend or subdivision, split-up or combination of shares), (C) Fundamental Transaction or (D) other similar transaction (other than any such transaction covered by Section 3(d)), in each case which entitles the holders of Common Stock to receive (either directly or upon subsequent liquidation) stock, securities or assets with respect to or in exchange for Common Stock:

(i) this Warrant Certificate shall, immediately after such transaction, remain outstanding and shall thereafter, in lieu of or in addition to (as the case may be) the number of Warrant Shares then exercisable under this Warrant Certificate, be exercisable for the kind and number of shares of stock or other securities or assets of the Company or of the successor Person resulting from such transaction to which the Holder would have been entitled upon such transaction if the Holder had exercised this Warrant Certificate in full immediately prior to the time of such transaction and acquired the applicable number of Warrant Shares then issuable hereunder as a result of such exercise (without taking into account any limitations or restrictions on the exercisability of this Warrant Certificate); and

(ii) appropriate adjustment (in form and substance satisfactory to the Holder) shall be made with respect to the Holder's rights under this Warrant Certificate to insure that the provisions of this Section 3 shall thereafter be applicable, as nearly as possible, to this Warrant Certificate in relation to any shares of stock, securities or assets thereafter acquirable upon exercise of this Warrant Certificate (including, in the case of any transaction in which the successor or

purchasing Person is other than the Company, an immediate adjustment in the Exercise Price to the value per share for the Common Stock reflected by the terms of such transaction, and a corresponding adjustment immediately shall be made to the number of Warrant Shares acquirable upon exercise of this Warrant Certificate, without regard to any limitations or restrictions on exercise, if the value so reflected is less than the Exercise Price in effect immediately prior to such transaction).

The provisions of this Section 3(e) shall similarly apply to successive reorganizations, reclassifications, Fundamental Transactions or similar transactions.

Notwithstanding anything to the contrary contained herein, with respect to any corporate event or other transaction contemplated by this Section 3(e), the Holder shall have the right to elect, prior to the consummation of such event or transaction, to exercise this Warrant instead of giving effect to Section 3(e).

(f) Other Dividends and Distributions. If the Company shall, at any time or from time to time after the date hereof, make or declare, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or any other distribution payable in cash, securities of the Company (other than a dividend or distribution of shares of Common Stock, Options or Convertible Securities in respect of outstanding shares of Common Stock) or other property, then, and in each such event, the Company shall ensure that provisions are made so that the Holder shall receive upon exercise of this Warrant Certificate, in addition to the number of Warrant Shares receivable thereupon, the kind and amount of cash, securities of the Company or other property which the Holder would have been entitled to receive had this Warrant Certificate been exercised in full into Warrant Shares on the date of such event and had the Holder thereafter, during the period from the date of such event to and including the date of exercise, retained such cash, securities or other property receivable by them as aforesaid during such period, giving application to all adjustments called for during such period under this Section 3 with respect to the rights of the Holder; *provided* that no such provision shall be made if the Holder receives, simultaneously with the distribution to the holders of Common Stock, a dividend or other distribution of such securities, cash or other property in an amount equal to the amount of such securities, cash or other property as the Holder would have received if this Warrant Certificate had been exercised in full into Warrant Shares on the date of such event.

(g) Certain Events. If any event of the type contemplated by the provisions of this Section 3 but not expressly provided for by such provisions (including, without limitation, the granting of stock appreciation rights, phantom stock rights or other rights with equity features in each case, other than with respect to any Excluded Issuance) occurs, then the Board of Directors of the Company shall make an appropriate adjustment in the Exercise Price of this Warrant Certificate so as to protect the rights of the Holder in a manner consistent with the provisions of this Section 3; *provided* that (i) no such adjustment pursuant to this Section 3(g) shall increase the Exercise Price or decrease the number of Warrant Shares issuable as otherwise determined pursuant to this Section 3 and (ii) for the avoidance of doubt, no adjustment pursuant to this Section 3(g) shall be made in connection with an Excluded Issuance.

(h) Certificate as to Adjustment. As promptly as reasonably practicable following any adjustment of the Exercise Price, but in any event not later than three business days thereafter, the Company shall furnish to the Holder a certificate of an executive officer setting forth in reasonable detail such adjustment and the facts upon which it is based and certifying the calculation thereof. As promptly as reasonably practicable following the receipt by the Company of a written request by the Holder, but in any event not later than three business days thereafter, the Company shall furnish to the Holder a certificate of an executive officer certifying the Exercise Price then in effect and the number of Warrant Shares or the amount, if any, of other shares of stock, securities or assets then issuable upon exercise of this Warrant Certificate.

(i) Fundamental Transaction. If, at any time while this Warrant is outstanding, the Company effects a Fundamental Transaction, then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one (1) share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the Exercise Price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such Exercise Price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction),

and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant and the other Loan Documents referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant and the other Loan Documents with the same effect as if such Successor Entity had been named as the Company herein.

(j) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

(k) Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, or (F) the Company seeks to engage in a Fundamental Transaction, then, in each case, the Company shall cause to be mailed to the Holder at its last address as it shall appear upon the Warrant Register (as defined below) of the Company, at least twenty (20) calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such Fundamental Transaction, reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such Fundamental Transaction, reclassification, consolidation, merger, sale, transfer or share exchange; *provided* that the failure to mail such notice or any defect therein or in the mailing thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice required to be provided hereunder may contain information that constitutes material, non-public information regarding the Company or any of its subsidiaries, the Company shall obtain the Holder's prior consent to receipt of such notice. If the Holder declines to receive any such notice pursuant to the immediately preceding sentence, the Company shall not be deemed to have breached its obligation to deliver such notice hereunder. The Holder shall remain entitled to exercise this Warrant during the 20-day

period commencing on the date of such notice through the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Intentionally Omitted.

Section 5. Transfer of Warrant.

(a) Transferability. Subject to compliance with any applicable securities laws, this Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within two (2) Trading Days of the date the Holder delivers to the Company a completed Assignment Form in the form attached hereto duly executed by the Holder assigning all or any portion of this Warrant. This Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

(b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 5(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated as of February 26, 2021 and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

(c) Transferee Representations. If, at the time of the surrender of this Warrant in connection with any transfer of this Warrant, the transfer of this Warrant shall not be eligible for resale without volume or manner-of-sale restrictions or current public information requirements pursuant to Rule 144, the Company may require, as a condition of allowing such transfer, that the Holder or transferee of this Warrant, as the case may be, deliver a written statement from the transferee to the Company certifying that the transferee is an “accredited investor” as defined in Rule 501(a) under the Securities Act, making the representations and certifications set forth in Section 5(e) of this Warrant and making such additional representations as the Company may, after consultation with its counsel, require in order to confirm compliance with applicable securities laws.

(d) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

(e) Representation by the Holder. The Holder, by the acceptance hereof, represents and warrants that it is acquiring this Warrant and, upon any exercise hereof, will acquire the Warrant Shares issuable upon such exercise, for its own account and not with a view to or for distributing or reselling such Warrant Shares or any part thereof in violation of the Securities Act or any applicable state securities law, except pursuant to sales registered or exempted under the Securities Act.

Section 6. Miscellaneous.

(a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting the rights of a Holder to receive Warrant Shares on a "cashless exercise," in no event will the Company be required to net cash settle an exercise of this Warrant.

(b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of this Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

(c) Removal of Restrictive Legends. Neither this Warrant nor any certificates evidencing Warrant Shares shall contain any legend restricting the transfer thereof in any of the following circumstances: (A) following any sale of this Warrant or such Warrant Shares issued or delivered to the Holder under or in connection herewith pursuant to Rule 144, (B) if this Warrant or such Warrant Shares are eligible for sale under Rule 144(b)(1), or (C) if such legend is not required under applicable requirements of the Securities Act (including judicial interpretations and pronouncements issued by the staff of the Commission) (collectively, the "Unrestricted Conditions"). In such circumstances, the Company shall seek to cause its counsel to issue a legal opinion to the Transfer Agent if required by such Transfer Agent to effect the issuance of Warrant Shares, without a restrictive legend or removal of the legend hereunder. If the Unrestricted Conditions are met at the time of issuance of this Warrant, the Warrant Shares or such other shares of Common Stock, then this Warrant, Warrant Shares or other Common Stock, as the case may be, shall be issued free of all legends.

(d) Replacement Warrant. The Company agrees that at such time as the Unrestricted Conditions have been satisfied it shall promptly (but in any event within ten (10) Business Days) following written request from the Holder issue a replacement Warrant or replacement Warrant Shares or replacement shares in respect of such other Common Stock, as the case may be, free of all restrictive legends ("Unlegended Shares").

(e) Authorized Shares; No Other Adjustments. The Company covenants that, during the period this Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock is listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue). The Company represents and warrants that, during the period commencing on the Original Issue Date through the Amendment Date, there were no events, actions, or circumstances that would have resulted in an adjustment under Section 3 of the Warrant (as such Section 3 existed prior to the Amendment Date), other than the cumulative adjustments reflected in the July 25, 2022 Certificate of Adjustment and incorporated herein.

(f) No Impairment. Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue unrestricted, fully paid and nonassessable Warrant Shares upon the exercise of this Warrant, and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant. Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

(g) Rule 144 Compliance. With a view to making available to the Holder the benefits of Rule 144 under the Securities Act and any other rule or regulation of the SEC that may at any time permit a holder to sell securities of the Company to the public without registration or pursuant to a Registration Statement, the Company shall:

(i) make and keep public information available, as those terms are understood and defined in Rule 144 under the Securities Act;

(ii) use reasonable best efforts to file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act; and

(iii) furnish to the Holder, promptly upon request, a written statement by the Company as to its compliance with the reporting requirements of Rule 144 under the Securities Act and of the Securities Act and the Exchange Act, a copy of the most recent annual or quarterly report of the Company, and such other reports and documents so filed or furnished by the Company as such holder may reasonably request in connection with the sale of Warrant Shares without registration.

(h) Governing Law. This Warrant and the rights and obligations of the parties hereunder shall be governed by, and construed in accordance with, the law of the State of New York, without regard to principles of conflicts of laws that would result in the application of the laws of any other jurisdiction.

(i) Submission to Jurisdiction. The Company agrees that any suit, action or proceeding with respect to this Warrant or any judgment entered by any court in respect thereof may be brought initially in the federal or state courts in New York, New York or in the courts of its own corporate domicile and irrevocably submits to the exclusive jurisdiction of each such court for the purpose of any such suit, action, proceeding or judgment. This Section is for the benefit of the Holder only and, as a result, the Holder shall not be prevented from taking proceedings in any other courts with jurisdiction. To the extent allowed by any applicable law, the Holder may take concurrent proceedings in any number of jurisdictions.

(j) Waiver of Venue, Etc. The Company irrevocably waives to the fullest extent permitted by law any objection that it may now or hereafter have to the laying of the venue of any suit, action or proceeding arising out of or relating to this Warrant and hereby further irrevocably waives to the fullest extent permitted by law any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. A final judgment (in respect of which time for all appeals has elapsed) in any such suit, action or proceeding shall be conclusive and may be enforced in any court to the jurisdiction of which the Company is or may be subject, by suit upon judgment.

(k) Waiver of Jury Trial. THE COMPANY AND THE HOLDER HEREBY IRREVOCABLY WAIVE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS WARRANT

OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.

(l) No Waiver. No failure on the part of the Holder to exercise and no delay in exercising, and no course of dealing with respect to, any right, power or privilege under this Warrant shall operate as a waiver thereof, nor shall any single or partial exercise of any right, power or privilege under this Warrant preclude any other or further exercise thereof or the exercise of any other right, power or privilege. The remedies provided herein are cumulative and not exclusive of any remedies provided by law.

(m) Expenses. If the Company fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any actual, reasonable and documented attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

(n) Notices. All notices, requests, instructions, directions and other communications provided for herein (including any modifications of, or waivers, requests or consents under, this Warrant) shall be given or made in writing (including by telecopy or email) delivered, if to the Company or the Holder, to its address specified on the signature pages hereto, or at such other address as shall be designated by such party in a written notice to the other party. Except as otherwise provided in this Warrant, all such communications shall be deemed to have been duly given upon receipt of a legible copy thereof, in each case given or addressed as aforesaid. All such communications provided for herein by telecopy shall be confirmed in writing promptly after the delivery of such communication (it being understood that non-receipt of written confirmation of such communication shall not invalidate such communication).

(o) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

(p) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to seek specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

(q) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall be binding upon and inure to the benefit of the successors and permitted assigns of the Company and the successors and permitted assigns of the Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the

Holder or any holder of Warrant Shares.

(r) Amendments, Etc. Except as otherwise expressly provided in this Warrant, any provision of this Warrant may be modified or supplemented only by an instrument in writing signed by the Company and the Holder.

(s) Severability. If any provision hereof is found by a court to be invalid or unenforceable, to the fullest extent permitted by any applicable Law the parties agree that such invalidity or unenforceability shall not impair the validity or enforceability of any other provision hereof.

(t) Captions. The captions and section headings appearing herein are included solely for convenience of reference and are not intended to affect the interpretation of any provision of this Warrant.

(u) Counterparts. This Warrant may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument and any of the parties hereto may execute this Warrant by signing any such counterpart.

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

AGILE THERAPEUTICS, INC.

By: /s/ Al Altomari
Name: Al Altomari
Title: Chairman and CEO

Address for Notices:

Agile Therapeutics, Inc.
500 College Road East
Suite 310
Princeton, New Jersey 08540
Attention: Chief Executive Officer

With a copy to (which shall not constitute notice):

Morgan, Lewis & Bockius LLP
170 Market Street
Philadelphia, PA 19103-2921
Attention: Andrew Budreika

Accepted and Agreed,

Perceptive Credit Holdings III, LP
By: Perceptive Credit Opportunities GP, LLC, its general partner

By: /s/ Sandeep Dixit
Name: Sandeep Dixit
Title: Chief Credit Officer

By: /s/ Sam Chawla
Name: Sam Chawla
Title: Portfolio Manager

Address for Notices:

Perceptive Credit Holdings III, LP
c/o Perceptive Advisors LLC
51 Astor Place, 10th Floor
New York, NY 10003
Attn: Sandeep Dixit
Email: Sandeep@perceptivelife.com

NOTICE OF EXERCISE

TO: AGILE THERAPEUTICS, INC.

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

[ ] in lawful money of the United States; or

[ ] the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

Check applicable box and fill in information:

[ ] The Warrant Shares shall be delivered to the following DWAC Account Number:

_____

_____

_____

[ ] The Warrant Shares shall be delivered by physical delivery of a certificate to:

_____

_____

_____

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____
Signature of Authorized Signatory of Investing Entity: _____
Name of Authorized Signatory: _____
Title of Authorized Signatory: _____
Date: _____

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name of Person to Whom Warrant is being Transferred: _____

Address of Person to Whom Warrant is being Transferred: _____

_____

_____

Number of Shares Subject to Warrant being Transferred: _____

Dated: _____ __, _____

Holder's Name: _____

Holder's Signature:

_____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Holder's Address:

_____

_____

Information in this exhibit identified by [***] is confidential and has been excluded pursuant to Item 601()(10)(iv) of Regulation S-K because it is both (i) not material and (ii) the type of information that the registrant customarily and actually treats as private and confidential.

SIXTH AMENDMENT TO PROJECT AGREEMENT (DETAILING – FIELD TEAM)

This Sixth Amendment (the "Amendment") dated January 3, 2023 (the "Effective Date") is made by and between Syneos Health Commercial Services, LLC, with an office at 500 Atrium Drive, Somerset, N.J. 08873 ("Syneos Health") and Agile Therapeutics, Inc. with an office located at 500 College Road East, Suite 310, Princeton, New Jersey 08540 (the "Client"). Syneos Health and Client may each be referred to herein as a "Party" and, collectively, as the "Parties."

W I T N E S S E T H:

WHEREAS, Syneos Health and Client are parties to a Project Agreement (Detailing – Field Team) made as of April 30, 2020, First Amendment to Project Agreement (Detailing – Field Team) dated June 1, 2020, Second Amendment to Project Agreement (Detailing – Field Team) dated January 1, 2021, Third Amendment to Project Agreement (Detailing – Field Team) dated July 1, 2021, Fourth Amendment to Project Agreement (Detailing – Field Team) dated September 1, 2021, and Firth Amendment to Project Agreement (Detailing – Field Team) dated February 1, 2022 (collectively, the "Agreement"); and

WHEREAS, Syneos Health and Client desire to amend the Agreement as set forth herein.

NOW THEREFORE, in consideration of the premises and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, it is agreed as follows:

1. Except as provided in this Amendment, the terms and conditions set forth in the Agreement shall remain unaffected by execution of this Amendment. To the extent any provisions or terms set forth in this Amendment conflict with the terms set forth in the Agreement, the terms set forth in this Amendment shall govern and control. Terms not otherwise defined herein, shall have the meanings set forth in the Agreement.

2. The Amended and Restated Exhibit A, the "Project Team" as defined is hereby amended to (a) set the number of engagement center representatives ("EC Reps") at [***]; (b) change references to Alliance Lead to National Business Director ("NBD") and (c) remove [***] sales trainer manager (the "STM"). Also, the table after the 2nd paragraph is hereby deleted in its entirety and replaced with the below table:

Position	Headcount	[***]
[***]		
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

3. The Amended and Restated Exhibit F, "[***]," is amended as follows:

(i) The table in Section I, "[***]" is hereby deleted in its entirety and replaced with the below table.

Position	Headcount	[***]
[***]		
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

(b) Section I(b), "[***]" paragraph (i) is hereby amended and restated as follows:

(i) Commencing on the Effective Date, Client shall pay Syneos Health a [***] as follows:

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

Syneos Health shall adjust the Fixed Monthly Fee prior to the initial fill of any Syneos Health Sales Representative or RSM prorated for any partial months, according to the Fixed Monthly Fee table outlined in subsection (c)(i), below.

The Implementation Fee and/or Fixed Monthly Fee set forth above are based upon the assumptions set forth in the recruitment/training timeline agreed to by the Parties. In the event that the assumptions set forth in the recruitment/training timeline are changed, the Implementation Fee and/or Fixed Monthly Fee shall be re-calculated and agreed-upon by the Parties.

4. This Amendment may be executed simultaneously in multiple counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. Execution and delivery of this Amendment by exchange of facsimile copies or via pdf file bearing the facsimile signature of a party hereto shall constitute a valid and binding execution and delivery of this Amendment by such party. Such facsimile copies and/or pdf versions shall constitute enforceable original documents.

5. The terms of this Amendment are intended by the Parties to be the final expression of their agreement with respect to the subject matter hereof and may not be contradicted by evidence of any prior or contemporaneous agreement. The Parties further intend that this Amendment constitute the complete and exclusive statement of its terms and shall supersede any prior agreement with respect to the subject matter hereof.

WHEREFORE, the parties hereto have caused this Amendment to be executed by their duly authorized representatives.

AGILE THERAPEUTICS, INC.	**SYNEOS HEALTH COMMERCIAL SERVICES, LLC**
By: /s/ Al Altomari	By: /s/ Corey Swinson
Name: Al Altomari	Name: Corey Swinson
Title: Chairman and CEO	Title: Director, Global Deal Management
Date: 1/25/2023	Date: 1/26/2023

Exhibit 10.33

AMENDED AND RESTATED EMPLOYMENT AGREEMENT

THIS AMENDED AND RESTATED EMPLOYMENT AGREEMENT (this "Agreement") is entered into as of November 22, 2022, by and between AGILE THERAPEUTICS, INC., a Delaware corporation (the "Company"), and Alfred Altomari (the "Executive"), collectively referred to as the "parties."

Recitals:

WHEREAS, the Company and the Executive entered into an Employment Agreement dated April 12, 2016, which was subsequently amended and restated on August 13, 2020 (the "Prior Agreement"); and

WHEREAS, the Company desires to continue to employ the Executive and to have the benefit of the Executive's skills and services, and the Executive desires to accept such continued employment with the Company, on the terms and conditions set forth herein; and

WHEREAS, this Agreement shall supersede and replace the Prior Agreement, which shall be of no further force or effect.

NOW, THEREFORE, in consideration of the mutual promises, covenants, and conditions set forth in this Agreement, the parties agree as follows:

SECTION 1. EMPLOYMENT

a. Position. The Company wishes to continue to employ the Executive as Chairman and Chief Executive Officer of the Company, and the Executive hereby agrees to continue in such position for the term of this Agreement and to perform those duties and responsibilities as shall be assigned to the Executive by the Board of Directors of the Company (the "Board") or its designee and that are consistent with the Executive's position.

b. The Executive's Commitment. The Executive shall consider the Executive's employment by the Company as the Executive's principal employment, shall devote the Executive's full working time and attention to the Executive's duties and responsibilities under this Agreement, and shall perform the Executive's duties and responsibilities to the best of the Executive's abilities. While subject to any provision of this Agreement, the Executive shall maintain loyalty to the Company and shall take no action that would directly or indirectly promote any competitor or injure the Company's interests. Subject to the foregoing, the Executive may engage in other business activities to the extent that they do not interfere with the Executive's obligations under this Agreement, provided that each of those activities is first disclosed to and approved by the Board.

c. Principal Place of Employment. The Executive acknowledges and agrees that the Executive's principal place of employment will be in the Company's offices located in Princeton, New Jersey and that the Executive will be required to travel for business in the course of performing his duties for the Company. The Executive will be subject to such on-site work and remote work policies applicable to similarly situated employees as the Company may establish from time to time.

d. Company Policies. The Executive acknowledges and agrees that the Executive shall be bound by all applicable employment and other policies applicable to similarly situated employees as the Company may establish from time to time.

SECTION 2. TERMINATION OF EMPLOYMENT

a. Term. The term of this Agreement shall commence on the date hereof and shall continue until the Executive's employment with the Company is terminated in accordance with Section 2b, 2c, 2d, or 2e hereof.

b. Termination for "Reasonable Cause." The Executive's employment may be terminated by the Company at any time, without prior notice, upon a showing of "Reasonable Cause," as defined below. Should the Executive's employment be terminated by the Company for "Reasonable Cause," no severance or other unearned compensation shall be payable by the Company to the Executive nor shall the Company be obligated to continue to provide to the Executive at the Company's expense, or reimburse the Executive for, any health insurance benefits after the effective date of the termination. "Reasonable Cause" shall be defined for the purposes of this Agreement as being any of the following:

(i) any act or omission by the Executive that reasonably constitutes dishonesty, disloyalty, fraud, deceit, gross negligence, willful misconduct, or recklessness, including, but not limited to the Executive's willful violation of the Company's bylaws or code of regulations, and that is directly or indirectly materially detrimental to the Company's best interest;

(ii) the Executive's intentional failure to perform any lawful duties assigned to the Executive by the Board or its designee after receiving notice and a reasonable opportunity to cure;

(iii) the commission of any act by the Executive that constitutes a felony under the laws of the United States or the state of the Company's principal place of business; and

(iv) any material breach by the Executive of Section 5, 6, 7, or 8 of this Agreement.

Furthermore, the termination by the Executive of the Executive's employment with the Company for any reason other than for Good Reason pursuant to Section 2d shall be deemed to be a termination of the Executive's employment for "Reasonable Cause" without any notice or other action on the part of the Company.

c. Death or Disability. The Executive's employment shall terminate immediately upon the Executive's death. The Executive's employment shall terminate immediately upon disability of the Executive to the extent consistent with applicable law. For purposes of this Agreement, the Executive shall be deemed to have a "disability" if, in the reasonable opinion of the Board, the Executive is unable to perform the essential functions of the Executive's job, with or without reasonable accommodation(s), for at least ninety (90) consecutive days because of

illness, incapacity, or physical or mental disability, and the Executive's inability to do so perform poses an undue hardship for the Company.

d. Termination by the Executive for Good Reason. The Executive may resign from employment with the Company for Good Reason, but only in accordance with the terms of this Section 2d. "Good Reason" shall be deemed to exist with respect to any termination by the Executive of the Executive's employment for any of the following reasons: (i) the relocation of the office of the Company at which the Executive is principally employed to a location that is more than fifty (50) miles from the location of such office as of the date of this Agreement; (ii) any failure by the Company to comply with any material term of this Agreement; or (iii) the demotion of the Executive to a lesser position than described in Section 1a hereof or a substantial diminution of the Executive's authority, duties, or responsibilities as in effect on the date of this Agreement or as may be hereafter increased; provided, however, that "Good Reason" shall not include a termination of the Executive's employment pursuant to Sections 2b or 2c hereof or, following a Change of Control (as defined in Section 4d below), a reduction in title, position, responsibilities, or duties solely by virtue of the Company being acquired and made part of, or operated as a subsidiary of, a larger company or organization, so long as such new duties and responsibilities are reasonably commensurate with the Executive's experience.

The Executive may not resign with Good Reason pursuant to this Section 2d, and shall not be considered to have done so for any purpose of this Agreement, unless (i) the Executive, within sixty (60) days after the initial existence of the act or failure to act by the Company that constitutes "Good Reason" within the meaning of this Agreement, provides the Company with written notice that describes, in particular detail, the act or failure to act that the Executive believes to constitute "Good Reason" and identifies the particular clause of this Section 2d that the Executive contends is applicable to such act or failure to act; (ii) the Company, within thirty (30) days after its receipt of such notice, fails or refuses to rescind such act or remedy such failure to act so as to eliminate "Good Reason" for the termination by the Executive of the Executive's employment relationship with the Company, and (iii) the Executive actually resigns from employment with the Company on or before that date that is six (6) calendar months after the initial existence of the act or failure to act by the Company that constitutes "Good Reason." If the requirements of the preceding sentence are not fully satisfied on a timely basis, then the resignation by the Executive from the Executive's employment with the Company shall not be deemed to have been for "Good Reason," the Executive shall not be entitled to any of the benefits to which the Executive would have been entitled if the Executive had resigned from employment with the Company for "Good Reason," and the Company shall not be required to pay any amount that would otherwise have been due to the Executive under Section 4a had the Executive resigned with "Good Reason."

e. Other Termination. The Executive's employment may also be terminated by the Company for any reason other than as set forth in Section 2b, 2c, or 2d.

SECTION 3. COMPENSATION, BENEFITS AND EXPENSES

a. Salary. The Company shall pay the Executive an annual base salary at the rate of $600,554 (the "Base Salary"), payable in accordance with the Company's payroll practices in effect from time to time.

b. Bonus. The Executive shall be eligible to receive an annual bonus ("Annual Bonus"). The Executive's Annual Bonus Target shall be 60% of the Executive's Base Salary. Whether the bonus will be awarded to the Executive and the amount of the annual bonus shall be determined by the Board or its Compensation Committee based upon achievement of such goals that shall be established by the Board. The Annual Bonus, if awarded to the Executive, shall be paid within two and one-half (2 ½) months after the close of each fiscal year.

c. Equity Program. The Executive shall be eligible to participate in equity incentive programs established by the Company from time to time in the future to provide stock options and other equity-based incentives to key employees of the Company. All such stock options and other equity-based incentives shall be awarded in the discretion of the Board pursuant to the terms of the Company's Amended and Restated 2014 Incentive Compensation Plan and/or such other plans as shall from time to time be established by the Company (the "Equity Plan").

d. Health and Long-Term Disability Insurance. The Executive shall be entitled to participate in such employee benefit plans (collectively the "Plans") as are implemented by the Company and available to executive officers of the Company. The Company shall have the right, from time to time and in its sole discretion, to modify and amend the Plans and benefits provided to its executive officers and other employees, including the Executive. In addition to any key man insurance taken out by the Company, and provided that the Executive can pass the required physical examinations, during the term of this Agreement the Company shall, at its election, either provide to the Executive or reimburse the Executive for the premiums for term life insurance in an amount equal to two times the sum of the Executive's Base Salary plus target Annual Bonus, up to $1,000,000, with Executive designating the beneficiary of such policy.

e. Paid Time Off. The Executive shall be eligible to participate in the Company's paid time off ("PTO") policy, as may be amended from time to time. Any PTO shall be accrued, used and otherwise governed in accordance with the Company's PTO policy in effect from time to time.

f. Effect of Termination on Salary and Benefits. The Executive's Base Salary and benefits under this Section 3 shall terminate effective immediately on the date of the termination of the Executive's employment by the Company, and from that date the Executive shall be entitled to severance benefits under Section 4 if and only to the extent such benefits are then payable in accordance with the terms and provisions of this Agreement.

g. Effect of Termination on Other Provisions. This Agreement shall continue in effect upon and after the termination of the Executive's employment for any reason necessary to enforce the provisions of this Agreement that apply subsequent to any such termination,

including any provisions relating to confidentiality, invention assignment, non-solicitation, and non-competition.

i. Expense Reimbursement. The Company shall reimburse the Executive for all reasonable out-of-pocket expenses incurred in connection with the Company's business and the Executive's performance of the Executive's obligations under this Agreement, in accordance with the applicable expense reimbursement policy of the Company, upon submission by the Executive to the Company of such written evidence of such expense as the Company may require. Any disputes as to the eligibility of an expense for reimbursement shall be resolved in the sole discretion of the Company.

h. Recovery of Incentive Compensation. Notwithstanding anything herein to the contrary, the Executive agrees that all incentive compensation, including cash and equity awards payable to the Executive under this Agreement or otherwise, shall be subject to any clawback policy adopted or implemented by the Board and all other applicable Company policies, consistent with applicable law.

SECTION 4. PAYMENTS AND BENEFITS UPON TERMINATION

a. Payments and Benefits upon Termination. Subject to the satisfaction of the terms of Section 4b, if during the term of this Agreement (i) the Executive's employment under this Agreement is terminated by the Company pursuant to Section 2e (i.e., other than a termination for Reasonable Cause pursuant to Section 2b or a termination upon death or disability pursuant to Section 2c), or the Executive resigns from employment with the Company with Good Reason pursuant to Section 2d (each a "Qualifying Termination"), or (ii) the Executive's employment under this Agreement terminates due to the Executive's disability pursuant to Section 2c, the Executive shall be entitled to receive from the Company the benefits set forth in subsection (i), (ii), or (iii) below, as applicable.

(i) *Qualifying Termination Not in Connection with a Change of Control*. If the Qualifying Termination occurs prior to the effective date of a Change of Control, or the Qualifying Termination occurs more than twelve (12) months after a Change of Control, the Executive shall be entitled to:

A. continuation of the Executive's Base Salary (at the salary rate then in effect) for twelve (12) months (the "Severance Period"), in accordance with the Company's payroll schedule, commencing on the sixtieth (60th) day after the Executive's effective date of termination, with the first such installment payment including any unpaid severance payments that would have been made on the normal payroll dates occurring during the first sixty (60) days following the date of termination, provided that if there is a Change of Control before all of the payments under this subsection (A) have been paid, such remaining payments shall be accelerated and paid in a lump sum within sixty (60) days following the Change of Control to the extent permitted by section 409A of the Internal Revenue Code of 1986, as amended (the "Code"); and

B. provided that the Executive is eligible for and timely elects to receive continued health coverage under the Company's health plan under the Consolidated Omnibus Budget Reconciliation Act ("COBRA"), and the Executive pays the full monthly COBRA premium cost for such health coverage, the Company shall reimburse the Executive monthly an amount equal to the monthly COBRA premium paid by the Executive, less the amount that the Executive would be required to contribute for similar coverage under the Company's medical plan if the Executive were an active employee for the Company, for the Severance Period, or until the Executive becomes employed by another employer offering any such benefits (whichever is earlier). The Executive agrees to provide the Company with notice of eligibility under another health plan within two (2) weeks of such eligibility. Such amounts shall commence on the sixtieth (60th) day after the Executive's effective date of termination, with the first such installment payment including any unpaid severance payments that would have been made on the normal payroll dates occurring during the first sixty (60) days following the date of termination. Notwithstanding the foregoing, the Company reserves the right to restructure the foregoing reimbursement arrangement in any manner necessary or appropriate to avoid penalties or adverse tax consequences to the Executive or the Company or any affiliate, as determined by the Company in its sole discretion.

(ii) *Qualifying Termination In Connection with Change of Control*. If the Qualifying Termination occurs on the date of, or within 12 months after, the effective date of a Change of Control (a "CoC Qualifying Termination"), the Executive shall be entitled to the same payments and benefits set forth under Section 4a(i) above, except that (A) the Severance Period for purposes of Sections 4a(i)(A) and (B) shall extend for twenty four (24) months instead of twelve (12) months, (B) the continued salary payments in Section 4a(i)(A) shall be paid in a lump sum within sixty (60) days following the Executive's termination date, instead of in the form of installment payments, (C) the Executive shall be entitled to a lump sum payment equal to the Executive's target Annual Bonus for the year in which the Executive's CoC Qualifying Termination occurs, payable within sixty (60) days following the Executive's termination date, and (D) each equity award granted to the Executive under the Equity Plan shall automatically vest in full upon the CoC Qualifying Termination.

(iii) *Disability*. If the Executive's employment under this Agreement terminates due to a disability pursuant to Section 2c, either before or after a Change of Control, the Executive shall be entitled to the same payments and benefits set forth under Section 4a(i) above, provided that if such termination due to a disability is on the date of, or within 12 months after, the effective date of a Change of Control, the continued salary payments in Section 4a(i)(A) shall be paid in a lump sum within sixty (60) days following the Executive's termination date, instead of in the form of installment payments.

(iv) *No Duplication of Benefits*. Notwithstanding anything to the contrary, the Executive shall be eligible to receive payments under subsection (i), (ii), or (iii) of this Section 4a (and, for the avoidance of doubt, shall not be eligible to receive payments under more than one such subsection). Additionally, the Executive shall not be eligible to participate in the Company's Change of Control Severance Plan, or any successor plan.

b. Execution of Release. The Executive shall not be entitled to any payments or benefits under Section 4a unless the Executive executes and does not revoke a Release and Agreement (the "Release"), as drafted by the Company at the time of the Executive's termination of employment, including, but not limited to, the following provisions in favor of the Company and its affiliates and assigns to the maximum extent permitted by applicable law:

(i) an unconditional release of all rights to any claims, charges, complaints, or grievances, known or unknown to the Executive, against the Company, its parent, subsidiary and affiliated companies, and assigns (and others, such as their former and current directors, employees, and agents) (together, the "Released Parties"), through the date of the Executive's termination from employment other than post termination payments and benefits pursuant to this Agreement;

(ii) a representation and warranty that the Executive has not filed or assigned any claims, charges, complaints, or grievances against the Released Parties;

(iii) an agreement not to use, disclose, or make copies of any confidential information of the Company, as well as to return any such confidential information and property to the Company upon execution of the Release; and

(iv) an agreement to indemnify the Released Parties in the event that the Executive breaches any portion of the Agreement or Release.

c. No Admission. The Executive acknowledges such a Release shall not be construed as an admission by the Company or any other releasee of any wrongdoing whatsoever against the Executive, and all of the releasees specifically deny any such wrongdoing.

d. Definition of Change of Control. As used in this Agreement, the term "Change of Control" means:

(i) any merger or consolidation in which voting securities of the Company possessing more than 50% of the total combined voting power of the Company's outstanding securities are transferred to a person or persons different from the person holding those securities immediately prior to such transaction and the composition of the Board following such transaction is such that the directors of the Company prior to the transaction constitute less than 50% of the Board membership following the transaction;

(ii) any acquisition, directly or indirectly, by a person or related group of persons (other than the Company or a person that directly or indirectly controls, is controlled by, or is under common control with, the Company) of beneficial ownership of voting securities of the Company possessing more than 50% of the total combined voting power of the Company's outstanding securities; provided, however, that, no Change of Control shall be deemed to occur by reason of the acquisition of shares of the Company's capital stock by an investor or group of investors in the Company in a capital-raising transaction; or

(iii) any sale, transfer, exclusive worldwide license or other disposition of all or substantially all of the assets of the Company.

e. Parachute Provisions. In the event the Company determines in good faith that any payments or benefits (whether made or provided pursuant to this Agreement or otherwise) ("Total Payments") provided to the Executive would otherwise exceed the amount (the "Safe Harbor Amount") that could be received by the Executive without the imposition of an excise tax under section 4999 of the Internal Revenue Code of 1986, as amended (the "Code"), then the Total Payments shall be reduced to the extent, and only to the extent, necessary to assure that their aggregate present value, as determined in accordance the applicable provisions of section 280G of the Code and the regulations thereunder, does not exceed the greater of the following dollar amounts: (i) the Safe Harbor Amount, or (ii) the greatest after-tax amount payable to the Executive after taking into account any excise tax imposed under section 4999 of the Code on the Total Payments. The Company shall pay all of the fees, including legal and accounting fees, associated with calculating the amounts set forth in this subsection 4e.

SECTION 5. CONFIDENTIALITY AND INVENTIONS

a. Confidential Information. Confidential Information means trade secrets, know-how, and other information relating to the Company's business and not generally available to the public, which is disclosed to the Executive or with which the Executive becomes familiar during the Executive's term of employment with the Company. Confidential Information includes information relating to the Company's business practices and prospective business interests, products, processes, equipment, manufacturing operations, marketing programs, research, product development, and engineering. From the date of this Agreement and during or after the Executive's term of employment, unless the Executive receives the Company's written consent or except as permitted by Section 5(e), the Executive will not disclose, use, disseminate, lecture upon, or publish any part of the Company's Confidential Information, whether or not developed by the Executive. Also, the Executive will have the same obligations with respect to the secret or confidential information of any other company or individual (including the Company's parent company), to which the Executive gains access in connection with the Executive's employment. The Executive agrees that the Executive will not disclose to the Company or induce the Company to use any secret confidential information of others, including former employers, with whom the Executive has obligations of secrecy. The Executive expressly agrees to be solely and individually liable to any of the Executive's previous employers for any breach of the Executive's obligations to those previous employers, contractual or otherwise.

b. Inventions. Inventions means discoveries, improvements, and ideas, whether patentable or not, made by the Executive solely or jointly with others, that relate to the business of the Company, including any of its products, processes, equipment, manufacturing operations, marketing programs, research, product development, or engineering activities. The Executive agrees that the Executive will promptly disclose to the Company all Inventions (including those in the formative stages) that relate to the business of the Company made during the Executive's term of employment whether or not during the Executive's normal working hours. The Executive agrees that the Executive will also promptly disclose to the Company any Inventions

that relate to the business of the Company made during the period of one (1) year after the termination of the term of the Executive's employment that relate to or constitute an improvement upon the Company's Confidential Information. The Executive shall keep and maintain written records concerning such Inventions and make these available to the Company at all times. The Company will hold such written records with the same degree of care as it does with other business documents of a confidential nature.

c. Assignment of Inventions. Inventions made in accordance with this Section 5 shall be the sole and exclusive property of the Company, except that the Executive shall retain full rights and title to any Inventions to which all of the following conditions apply:

(i) no equipment, supplies, facilities, or Confidential Information of the Company was used in the Invention's development;

(ii) the Invention was developed entirely on the Executive's own time;

(iii) the Invention does not relate to the Company's business or to the Company's actual or clearly anticipated research and development program; and

(iv) the Invention does not result from any work performed by the Executive for the Company.

During and after the Executive's term of employment, the Executive or the Executive's legal representative shall, at the Company's request and expense, execute domestic and foreign patent applications and assignments to the Company concerning Inventions owned by the Company under this section, and take all other actions as the Company may request to perfect and maintain the Company's rights in same.

d. Documents. The Executive acknowledges that all originals and copies of drawings, blueprints, manuals, reports, notebooks, computer programs, photographs and any other recorded, written, or printed matter relating to research, manufacturing operations, or the business affairs of the Company made or received by the Executive during the Executive's employment are the property of the Company. The rights comprised in the copyright of any of the above documents made by the Executive during the Executive's employment shall be owned exclusively by the Company. The Executive agrees not to retain such property or copies thereof after termination of the term of the Executive's employment and to promptly surrender such property at any time at the request of the Company. The Executive agrees to similarly return all other property of the Company such as equipment, samples, and models.

e. Permitted Conduct. Nothing in this Agreement, including in this Section 5, restricts or prohibits the Executive or the Executive's counsel from initiating communications directly with, responding to any inquiry from, volunteering information to, or providing testimony before a self-regulatory authority or a governmental, law enforcement, or regulatory authority, including the U.S. Equal Employment Opportunity Commission ("EEOC"), the Department of Labor ("DOL"), the National Labor Relations Board ("NLRB"), the Department of Justice ("DOJ"), the Securities and Exchange Commission ("SEC"), FINRA, the Congress,

and any agency Inspector General (collectively, the "Regulators"), from participating in any reporting of, investigation into, or proceeding regarding suspected violations of law, or from making other disclosures that are protected under the whistleblower provisions of state or federal law or regulation. The Executive does not need the prior authorization of the Company to engage in such communications with the Regulators, respond to such inquiries from the Regulators, provide Confidential Information or documents containing Confidential Information to the Regulators, or make any such reports or disclosures to the Regulators. The Executive is not required to notify the Company that the Executive has engaged in such communications with the Regulators. The Executive recognizes and agrees that, in connection with any such activity outlined above, the Executive must inform the Regulators that the information the Executive is providing is confidential. Despite the foregoing, the Executive is not permitted to reveal to any third-party, including any governmental, law enforcement, or regulatory authority, information the Executive came to learn during the course of the Executive's employment with the Company that is protected from disclosure by any applicable privilege, including but not limited to the attorney-client privilege, attorney work product doctrine, and/or other applicable legal privileges. The Company does not waive any applicable privileges or the right to continue to protect its privileged attorney-client information, attorney work product, and other privileged information. Additionally, the Executive recognizes that the Executive's ability to disclose information may be limited or prohibited by applicable law and the Company does not consent to disclosures that would violate applicable law. Nothing in this Agreement is intended to, or has the effect of, requiring the Executive to conceal facts and details associated with the Executive's own claims of discrimination, harassment or retaliation under the New Jersey Law Against Discrimination ("NJLAD"). Even though the parties may have agreed to keep the settlement and underlying facts confidential, such a provision is unenforceable against the Company if the Executive publicly reveals sufficient details of the claim so that the Company is reasonably identifiable. For the avoidance of doubt, the Executive acknowledges that the Executive's right to discuss the underlying facts and details of the Executive's NJLAD claims, subject to the conditions above, does not negate or diminish any other provision of the Agreement, including but not limited to the Executive's general release of claims and the Executive's agreement to protect and not disclose Confidential Information and/or privileged information and to keep the specific terms of any agreement (e.g., settlement payments and other consideration) confidential.

SECTION 6. RESTRICTIVE COVENANT

During the Restricted Period, the Executive shall not engage, directly or indirectly, in any "competitive business." As used in this Agreement, a "competitive business" shall mean any business that is engaged, directly or indirectly, in the research, development, manufacturing, distribution, licensing or sale of technology, products, or services relating to hormonal contraception in the United States and any other geographic region in which the Company conducts business or, at the time of the Executive's termination from employment for any reason, plans to conduct business; provided, however, that a "competitive business" shall not include the acquiring, surviving, or licensing company in a Change of Control transaction if the Executive shall become an employee of or a consultant to such company with the knowledge and consent of the Company. For purposes of this Agreement, the term "Restricted Period" shall mean the period from and after the date of this Agreement and through the twelve (12) month

period after the termination of the term of the Executive's employment hereunder, provided that the Restricted Period shall be for a period of twenty four (24) months (instead of twelve (12) months) after the termination of the term of the Executive's employment hereunder if the Executive has a CoC Qualifying Termination.

SECTION 7. NON-SOLICITATION

During the Restricted Period, the Executive shall not, directly or indirectly, solicit, entice or induce any Person to cease doing business (or reduce the scope of business) with the Company, to alter the scope or nature of any relationship with the Company, or to engage in a competitive business. "Person" for the purposes of this paragraph means an individual, organization, company, association or entity which, at the time of the Executive's termination of employment for any reason, is doing any business with, or has any employment, contractor, customer, vendor, vendee, or business relationship with, the Company; provided, however, that an individual classified by the Company as an employee and who does not supervise other employees and does not have access to Confidential Information is excluded from the definition of Person. The Executive shall not communicate with any Person for any such purpose or authorize or knowingly approve such communications by any other person or entity.

SECTION 8. REPRESENTATION AND WARRANTY BY THE EXECUTIVE

The Executive hereby represents and warrants to the Company, the same being part of the essence of this Agreement that, as of the date of this Agreement, the Executive is not a party to any agreement, contract, or understanding, and that no facts or circumstances exist, that would in any way restrict or prohibit the Executive in any material way from undertaking or performing any of the Executive's obligations under this Agreement. The foregoing representation and warranty shall remain in effect throughout the term of the Executive's employment hereunder.

SECTION 9. REMEDIES

a. Equitable Relief. The parties acknowledge and agree that irreparable harm would result in the event of a breach or threat of a breach by the Executive of Section 5, 6, 7, or 10 or the making of any untrue representation or warranty by the Executive in this Agreement. Therefore, in such an event, and notwithstanding any other provision of this Agreement:

(i) the Company shall be entitled to a restraining order, order of specific performance, or other injunctive relief, without showing actual damage and without bond or other security; and

(ii) the Company's obligation to make any payment or provide any benefit under this Agreement, including without limitation any severance benefits, shall immediately cease.

b. Remedies Not Exclusive. The Company's remedies under this Section 9 are not exclusive, and shall not prejudice or prohibit any other rights or remedies under this Agreement or otherwise. To the extent required to be enforceable by applicable law, the cessation of the

Company's obligation to make payments or continue benefits under this Section 9 shall be deemed to be in the nature of liquidated damages.

SECTION 10. RETURN OF COMPANY PROPERTY

Immediately upon termination of the term of the Executive's employment or upon the Company's earlier request, the Executive shall return to the Company all Confidential Information and other items described in Section 5 and all originals and copies of any other property or information owned by the Company or relating to its business, that the Executive has in the Executive's possession or under the Executive's control, including all credit cards, papers, books, equipment, files, and samples. To the extent that the Executive made use of the Executive's own personal device(s) (e.g., smartphone, laptop, iPad, thumbdrive, etc.) during and in connection with the term of the Executive's employment, the Executive agrees to deliver such personal device(s) to the Company for review and permit the Company to delete and permanently erase all of the Company's Confidential Information from such personal device(s). The Executive understands that personal information contained on such devices will be subject to the Company's or the Company's designee's review for the purposes of identifying and removing Confidential Information.

SECTION 11. MISCELLANEOUS PROVISIONS

a. Notices. Unless otherwise agreed in writing by a party entitled to notice, all notices required by this Agreement shall be in writing and shall be deemed given when physically delivered to and acknowledged by receipt by a party or its duly authorized attorney or legal representative, or when deposited postage paid, registered or certified mail, addressed to the party at its principal business or residence as set forth in the Company's records or as known to or reasonably ascertainable by the party required to give notice.

b. General Rules of Construction. The parties have participated jointly in negotiating and drafting of this Agreement. If a question concerning intent or interpretation arises, no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of authorship. Any reference to any federal, state, local, or foreign statute or law shall be deemed also to refer to all related rules and regulations unless the context requires otherwise.

c. Meaning of Certain Words. The word "including" shall mean "including without limitation."

d. Waivers. No assent, express or implied, by any party to any breach or default under this Agreement shall constitute a waiver of or assent to any breach or default of any other provision of this Agreement or any breach or default of the same provision on any other occasion.

e. Binding Effect; No Third Party Beneficiaries. This Agreement shall bind and benefit the parties and their respective heirs, devisees, beneficiaries, grantees, donees, legal representatives, successors, and assigns. Nothing in this Agreement shall be construed to confer any rights or benefits on third party beneficiaries.

f. **Assignment.** Neither party may assign this Agreement or any interest herein without the other's prior written consent; provided that the Company may assign its interest to another entity that it controls, is controlled by, or is under common control with or to a successor in interest upon a Change of Control.

g. **Captions.** Titles or captions contained in this Agreement are for convenience and are not intended to affect the substantive meaning of any provision.

h. **Severability.** If any provision of this Agreement, including the Confidential Information provision of this Agreement, is found in binding arbitration or by a court or other tribunal of competent jurisdiction to be invalid or unenforceable, the attempt shall first be made to read that provision in such a way as to make it valid and enforceable in light of the parties' apparent intent as evidenced by this Agreement. If such a reading is impossible, the tribunal having jurisdiction may revise the provision in any reasonable manner, to the extent necessary to make it binding and enforceable. If no such revision is possible, the offending provision shall be deemed stricken from the Agreement, and every other provision shall remain in full force and effect.

i. **Counterparts.** This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

j. **Survival.** The provisions of this Agreement that by their terms are intended to continue beyond the termination of the term of the Executive's employment shall survive such termination of employment and shall continue in effect for the respective periods therein provided or contemplated.

k. **Tax Withholding**. All payments under this Agreement shall be made subject to applicable tax withholding, and the Company shall withhold from any payments under this Agreement all federal, state, and local taxes as the Company is required to withhold pursuant to any law or governmental rule or regulation. The Executive shall be solely responsible for all federal, state, and local taxes due with respect to any payment received under this Agreement or otherwise in connection with the Executive's employment.

l. **Section 409A.** This Agreement is intended to comply with the requirements of Section 409A of the Code and the regulations thereunder ("Section 409A"), and shall in all respects be administered in accordance with Section 409A. Notwithstanding anything in this Agreement to the contrary, distributions may only be made under this Agreement upon an event and in a manner permitted by Section 409A or an applicable exemption. If the payment of severance benefits would otherwise be accelerated under this Agreement and paid in a lump sum upon a Change of Control, and such Change of Control is not a "change in control event" under Section 409A, such severance payments shall not be accelerated and shall instead be paid on the regularly scheduled payment date. Severance benefits provided under this Agreement are intended to be exempt from Section 409A under the "separation pay exception" to the maximum extent applicable. Further, any payments that qualify for the "short-term deferral" exception or another exception under Section 409A shall be paid under the applicable exception. All

separation payments to be made upon a termination of employment under this Agreement may only be made upon a "separation from service" under Section 409A. For purposes of Section 409A, each payment hereunder shall be treated as a separate payment and the right to a series of payments under this Agreement shall be treated as a right to a series of separate payments. With respect to payments that are subject to Section 409A, in no event may the Executive, directly or indirectly, designate the calendar year of a payment, and if a payment that is subject to execution of a Release Agreement could be made in more than one taxable year, payment will be made in the later taxable year. If and to the extent that reimbursements or other in-kind benefits under this Agreement constitute "nonqualified deferred compensation" for purposes of Section 409A, such reimbursements or other in-kind benefits shall be made or provided in accordance with the requirements of Section 409A. Notwithstanding the foregoing, although the Company has made every effort to ensure that the payments and benefits provided under this Agreement comply with Section 409A, in no event shall the Company be liable for all or any portion of any taxes, penalties, interest, or other expenses that may be incurred by the Executive on account of non-compliance with Section 409A.

m. Governing Law. This Agreement shall be governed by and construed under the laws of the United States and the State of New Jersey.

n. Board Information. The Executive shall at all times promptly give to the Board (in writing if so requested) all such information as it may require in connection with matters relating to the Executive's employment or with the Company or the business of the Company.

o. Effective Date. This Agreement shall be effective immediately on the date duly executed by both parties.

p. Full Agreement; Modification. This Agreement supersedes the Prior Agreement and all other consulting and employment arrangements between the Executive and the Company. This Agreement constitutes the entire agreement of the parties concerning its subject matter and supersedes all other oral or written understandings, discussions, and agreements, and may be modified only in a writing signed by both parties. The parties acknowledge that they have read and fully understand the contents of this Agreement and execute it after having an opportunity to consult with legal counsel.

q. Counterparts; Delivery. This Agreement may be executed by the parties in separate counterparts and may be delivered by either or both parties by facsimile or electronic transmission.

(Signature page follows.)

IN WITNESS WHEREOF, and intending to be legally bound hereby, the parties have executed this Agreement to be effective as of the date specified above.

AGILE THERAPEUTICS, INC.

/s/ Al Altomari
Name: Al Altomari

By: /s/ Geoffrey Gilmore
Name: Geoffrey Gilmore
Title: SVP & Chief Administrative Officer

SCHEDULE A

Permitted Activities

Description of Activity	Nature of Work	Hours Per Week	Anticipated Compensation
Insmed, Inc.	Board member, Audit and Compensation (Chair) Committees member	5 board and committee meetings per year	$75,000 per year plus Equity
TASK Soup Kitchen	Board member	9 meetings per year	none
Drexel University	Advisory Board member	4 meetings per year	none

Exhibit 10.34

AMENDED AND RESTATED EMPLOYMENT AGREEMENT

THIS AMENDED AND RESTATED EMPLOYMENT AGREEMENT (this "Agreement") is entered into as of November 1, 2022, by and between AGILE THERAPEUTICS, INC., a Delaware corporation (the "Company"), and Geoffrey P. Gilmore (the "Executive"), collectively referred to as the "parties."

Recitals:

WHEREAS, the Company and the Executive entered into an Employment Agreement dated April 12, 2016, which was subsequently amended and restated on August 13, 2020 (the "Prior Agreement"); and

WHEREAS, the Company desires to continue to employ the Executive and to have the benefit of the Executive's skills and services, and the Executive desires to accept such continued employment with the Company, on the terms and conditions set forth herein; and

WHEREAS, this Agreement shall supersede and replace the Prior Agreement, which shall be of no further force or effect.

NOW, THEREFORE, in consideration of the mutual promises, covenants, and conditions set forth in this Agreement, the parties agree as follows:

SECTION 1. EMPLOYMENT

a. Position. The Company wishes to continue to employ the Executive as Senior Vice President, Chief Administrative Officer of the Company reporting to the Chairman and Chief Executive Officer of the Company, and the Executive hereby agrees to continue in such position for the term of this Agreement and to perform those duties and responsibilities as shall be assigned to the Executive by the Board of Directors of the Company (the "Board") or its designee and that are consistent with the Executive's position.

b. The Executive's Commitment. The Executive shall consider the Executive's employment by the Company as the Executive's principal employment, shall devote the Executive's full working time and attention to the Executive's duties and responsibilities under this Agreement, and shall perform the Executive's duties and responsibilities to the best of the Executive's abilities. While subject to any provision of this Agreement, the Executive shall maintain loyalty to the Company and shall take no action that would directly or indirectly promote any competitor or injure the Company's interests. Subject to the foregoing, the Executive may engage in other business activities to the extent that they do not interfere with the Executive's obligations under this Agreement, provided that each of those activities is first disclosed to and approved by the Board.

c. Principal Place of Employment. The Executive acknowledges and agrees that the Executive's principal place of employment will be in the Company's offices located in Princeton, New Jersey and that the Executive will be required to travel for business in the course of performing his duties for the Company. The Executive will be subject to such on-site work

and remote work policies applicable to similarly situated employees as the Company may establish from time to time.

d. Company Policies. The Executive acknowledges and agrees that the Executive shall be bound by all applicable employment and other policies applicable to similarly situated employees as the Company may establish from time to time.

SECTION 2. TERMINATION OF EMPLOYMENT

a. Term. The term of this Agreement shall commence on the date hereof and shall continue until the Executive's employment with the Company is terminated in accordance with Section 2b, 2c, 2d, or 2e hereof.

b. Termination for "Reasonable Cause." The Executive's employment may be terminated by the Company at any time, without prior notice, upon a showing of "Reasonable Cause," as defined below. Should the Executive's employment be terminated by the Company for "Reasonable Cause," no severance or other unearned compensation shall be payable by the Company to the Executive nor shall the Company be obligated to continue to provide to the Executive at the Company's expense, or reimburse the Executive for, any health insurance benefits after the effective date of the termination. "Reasonable Cause" shall be defined for the purposes of this Agreement as being any of the following:

(i) any act or omission by the Executive that reasonably constitutes dishonesty, disloyalty, fraud, deceit, gross negligence, willful misconduct, or recklessness, including, but not limited to the Executive's willful violation of the Company's bylaws or code of regulations, and that is directly or indirectly materially detrimental to the Company's best interest;

(ii) the Executive's intentional failure to perform any lawful duties assigned to the Executive by the Board or its designee after receiving notice and a reasonable opportunity to cure;

(iii) the commission of any act by the Executive that constitutes a felony under the laws of the United States or the state of the Company's principal place of business; and

(iv) any material breach by the Executive of Section 5, 6, 7, or 8 of this Agreement.

Furthermore, the termination by the Executive of the Executive's employment with the Company for any reason other than for Good Reason pursuant to Section 2d shall be deemed to be a termination of the Executive's employment for "Reasonable Cause" without any notice or other action on the part of the Company.

c. Death or Disability. The Executive's employment shall terminate immediately upon the Executive's death. The Executive's employment shall terminate immediately upon disability of the Executive to the extent consistent with applicable law. For purposes of this

Agreement, the Executive shall be deemed to have a "disability" if, in the reasonable opinion of the Board, the Executive is unable to perform the essential functions of the Executive's job, with or without reasonable accommodation(s), for at least ninety (90) consecutive days because of illness, incapacity, or physical or mental disability, and the Executive's inability to do so perform poses an undue hardship for the Company.

d. Termination by the Executive for Good Reason. The Executive may resign from employment with the Company for Good Reason, but only in accordance with the terms of this Section 2d. "Good Reason" shall be deemed to exist with respect to any termination by the Executive of the Executive's employment for any of the following reasons: (i) the relocation of the office of the Company at which the Executive is principally employed to a location that is more than fifty (50) miles from the location of such office as of the date of this Agreement; (ii) any failure by the Company to comply with any material term of this Agreement; or (iii) the demotion of the Executive to a lesser position than described in Section 1a hereof or a substantial diminution of the Executive's authority, duties, or responsibilities as in effect on the date of this Agreement or as may be hereafter increased; provided, however, that "Good Reason" shall not include a termination of the Executive's employment pursuant to Sections 2b or 2c hereof or, following a Change of Control (as defined in Section 4d below), a reduction in title, position, responsibilities, or duties solely by virtue of the Company being acquired and made part of, or operated as a subsidiary of, a larger company or organization, so long as such new duties and responsibilities are reasonably commensurate with the Executive's experience.

The Executive may not resign with Good Reason pursuant to this Section 2d, and shall not be considered to have done so for any purpose of this Agreement, unless (i) the Executive, within sixty (60) days after the initial existence of the act or failure to act by the Company that constitutes "Good Reason" within the meaning of this Agreement, provides the Company with written notice that describes, in particular detail, the act or failure to act that the Executive believes to constitute "Good Reason" and identifies the particular clause of this Section 2d that the Executive contends is applicable to such act or failure to act; (ii) the Company, within thirty (30) days after its receipt of such notice, fails or refuses to rescind such act or remedy such failure to act so as to eliminate "Good Reason" for the termination by the Executive of the Executive's employment relationship with the Company, and (iii) the Executive actually resigns from employment with the Company on or before that date that is six (6) calendar months after the initial existence of the act or failure to act by the Company that constitutes "Good Reason." If the requirements of the preceding sentence are not fully satisfied on a timely basis, then the resignation by the Executive from the Executive's employment with the Company shall not be deemed to have been for "Good Reason," the Executive shall not be entitled to any of the benefits to which the Executive would have been entitled if the Executive had resigned from employment with the Company for "Good Reason," and the Company shall not be required to pay any amount that would otherwise have been due to the Executive under Section 4a had the Executive resigned with "Good Reason."

e. Other Termination. The Executive's employment may also be terminated by the Company for any reason other than as set forth in Section 2b, 2c, or 2d.

SECTION 3. COMPENSATION, BENEFITS AND EXPENSES

a. Salary. The Company shall pay the Executive an annual base salary at the rate of $450,000 (the "Base Salary"), payable in accordance with the Company's payroll practices in effect from time to time.

b. Bonus. The Executive shall be eligible to receive an annual bonus ("Annual Bonus"). The Executive's Annual Bonus Target shall be 45% of the Executive's Base Salary. Whether the bonus will be awarded to the Executive and the amount of the annual bonus shall be determined by the Board or its Compensation Committee based upon achievement of such goals that shall be established by the Board. The Annual Bonus, if awarded to the Executive, shall be paid within two and one-half (2 ½) months after the close of each fiscal year.

c. Equity Program. The Executive shall be eligible to participate in equity incentive programs established by the Company from time to time in the future to provide stock options and other equity-based incentives to key employees of the Company. All such stock options and other equity-based incentives shall be awarded in the discretion of the Board pursuant to the terms of the Company's Amended and Restated 2014 Incentive Compensation Plan and/or such other plans as shall from time to time be established by the Company (the "Equity Plan").

d. Health and Long-Term Disability Insurance. The Executive shall be entitled to participate in such employee benefit plans (collectively the "Plans") as are implemented by the Company and available to executive officers of the Company. The Company shall have the right, from time to time and in its sole discretion, to modify and amend the Plans and benefits provided to its executive officers and other employees, including the Executive. In addition to any key man insurance taken out by the Company, and provided that the Executive can pass the required physical examinations, during the term of this Agreement the Company shall, at its election, either provide to the Executive or reimburse the Executive for the premiums for term life insurance in an amount equal to two times the sum of the Executive's Base Salary plus target Annual Bonus, up to $1,000,000, with Executive designating the beneficiary of such policy.

e. Paid Time Off. The Executive shall be eligible to participate in the Company's paid time off ("PTO") policy, as may be amended from time to time. Any PTO shall be accrued, used and otherwise governed in accordance with the Company's PTO policy in effect from time to time.

f. Effect of Termination on Salary and Benefits. The Executive's Base Salary and benefits under this Section 3 shall terminate effective immediately on the date of the termination of the Executive's employment by the Company, and from that date the Executive shall be entitled to severance benefits under Section 4 if and only to the extent such benefits are then payable in accordance with the terms and provisions of this Agreement.

g. Effect of Termination on Other Provisions. This Agreement shall continue in effect upon and after the termination of the Executive's employment for any reason necessary to enforce the provisions of this Agreement that apply subsequent to any such termination,

including any provisions relating to confidentiality, invention assignment, non-solicitation, and non-competition.

i. Expense Reimbursement. The Company shall reimburse the Executive for all reasonable out-of-pocket expenses incurred in connection with the Company's business and the Executive's performance of the Executive's obligations under this Agreement, in accordance with the applicable expense reimbursement policy of the Company, upon submission by the Executive to the Company of such written evidence of such expense as the Company may require. Any disputes as to the eligibility of an expense for reimbursement shall be resolved in the sole discretion of the Company.

h. Recovery of Incentive Compensation. Notwithstanding anything herein to the contrary, the Executive agrees that all incentive compensation, including cash and equity awards payable to the Executive under this Agreement or otherwise, shall be subject to any clawback policy adopted or implemented by the Board and all other applicable Company policies, consistent with applicable law.

SECTION 4. PAYMENTS AND BENEFITS UPON TERMINATION

a. Payments and Benefits upon Termination. Subject to the satisfaction of the terms of Section 4b, if during the term of this Agreement (i) the Executive's employment under this Agreement is terminated by the Company pursuant to Section 2e (i.e., other than a termination for Reasonable Cause pursuant to Section 2b or a termination upon death or disability pursuant to Section 2c), or the Executive resigns from employment with the Company with Good Reason pursuant to Section 2d (each a "Qualifying Termination"), or (ii) the Executive's employment under this Agreement terminates due to the Executive's disability pursuant to Section 2c, the Executive shall be entitled to receive from the Company the benefits set forth in subsection (i), (ii), or (iii) below, as applicable.

(i) *Qualifying Termination Not in Connection with a Change of Control*. If the Qualifying Termination occurs prior to the effective date of a Change of Control, or the Qualifying Termination occurs more than twelve (12) months after a Change of Control, the Executive shall be entitled to:

A. continuation of the Executive's Base Salary (at the salary rate then in effect) for twelve (12) months (the "Severance Period"), in accordance with the Company's payroll schedule, commencing on the sixtieth (60th) day after the Executive's effective date of termination, with the first such installment payment including any unpaid severance payments that would have been made on the normal payroll dates occurring during the first sixty (60) days following the date of termination, provided that if there is a Change of Control before all of the payments under this subsection (A) have been paid, such remaining payments shall be accelerated and paid in a lump sum within sixty (60) days following the Change of Control to the extent permitted by section 409A of the Internal Revenue Code of 1986, as amended (the "Code"); and

B. provided that the Executive is eligible for and timely elects to receive continued health coverage under the Company's health plan under the Consolidated Omnibus Budget Reconciliation Act ("COBRA"), and the Executive pays the full monthly COBRA premium cost for such health coverage, the Company shall reimburse the Executive monthly an amount equal to the monthly COBRA premium paid by the Executive, less the amount that the Executive would be required to contribute for similar coverage under the Company's medical plan if the Executive were an active employee for the Company, for the Severance Period, or until the Executive becomes employed by another employer offering any such benefits (whichever is earlier). The Executive agrees to provide the Company with notice of eligibility under another health plan within two (2) weeks of such eligibility. Such amounts shall commence on the sixtieth (60th) day after the Executive's effective date of termination, with the first such installment payment including any unpaid severance payments that would have been made on the normal payroll dates occurring during the first sixty (60) days following the date of termination. Notwithstanding the foregoing, the Company reserves the right to restructure the foregoing reimbursement arrangement in any manner necessary or appropriate to avoid penalties or adverse tax consequences to the Executive or the Company or any affiliate, as determined by the Company in its sole discretion.

(ii) *Qualifying Termination In Connection with Change of Control*. If the Qualifying Termination occurs on the date of, or within 12 months after, the effective date of a Change of Control (a "CoC Qualifying Termination"), the Executive shall be entitled to the same payments and benefits set forth under Section 4a(i) above, except that (A) the Severance Period for purposes of Sections 4a(i)(A) and (B) shall extend for eighteen (18) months instead of twelve (12) months, (B) the continued salary payments in Section 4a(i)(A) shall be paid in a lump sum within sixty (60) days following the Executive's termination date, instead of in the form of installment payments, (C) the Executive shall be entitled to a lump sum payment equal to the Executive's target Annual Bonus for the year in which the Executive's CoC Qualifying Termination occurs, payable within sixty (60) days following the Executive's termination date, and (D) each equity award granted to the Executive under the Equity Plan shall automatically vest in full upon the CoC Qualifying Termination.

(iii) *Disability*. If the Executive's employment under this Agreement terminates due to a disability pursuant to Section 2c, either before or after a Change of Control, the Executive shall be entitled to the same payments and benefits set forth under Section 4a(i) above, provided that if such termination due to a disability is on the date of, or within 12 months after, the effective date of a Change of Control, the continued salary payments in Section 4a(i)(A) shall be paid in a lump sum within sixty (60) days following the Executive's termination date, instead of in the form of installment payments.

(iv) *No Duplication of Benefits*. Notwithstanding anything to the contrary, the Executive shall be eligible to receive payments under subsection (i), (ii), or (iii) of this Section 4a (and, for the avoidance of doubt, shall not be eligible to receive payments under more than one such subsection). Additionally, the Executive shall not be eligible to participate in the Company's Change of Control Severance Plan, or any successor plan.

b. Execution of Release. The Executive shall not be entitled to any payments or benefits under Section 4a unless the Executive executes and does not revoke a Release and Agreement (the "Release"), as drafted by the Company at the time of the Executive's termination of employment, including, but not limited to, the following provisions in favor of the Company and its affiliates and assigns to the maximum extent permitted by applicable law:

(i) an unconditional release of all rights to any claims, charges, complaints, or grievances, known or unknown to the Executive, against the Company, its parent, subsidiary and affiliated companies, and assigns (and others, such as their former and current directors, employees, and agents) (together, the "Released Parties"), through the date of the Executive's termination from employment other than post termination payments and benefits pursuant to this Agreement;

(ii) a representation and warranty that the Executive has not filed or assigned any claims, charges, complaints, or grievances against the Released Parties;

(iii) an agreement not to use, disclose, or make copies of any confidential information of the Company, as well as to return any such confidential information and property to the Company upon execution of the Release; and

(iv) an agreement to indemnify the Released Parties in the event that the Executive breaches any portion of the Agreement or Release.

c. No Admission. The Executive acknowledges such a Release shall not be construed as an admission by the Company or any other releasee of any wrongdoing whatsoever against the Executive, and all of the releasees specifically deny any such wrongdoing.

d. Definition of Change of Control. As used in this Agreement, the term "Change of Control" means:

(i) any merger or consolidation in which voting securities of the Company possessing more than 50% of the total combined voting power of the Company's outstanding securities are transferred to a person or persons different from the person holding those securities immediately prior to such transaction and the composition of the Board following such transaction is such that the directors of the Company prior to the transaction constitute less than 50% of the Board membership following the transaction;

(ii) any acquisition, directly or indirectly, by a person or related group of persons (other than the Company or a person that directly or indirectly controls, is controlled by, or is under common control with, the Company) of beneficial ownership of voting securities of the Company possessing more than 50% of the total combined voting power of the Company's outstanding securities; provided, however, that, no Change of Control shall be deemed to occur by reason of the acquisition of shares of the Company's capital stock by an investor or group of investors in the Company in a capital-raising transaction; or

(iii) any sale, transfer, exclusive worldwide license or other disposition of all or substantially all of the assets of the Company.

e. Parachute Provisions. In the event the Company determines in good faith that any payments or benefits (whether made or provided pursuant to this Agreement or otherwise) ("Total Payments") provided to the Executive would otherwise exceed the amount (the "Safe Harbor Amount") that could be received by the Executive without the imposition of an excise tax under section 4999 of the Internal Revenue Code of 1986, as amended (the "Code"), then the Total Payments shall be reduced to the extent, and only to the extent, necessary to assure that their aggregate present value, as determined in accordance the applicable provisions of section 280G of the Code and the regulations thereunder, does not exceed the greater of the following dollar amounts: (i) the Safe Harbor Amount, or (ii) the greatest after-tax amount payable to the Executive after taking into account any excise tax imposed under section 4999 of the Code on the Total Payments. The Company shall pay all of the fees, including legal and accounting fees, associated with calculating the amounts set forth in this subsection 4e.

SECTION 5. CONFIDENTIALITY AND INVENTIONS

a. Confidential Information. Confidential Information means trade secrets, know-how, and other information relating to the Company's business and not generally available to the public, which is disclosed to the Executive or with which the Executive becomes familiar during the Executive's term of employment with the Company. Confidential Information includes information relating to the Company's business practices and prospective business interests, products, processes, equipment, manufacturing operations, marketing programs, research, product development, and engineering. From the date of this Agreement and during or after the Executive's term of employment, unless the Executive receives the Company's written consent or except as permitted by Section 5(e), the Executive will not disclose, use, disseminate, lecture upon, or publish any part of the Company's Confidential Information, whether or not developed by the Executive. Also, the Executive will have the same obligations with respect to the secret or confidential information of any other company or individual (including the Company's parent company), to which the Executive gains access in connection with the Executive's employment. The Executive agrees that the Executive will not disclose to the Company or induce the Company to use any secret confidential information of others, including former employers, with whom the Executive has obligations of secrecy. The Executive expressly agrees to be solely and individually liable to any of the Executive's previous employers for any breach of the Executive's obligations to those previous employers, contractual or otherwise.

b. Inventions. Inventions means discoveries, improvements, and ideas, whether patentable or not, made by the Executive solely or jointly with others, that relate to the business of the Company, including any of its products, processes, equipment, manufacturing operations, marketing programs, research, product development, or engineering activities. The Executive agrees that the Executive will promptly disclose to the Company all Inventions (including those in the formative stages) that relate to the business of the Company made during the Executive's term of employment whether or not during the Executive's normal working hours. The Executive agrees that the Executive will also promptly disclose to the Company any Inventions

that relate to the business of the Company made during the period of one (1) year after the termination of the term of the Executive's employment that relate to or constitute an improvement upon the Company's Confidential Information. The Executive shall keep and maintain written records concerning such Inventions and make these available to the Company at all times. The Company will hold such written records with the same degree of care as it does with other business documents of a confidential nature.

c. Assignment of Inventions. Inventions made in accordance with this Section 5 shall be the sole and exclusive property of the Company, except that the Executive shall retain full rights and title to any Inventions to which all of the following conditions apply:

(i) no equipment, supplies, facilities, or Confidential Information of the Company was used in the Invention's development;

(ii) the Invention was developed entirely on the Executive's own time;

(iii) the Invention does not relate to the Company's business or to the Company's actual or clearly anticipated research and development program; and

(iv) the Invention does not result from any work performed by the Executive for the Company.

During and after the Executive's term of employment, the Executive or the Executive's legal representative shall, at the Company's request and expense, execute domestic and foreign patent applications and assignments to the Company concerning Inventions owned by the Company under this section, and take all other actions as the Company may request to perfect and maintain the Company's rights in same.

d. Documents. The Executive acknowledges that all originals and copies of drawings, blueprints, manuals, reports, notebooks, computer programs, photographs and any other recorded, written, or printed matter relating to research, manufacturing operations, or the business affairs of the Company made or received by the Executive during the Executive's employment are the property of the Company. The rights comprised in the copyright of any of the above documents made by the Executive during the Executive's employment shall be owned exclusively by the Company. The Executive agrees not to retain such property or copies thereof after termination of the term of the Executive's employment and to promptly surrender such property at any time at the request of the Company. The Executive agrees to similarly return all other property of the Company such as equipment, samples, and models.

e. Permitted Conduct. Nothing in this Agreement, including in this Section 5, restricts or prohibits the Executive or the Executive's counsel from initiating communications directly with, responding to any inquiry from, volunteering information to, or providing testimony before a self-regulatory authority or a governmental, law enforcement, or regulatory authority, including the U.S. Equal Employment Opportunity Commission ("EEOC"), the Department of Labor ("DOL"), the National Labor Relations Board ("NLRB"), the Department of Justice ("DOJ"), the Securities and Exchange Commission ("SEC"), FINRA, the Congress,

and any agency Inspector General (collectively, the "Regulators"), from participating in any reporting of, investigation into, or proceeding regarding suspected violations of law, or from making other disclosures that are protected under the whistleblower provisions of state or federal law or regulation. The Executive does not need the prior authorization of the Company to engage in such communications with the Regulators, respond to such inquiries from the Regulators, provide Confidential Information or documents containing Confidential Information to the Regulators, or make any such reports or disclosures to the Regulators. The Executive is not required to notify the Company that the Executive has engaged in such communications with the Regulators. The Executive recognizes and agrees that, in connection with any such activity outlined above, the Executive must inform the Regulators that the information the Executive is providing is confidential. Despite the foregoing, the Executive is not permitted to reveal to any third-party, including any governmental, law enforcement, or regulatory authority, information the Executive came to learn during the course of the Executive's employment with the Company that is protected from disclosure by any applicable privilege, including but not limited to the attorney-client privilege, attorney work product doctrine, and/or other applicable legal privileges. The Company does not waive any applicable privileges or the right to continue to protect its privileged attorney-client information, attorney work product, and other privileged information. Additionally, the Executive recognizes that the Executive's ability to disclose information may be limited or prohibited by applicable law and the Company does not consent to disclosures that would violate applicable law. Nothing in this Agreement is intended to, or has the effect of, requiring the Executive to conceal facts and details associated with the Executive's own claims of discrimination, harassment or retaliation under the New Jersey Law Against Discrimination ("NJLAD"). Even though the parties may have agreed to keep the settlement and underlying facts confidential, such a provision is unenforceable against the Company if the Executive publicly reveals sufficient details of the claim so that the Company is reasonably identifiable. For the avoidance of doubt, the Executive acknowledges that the Executive's right to discuss the underlying facts and details of the Executive's NJLAD claims, subject to the conditions above, does not negate or diminish any other provision of the Agreement, including but not limited to the Executive's general release of claims and the Executive's agreement to protect and not disclose Confidential Information and/or privileged information and to keep the specific terms of any agreement (e.g., settlement payments and other consideration) confidential.

SECTION 6. RESTRICTIVE COVENANT

During the Restricted Period, the Executive shall not engage, directly or indirectly, in any "competitive business." As used in this Agreement, a "competitive business" shall mean any business that is engaged, directly or indirectly, in the research, development, manufacturing, distribution, licensing or sale of technology, products, or services relating to hormonal contraception in the United States and any other geographic region in which the Company conducts business or, at the time of the Executive's termination from employment for any reason, plans to conduct business; provided, however, that a "competitive business" shall not include the acquiring, surviving, or licensing company in a Change of Control transaction if the Executive shall become an employee of or a consultant to such company with the knowledge and consent of the Company. For purposes of this Agreement, the term "Restricted Period" shall mean the period from and after the date of this Agreement and through the twelve (12) month

period after the termination of the term of the Executive's employment hereunder, provided that the Restricted Period shall be for a period of eighteen (18) months (instead of twelve (12) months) after the termination of the term of the Executive's employment hereunder if the Executive has a CoC Qualifying Termination.

SECTION 7. NON-SOLICITATION

During the Restricted Period, the Executive shall not, directly or indirectly, solicit, entice or induce any Person to cease doing business (or reduce the scope of business) with the Company, to alter the scope or nature of any relationship with the Company, or to engage in a competitive business. "Person" for the purposes of this paragraph means an individual, organization, company, association or entity which, at the time of the Executive's termination of employment for any reason, is doing any business with, or has any employment, contractor, customer, vendor, vendee, or business relationship with, the Company; provided, however, that an individual classified by the Company as an employee and who does not supervise other employees and does not have access to Confidential Information is excluded from the definition of Person. The Executive shall not communicate with any Person for any such purpose or authorize or knowingly approve such communications by any other person or entity.

SECTION 8. REPRESENTATION AND WARRANTY BY THE EXECUTIVE

The Executive hereby represents and warrants to the Company, the same being part of the essence of this Agreement that, as of the date of this Agreement, the Executive is not a party to any agreement, contract, or understanding, and that no facts or circumstances exist, that would in any way restrict or prohibit the Executive in any material way from undertaking or performing any of the Executive's obligations under this Agreement. The foregoing representation and warranty shall remain in effect throughout the term of the Executive's employment hereunder.

SECTION 9. REMEDIES

a. Equitable Relief. The parties acknowledge and agree that irreparable harm would result in the event of a breach or threat of a breach by the Executive of Section 5, 6, 7, or 10 or the making of any untrue representation or warranty by the Executive in this Agreement. Therefore, in such an event, and notwithstanding any other provision of this Agreement:

(i) the Company shall be entitled to a restraining order, order of specific performance, or other injunctive relief, without showing actual damage and without bond or other security; and

(ii) the Company's obligation to make any payment or provide any benefit under this Agreement, including without limitation any severance benefits, shall immediately cease.

b. Remedies Not Exclusive. The Company's remedies under this Section 9 are not exclusive, and shall not prejudice or prohibit any other rights or remedies under this Agreement or otherwise. To the extent required to be enforceable by applicable law, the cessation of the

Company's obligation to make payments or continue benefits under this Section 9 shall be deemed to be in the nature of liquidated damages.

SECTION 10. RETURN OF COMPANY PROPERTY

Immediately upon termination of the term of the Executive's employment or upon the Company's earlier request, the Executive shall return to the Company all Confidential Information and other items described in Section 5 and all originals and copies of any other property or information owned by the Company or relating to its business, that the Executive has in the Executive's possession or under the Executive's control, including all credit cards, papers, books, equipment, files, and samples. To the extent that the Executive made use of the Executive's own personal device(s) (e.g., smartphone, laptop, iPad, thumbdrive, etc.) during and in connection with the term of the Executive's employment, the Executive agrees to deliver such personal device(s) to the Company for review and permit the Company to delete and permanently erase all of the Company's Confidential Information from such personal device(s). The Executive understands that personal information contained on such devices will be subject to the Company's or the Company's designee's review for the purposes of identifying and removing Confidential Information.

SECTION 11. MISCELLANEOUS PROVISIONS

a. Notices. Unless otherwise agreed in writing by a party entitled to notice, all notices required by this Agreement shall be in writing and shall be deemed given when physically delivered to and acknowledged by receipt by a party or its duly authorized attorney or legal representative, or when deposited postage paid, registered or certified mail, addressed to the party at its principal business or residence as set forth in the Company's records or as known to or reasonably ascertainable by the party required to give notice.

b. General Rules of Construction. The parties have participated jointly in negotiating and drafting of this Agreement. If a question concerning intent or interpretation arises, no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of authorship. Any reference to any federal, state, local, or foreign statute or law shall be deemed also to refer to all related rules and regulations unless the context requires otherwise.

c. Meaning of Certain Words. The word "including" shall mean "including without limitation."

d. Waivers. No assent, express or implied, by any party to any breach or default under this Agreement shall constitute a waiver of or assent to any breach or default of any other provision of this Agreement or any breach or default of the same provision on any other occasion.

e. Binding Effect; No Third Party Beneficiaries. This Agreement shall bind and benefit the parties and their respective heirs, devisees, beneficiaries, grantees, donees, legal representatives, successors, and assigns. Nothing in this Agreement shall be construed to confer any rights or benefits on third party beneficiaries.

f. **Assignment.** Neither party may assign this Agreement or any interest herein without the other's prior written consent; provided that the Company may assign its interest to another entity that it controls, is controlled by, or is under common control with or to a successor in interest upon a Change of Control.

g. **Captions.** Titles or captions contained in this Agreement are for convenience and are not intended to affect the substantive meaning of any provision.

h. **Severability.** If any provision of this Agreement, including the Confidential Information provision of this Agreement, is found in binding arbitration or by a court or other tribunal of competent jurisdiction to be invalid or unenforceable, the attempt shall first be made to read that provision in such a way as to make it valid and enforceable in light of the parties' apparent intent as evidenced by this Agreement. If such a reading is impossible, the tribunal having jurisdiction may revise the provision in any reasonable manner, to the extent necessary to make it binding and enforceable. If no such revision is possible, the offending provision shall be deemed stricken from the Agreement, and every other provision shall remain in full force and effect.

i. **Counterparts.** This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

j. **Survival.** The provisions of this Agreement that by their terms are intended to continue beyond the termination of the term of the Executive's employment shall survive such termination of employment and shall continue in effect for the respective periods therein provided or contemplated.

k. **Tax Withholding**. All payments under this Agreement shall be made subject to applicable tax withholding, and the Company shall withhold from any payments under this Agreement all federal, state, and local taxes as the Company is required to withhold pursuant to any law or governmental rule or regulation. The Executive shall be solely responsible for all federal, state, and local taxes due with respect to any payment received under this Agreement or otherwise in connection with the Executive's employment.

l. **Section 409A.** This Agreement is intended to comply with the requirements of Section 409A of the Code and the regulations thereunder ("Section 409A"), and shall in all respects be administered in accordance with Section 409A. Notwithstanding anything in this Agreement to the contrary, distributions may only be made under this Agreement upon an event and in a manner permitted by Section 409A or an applicable exemption. If the payment of severance benefits would otherwise be accelerated under this Agreement and paid in a lump sum upon a Change of Control, and such Change of Control is not a "change in control event" under Section 409A, such severance payments shall not be accelerated and shall instead be paid on the regularly scheduled payment date. Severance benefits provided under this Agreement are intended to be exempt from Section 409A under the "separation pay exception" to the maximum extent applicable. Further, any payments that qualify for the "short-term deferral" exception or another exception under Section 409A shall be paid under the applicable exception. All

separation payments to be made upon a termination of employment under this Agreement may only be made upon a "separation from service" under Section 409A. For purposes of Section 409A, each payment hereunder shall be treated as a separate payment and the right to a series of payments under this Agreement shall be treated as a right to a series of separate payments. With respect to payments that are subject to Section 409A, in no event may the Executive, directly or indirectly, designate the calendar year of a payment, and if a payment that is subject to execution of a Release Agreement could be made in more than one taxable year, payment will be made in the later taxable year. If and to the extent that reimbursements or other in-kind benefits under this Agreement constitute "nonqualified deferred compensation" for purposes of Section 409A, such reimbursements or other in-kind benefits shall be made or provided in accordance with the requirements of Section 409A. Notwithstanding the foregoing, although the Company has made every effort to ensure that the payments and benefits provided under this Agreement comply with Section 409A, in no event shall the Company be liable for all or any portion of any taxes, penalties, interest, or other expenses that may be incurred by the Executive on account of non-compliance with Section 409A.

m. Governing Law. This Agreement shall be governed by and construed under the laws of the United States and the State of New Jersey.

n. Board Information. The Executive shall at all times promptly give to the Board (in writing if so requested) all such information as it may require in connection with matters relating to the Executive's employment or with the Company or the business of the Company.

o. Effective Date. This Agreement shall be effective immediately on the date duly executed by both parties.

p. Full Agreement; Modification. This Agreement supersedes the Prior Agreement and all other consulting and employment arrangements between the Executive and the Company. This Agreement constitutes the entire agreement of the parties concerning its subject matter and supersedes all other oral or written understandings, discussions, and agreements, and may be modified only in a writing signed by both parties. The parties acknowledge that they have read and fully understand the contents of this Agreement and execute it after having an opportunity to consult with legal counsel.

q. Counterparts; Delivery. This Agreement may be executed by the parties in separate counterparts and may be delivered by either or both parties by facsimile or electronic transmission.

(Signature page follows.)

IN WITNESS WHEREOF, and intending to be legally bound hereby, the parties have executed this Agreement to be effective as of the date specified above.

AGILE THERAPEUTICS, INC.

/s/ Geoffrey P. Gilmore
Name: Geoffrey P. Gilmore

By: /s/ Al Altomari
Name: Al Altomari
Title: Chairman and Chief Executive Officer

Exhibit 10.35

AMENDED AND RESTATED EMPLOYMENT AGREEMENT

THIS AMENDED AND RESTATED EMPLOYMENT AGREEMENT (this "Agreement") is entered into as of November 1, 2022, by and between AGILE THERAPEUTICS, INC., a Delaware corporation (the "Company"), and Paul Korner, M.D. (the "Executive"), collectively referred to as the "parties."

Recitals:

WHEREAS, the Company and the Executive entered into an Employment Agreement dated August 17, 2020 (the "Prior Agreement"); and

WHEREAS, the Company desires to continue to employ the Executive and to have the benefit of the Executive's skills and services, and the Executive desires to accept such continued employment with the Company, on the terms and conditions set forth herein; and

WHEREAS, this Agreement shall supersede and replace the Prior Agreement, which shall be of no further force or effect.

NOW, THEREFORE, in consideration of the mutual promises, covenants, and conditions set forth in this Agreement, the parties agree as follows:

SECTION 1. EMPLOYMENT

a. Position. The Company wishes to continue to employ the Executive as Senior Vice President and Chief Medical Officer the Company reporting to the Chairman and Chief Executive Officer of the Company, and the Executive hereby agrees to continue in such position for the term of this Agreement and to perform those duties and responsibilities as shall be assigned to the Executive by the Board of Directors of the Company (the "Board") or its designee and that are consistent with the Executive's position.

b. The Executive's Commitment. The Executive shall consider the Executive's employment by the Company as the Executive's principal employment, shall devote the Executive's full working time and attention to the Executive's duties and responsibilities under this Agreement, and shall perform the Executive's duties and responsibilities to the best of the Executive's abilities. While subject to any provision of this Agreement, the Executive shall maintain loyalty to the Company and shall take no action that would directly or indirectly promote any competitor or injure the Company's interests. Subject to the foregoing, the Executive may engage in other business activities to the extent that they do not interfere with the Executive's obligations under this Agreement, provided that each of those activities is first disclosed to and approved by the Board. Schedule A to this Agreement contains a list of the other business activities in which the Executive is currently engaged and, to the extent applicable, the dates by which certain of those activities will be terminated.

c. Principal Place of Employment. The Executive acknowledges and agrees that the Executive's principal place of employment will be in the Company's offices located in Princeton, New Jersey and that the Executive will be required to travel for business in the course

of performing his duties for the Company. The Executive will be subject to such on-site work and remote work policies applicable to similarly situated employees as the Company may establish from time to time.

d. Company Policies. The Executive acknowledges and agrees that the Executive shall be bound by all applicable employment and other policies applicable to similarly situated employees as the Company may establish from time to time.

SECTION 2. TERMINATION OF EMPLOYMENT

a. Term. The term of this Agreement shall commence on the date hereof and shall continue until the Executive's employment with the Company is terminated in accordance with Section 2b, 2c, 2d, or 2e hereof.

b. Termination for "Reasonable Cause." The Executive's employment may be terminated by the Company at any time, without prior notice, upon a showing of "Reasonable Cause," as defined below. Should the Executive's employment be terminated by the Company for "Reasonable Cause," no severance or other unearned compensation shall be payable by the Company to the Executive nor shall the Company be obligated to continue to provide to the Executive at the Company's expense, or reimburse the Executive for, any health insurance benefits after the effective date of the termination. "Reasonable Cause" shall be defined for the purposes of this Agreement as being any of the following:

(i) any act or omission by the Executive that reasonably constitutes dishonesty, disloyalty, fraud, deceit, gross negligence, willful misconduct, or recklessness, including, but not limited to the Executive's willful violation of the Company's bylaws or code of regulations, and that is directly or indirectly materially detrimental to the Company's best interest;

(ii) the Executive's intentional failure to perform any lawful duties assigned to the Executive by the Board or its designee after receiving notice and a reasonable opportunity to cure;

(iii) the commission of any act by the Executive that constitutes a felony under the laws of the United States or the state of the Company's principal place of business; and

(iv) any material breach by the Executive of Section 5, 6, 7, or 8 of this Agreement.

Furthermore, the termination by the Executive of the Executive's employment with the Company for any reason other than for Good Reason pursuant to Section 2d shall be deemed to be a termination of the Executive's employment for "Reasonable Cause" without any notice or other action on the part of the Company.

c. Death or Disability. The Executive's employment shall terminate immediately upon the Executive's death. The Executive's employment shall terminate immediately upon

disability of the Executive to the extent consistent with applicable law. For purposes of this Agreement, the Executive shall be deemed to have a "disability" if, in the reasonable opinion of the Board, the Executive is unable to perform the essential functions of the Executive's job, with or without reasonable accommodation(s), for at least ninety (90) consecutive days because of illness, incapacity, or physical or mental disability, and the Executive's inability to do so perform poses an undue hardship for the Company.

d. Termination by the Executive for Good Reason. The Executive may resign from employment with the Company for Good Reason, but only in accordance with the terms of this Section 2d. "Good Reason" shall be deemed to exist with respect to any termination by the Executive of the Executive's employment for any of the following reasons: (i) the relocation of the office of the Company at which the Executive is principally employed to a location that is more than fifty (50) miles from the location of such office as of the date of this Agreement; (ii) any failure by the Company to comply with any material term of this Agreement; or (iii) the demotion of the Executive to a lesser position than described in Section 1a hereof or a substantial diminution of the Executive's authority, duties, or responsibilities as in effect on the date of this Agreement or as may be hereafter increased; provided, however, that "Good Reason" shall not include a termination of the Executive's employment pursuant to Sections 2b or 2c hereof or, following a Change of Control (as defined in Section 4d below), a reduction in title, position, responsibilities, or duties solely by virtue of the Company being acquired and made part of, or operated as a subsidiary of, a larger company or organization, so long as such new duties and responsibilities are reasonably commensurate with the Executive's experience.

The Executive may not resign with Good Reason pursuant to this Section 2d, and shall not be considered to have done so for any purpose of this Agreement, unless (i) the Executive, within sixty (60) days after the initial existence of the act or failure to act by the Company that constitutes "Good Reason" within the meaning of this Agreement, provides the Company with written notice that describes, in particular detail, the act or failure to act that the Executive believes to constitute "Good Reason" and identifies the particular clause of this Section 2d that the Executive contends is applicable to such act or failure to act; (ii) the Company, within thirty (30) days after its receipt of such notice, fails or refuses to rescind such act or remedy such failure to act so as to eliminate "Good Reason" for the termination by the Executive of the Executive's employment relationship with the Company, and (iii) the Executive actually resigns from employment with the Company on or before that date that is six (6) calendar months after the initial existence of the act or failure to act by the Company that constitutes "Good Reason." If the requirements of the preceding sentence are not fully satisfied on a timely basis, then the resignation by the Executive from the Executive's employment with the Company shall not be deemed to have been for "Good Reason," the Executive shall not be entitled to any of the benefits to which the Executive would have been entitled if the Executive had resigned from employment with the Company for "Good Reason," and the Company shall not be required to pay any amount that would otherwise have been due to the Executive under Section 4a had the Executive resigned with "Good Reason."

e. Other Termination. The Executive's employment may also be terminated by the Company for any reason other than as set forth in Section 2b, 2c, or 2d.

SECTION 3. COMPENSATION, BENEFITS AND EXPENSES

a. Salary. The Company shall pay the Executive an annual base salary at the rate of $425,000 (the "Base Salary"), payable in accordance with the Company's payroll practices in effect from time to time.

b. Bonus. The Executive shall be eligible to receive an annual bonus ("Annual Bonus"). The Executive's Annual Bonus Target shall be 45% of the Executive's Base Salary. Whether the bonus will be awarded to the Executive and the amount of the annual bonus shall be determined by the Board or its Compensation Committee based upon achievement of such goals that shall be established by the Board. The Annual Bonus, if awarded to the Executive, shall be paid within two and one-half (2 ½) months after the close of each fiscal year.

c. Equity Program. The Executive shall be eligible to participate in equity incentive programs established by the Company from time to time in the future to provide stock options and other equity-based incentives to key employees of the Company. All such stock options and other equity-based incentives shall be awarded in the discretion of the Board pursuant to the terms of the Company's Amended and Restated 2014 Incentive Compensation Plan and/or such other plans as shall from time to time be established by the Company (the "Equity Plan").

d. Health and Long-Term Disability Insurance. The Executive shall be entitled to participate in such employee benefit plans (collectively the "Plans") as are implemented by the Company and available to executive officers of the Company. The Company shall have the right, from time to time and in its sole discretion, to modify and amend the Plans and benefits provided to its executive officers and other employees, including the Executive. In addition to any key man insurance taken out by the Company, and provided that the Executive can pass the required physical examinations, during the term of this Agreement the Company shall, at its election, either provide to the Executive or reimburse the Executive for the premiums for term life insurance in an amount equal to two times the sum of the Executive's Base Salary plus target Annual Bonus, up to $1,000,000, with Executive designating the beneficiary of such policy.

e. Paid Time Off. The Executive shall be eligible to participate in the Company's paid time off ("PTO") policy, as may be amended from time to time. Any PTO shall be accrued, used and otherwise governed in accordance with the Company's PTO policy in effect from time to time.

f. Effect of Termination on Salary and Benefits. The Executive's Base Salary and benefits under this Section 3 shall terminate effective immediately on the date of the termination of the Executive's employment by the Company, and from that date the Executive shall be entitled to severance benefits under Section 4 if and only to the extent such benefits are then payable in accordance with the terms and provisions of this Agreement.

g. Effect of Termination on Other Provisions. This Agreement shall continue in effect upon and after the termination of the Executive's employment for any reason necessary to enforce the provisions of this Agreement that apply subsequent to any such termination,

including any provisions relating to confidentiality, invention assignment, non-solicitation, and non-competition.

i. Expense Reimbursement. The Company shall reimburse the Executive for all reasonable out-of-pocket expenses incurred in connection with the Company's business and the Executive's performance of the Executive's obligations under this Agreement, in accordance with the applicable expense reimbursement policy of the Company, upon submission by the Executive to the Company of such written evidence of such expense as the Company may require. Any disputes as to the eligibility of an expense for reimbursement shall be resolved in the sole discretion of the Company.

h. Recovery of Incentive Compensation. Notwithstanding anything herein to the contrary, the Executive agrees that all incentive compensation, including cash and equity awards payable to the Executive under this Agreement or otherwise, shall be subject to any clawback policy adopted or implemented by the Board and all other applicable Company policies, consistent with applicable law.

SECTION 4. PAYMENTS AND BENEFITS UPON TERMINATION

a. Payments and Benefits upon Termination. Subject to the satisfaction of the terms of Section 4b, if during the term of this Agreement (i) the Executive's employment under this Agreement is terminated by the Company pursuant to Section 2e (i.e., other than a termination for Reasonable Cause pursuant to Section 2b or a termination upon death or disability pursuant to Section 2c), or the Executive resigns from employment with the Company with Good Reason pursuant to Section 2d (each a "Qualifying Termination"), or (ii) the Executive's employment under this Agreement terminates due to the Executive's disability pursuant to Section 2c, the Executive shall be entitled to receive from the Company the benefits set forth in subsection (i), (ii), or (iii) below, as applicable.

(i) *Qualifying Termination Not in Connection with a Change of Control*. If the Qualifying Termination occurs prior to the effective date of a Change of Control, or the Qualifying Termination occurs more than twelve (12) months after a Change of Control, the Executive shall be entitled to:

A. continuation of the Executive's Base Salary (at the salary rate then in effect) for twelve (12) months (the "Severance Period"), in accordance with the Company's payroll schedule, commencing on the sixtieth (60th) day after the Executive's effective date of termination, with the first such installment payment including any unpaid severance payments that would have been made on the normal payroll dates occurring during the first sixty (60) days following the date of termination, provided that if there is a Change of Control before all of the payments under this subsection (A) have been paid, such remaining payments shall be accelerated and paid in a lump sum within sixty (60) days following the Change of Control to the extent permitted by section 409A of the Internal Revenue Code of 1986, as amended (the "Code"); and

B. provided that the Executive is eligible for and timely elects to receive continued health coverage under the Company's health plan under the Consolidated

Omnibus Budget Reconciliation Act ("COBRA"), and the Executive pays the full monthly COBRA premium cost for such health coverage, the Company shall reimburse the Executive monthly an amount equal to the monthly COBRA premium paid by the Executive, less the amount that the Executive would be required to contribute for similar coverage under the Company's medical plan if the Executive were an active employee for the Company, for the Severance Period, or until the Executive becomes employed by another employer offering any such benefits (whichever is earlier). The Executive agrees to provide the Company with notice of eligibility under another health plan within two (2) weeks of such eligibility. Such amounts shall commence on the sixtieth (60th) day after the Executive's effective date of termination, with the first such installment payment including any unpaid severance payments that would have been made on the normal payroll dates occurring during the first sixty (60) days following the date of termination. Notwithstanding the foregoing, the Company reserves the right to restructure the foregoing reimbursement arrangement in any manner necessary or appropriate to avoid penalties or adverse tax consequences to the Executive or the Company or any affiliate, as determined by the Company in its sole discretion.

(ii) *Qualifying Termination In Connection with Change of Control*. If the Qualifying Termination occurs on the date of, or within 12 months after, the effective date of a Change of Control (a "CoC Qualifying Termination"), the Executive shall be entitled to the same payments and benefits set forth under Section 4a(i) above, except that (A) the Severance Period for purposes of Sections 4a(i)(A) and (B) shall extend for eighteen (18) months instead of twelve (12) months, (B) the continued salary payments in Section 4a(i)(A) shall be paid in a lump sum within sixty (60) days following the Executive's termination date, instead of in the form of installment payments, (C) the Executive shall be entitled to a lump sum payment equal to the Executive's target Annual Bonus for the year in which the Executive's CoC Qualifying Termination occurs, payable within sixty (60) days following the Executive's termination date, and (D) each equity award granted to the Executive under the Equity Plan shall automatically vest in full upon the CoC Qualifying Termination.

(iii) *Disability*. If the Executive's employment under this Agreement terminates due to a disability pursuant to Section 2c, either before or after a Change of Control, the Executive shall be entitled to the same payments and benefits set forth under Section 4a(i) above, provided that if such termination due to a disability is on the date of, or within 12 months after, the effective date of a Change of Control, the continued salary payments in Section 4a(i)(A) shall be paid in a lump sum within sixty (60) days following the Executive's termination date, instead of in the form of installment payments.

(iv) *No Duplication of Benefits*. Notwithstanding anything to the contrary, the Executive shall be eligible to receive payments under subsection (i), (ii), or (iii) of this Section 4a (and, for the avoidance of doubt, shall not be eligible to receive payments under more than one such subsection). Additionally, the Executive shall not be eligible to participate in the Company's Change of Control Severance Plan, or any successor plan.

b. Execution of Release. The Executive shall not be entitled to any payments or benefits under Section 4a unless the Executive executes and does not revoke a Release and Agreement (the "Release"), as drafted by the Company at the time of the Executive's termination

of employment, including, but not limited to, the following provisions in favor of the Company and its affiliates and assigns to the maximum extent permitted by applicable law:

(i) an unconditional release of all rights to any claims, charges, complaints, or grievances, known or unknown to the Executive, against the Company, its parent, subsidiary and affiliated companies, and assigns (and others, such as their former and current directors, employees, and agents) (together, the "Released Parties"), through the date of the Executive's termination from employment other than post termination payments and benefits pursuant to this Agreement;

(ii) a representation and warranty that the Executive has not filed or assigned any claims, charges, complaints, or grievances against the Released Parties;

(iii) an agreement not to use, disclose, or make copies of any confidential information of the Company, as well as to return any such confidential information and property to the Company upon execution of the Release; and

(iv) an agreement to indemnify the Released Parties in the event that the Executive breaches any portion of the Agreement or Release.

c. No Admission. The Executive acknowledges such a Release shall not be construed as an admission by the Company or any other releasee of any wrongdoing whatsoever against the Executive, and all of the releasees specifically deny any such wrongdoing.

d. Definition of Change of Control. As used in this Agreement, the term "Change of Control" means:

(i) any merger or consolidation in which voting securities of the Company possessing more than 50% of the total combined voting power of the Company's outstanding securities are transferred to a person or persons different from the person holding those securities immediately prior to such transaction and the composition of the Board following such transaction is such that the directors of the Company prior to the transaction constitute less than 50% of the Board membership following the transaction;

(ii) any acquisition, directly or indirectly, by a person or related group of persons (other than the Company or a person that directly or indirectly controls, is controlled by, or is under common control with, the Company) of beneficial ownership of voting securities of the Company possessing more than 50% of the total combined voting power of the Company's outstanding securities; provided, however, that, no Change of Control shall be deemed to occur by reason of the acquisition of shares of the Company's capital stock by an investor or group of investors in the Company in a capital-raising transaction; or

(iii) any sale, transfer, exclusive worldwide license or other disposition of all or substantially all of the assets of the Company.

e. Parachute Provisions. In the event the Company determines in good faith that any payments or benefits (whether made or provided pursuant to this Agreement or otherwise)

("Total Payments") provided to the Executive would otherwise exceed the amount (the "Safe Harbor Amount") that could be received by the Executive without the imposition of an excise tax under section 4999 of the Internal Revenue Code of 1986, as amended (the "Code"), then the Total Payments shall be reduced to the extent, and only to the extent, necessary to assure that their aggregate present value, as determined in accordance the applicable provisions of section 280G of the Code and the regulations thereunder, does not exceed the greater of the following dollar amounts: (i) the Safe Harbor Amount, or (ii) the greatest after-tax amount payable to the Executive after taking into account any excise tax imposed under section 4999 of the Code on the Total Payments. The Company shall pay all of the fees, including legal and accounting fees, associated with calculating the amounts set forth in this subsection 4e.

SECTION 5. CONFIDENTIALITY AND INVENTIONS

a. Confidential Information. Confidential Information means trade secrets, know-how, and other information relating to the Company's business and not generally available to the public, which is disclosed to the Executive or with which the Executive becomes familiar during the Executive's term of employment with the Company. Confidential Information includes information relating to the Company's business practices and prospective business interests, products, processes, equipment, manufacturing operations, marketing programs, research, product development, and engineering. From the date of this Agreement and during or after the Executive's term of employment, unless the Executive receives the Company's written consent or except as permitted by Section 5(e), the Executive will not disclose, use, disseminate, lecture upon, or publish any part of the Company's Confidential Information, whether or not developed by the Executive. Also, the Executive will have the same obligations with respect to the secret or confidential information of any other company or individual (including the Company's parent company), to which the Executive gains access in connection with the Executive's employment. The Executive agrees that the Executive will not disclose to the Company or induce the Company to use any secret confidential information of others, including former employers, with whom the Executive has obligations of secrecy. The Executive expressly agrees to be solely and individually liable to any of the Executive's previous employers for any breach of the Executive's obligations to those previous employers, contractual or otherwise.

b. Inventions. Inventions means discoveries, improvements, and ideas, whether patentable or not, made by the Executive solely or jointly with others, that relate to the business of the Company, including any of its products, processes, equipment, manufacturing operations, marketing programs, research, product development, or engineering activities. The Executive agrees that the Executive will promptly disclose to the Company all Inventions (including those in the formative stages) that relate to the business of the Company made during the Executive's term of employment whether or not during the Executive's normal working hours. The Executive agrees that the Executive will also promptly disclose to the Company any Inventions that relate to the business of the Company made during the period of one (1) year after the termination of the term of the Executive's employment that relate to or constitute an improvement upon the Company's Confidential Information. The Executive shall keep and maintain written records concerning such Inventions and make these available to the Company at all times. The Company will hold such written records with the same degree of care as it does with other business documents of a confidential nature.

c. Assignment of Inventions. Inventions made in accordance with this Section 5 shall be the sole and exclusive property of the Company, except that the Executive shall retain full rights and title to any Inventions to which all of the following conditions apply:

(i) no equipment, supplies, facilities, or Confidential Information of the Company was used in the Invention's development;

(ii) the Invention was developed entirely on the Executive's own time;

(iii) the Invention does not relate to the Company's business or to the Company's actual or clearly anticipated research and development program; and

(iv) the Invention does not result from any work performed by the Executive for the Company.

During and after the Executive's term of employment, the Executive or the Executive's legal representative shall, at the Company's request and expense, execute domestic and foreign patent applications and assignments to the Company concerning Inventions owned by the Company under this section, and take all other actions as the Company may request to perfect and maintain the Company's rights in same.

d. Documents. The Executive acknowledges that all originals and copies of drawings, blueprints, manuals, reports, notebooks, computer programs, photographs and any other recorded, written, or printed matter relating to research, manufacturing operations, or the business affairs of the Company made or received by the Executive during the Executive's employment are the property of the Company. The rights comprised in the copyright of any of the above documents made by the Executive during the Executive's employment shall be owned exclusively by the Company. The Executive agrees not to retain such property or copies thereof after termination of the term of the Executive's employment and to promptly surrender such property at any time at the request of the Company. The Executive agrees to similarly return all other property of the Company such as equipment, samples, and models.

e. Permitted Conduct. Nothing in this Agreement, including in this Section 5, restricts or prohibits the Executive or the Executive's counsel from initiating communications directly with, responding to any inquiry from, volunteering information to, or providing testimony before a self-regulatory authority or a governmental, law enforcement, or regulatory authority, including the U.S. Equal Employment Opportunity Commission ("EEOC"), the Department of Labor ("DOL"), the National Labor Relations Board ("NLRB"), the Department of Justice ("DOJ"), the Securities and Exchange Commission ("SEC"), FINRA, the Congress, and any agency Inspector General (collectively, the "Regulators"), from participating in any reporting of, investigation into, or proceeding regarding suspected violations of law, or from making other disclosures that are protected under the whistleblower provisions of state or federal law or regulation. The Executive does not need the prior authorization of the Company to engage in such communications with the Regulators, respond to such inquiries from the Regulators, provide Confidential Information or documents containing Confidential Information to the Regulators, or make any such reports or disclosures to the Regulators. The Executive is not required to notify the Company that the Executive has engaged in such communications with

the Regulators. The Executive recognizes and agrees that, in connection with any such activity outlined above, the Executive must inform the Regulators that the information the Executive is providing is confidential. Despite the foregoing, the Executive is not permitted to reveal to any third-party, including any governmental, law enforcement, or regulatory authority, information the Executive came to learn during the course of the Executive's employment with the Company that is protected from disclosure by any applicable privilege, including but not limited to the attorney-client privilege, attorney work product doctrine, and/or other applicable legal privileges. The Company does not waive any applicable privileges or the right to continue to protect its privileged attorney-client information, attorney work product, and other privileged information. Additionally, the Executive recognizes that the Executive's ability to disclose information may be limited or prohibited by applicable law and the Company does not consent to disclosures that would violate applicable law. Nothing in this Agreement is intended to, or has the effect of, requiring the Executive to conceal facts and details associated with the Executive's own claims of discrimination, harassment or retaliation under the New Jersey Law Against Discrimination ("NJLAD"). Even though the parties may have agreed to keep the settlement and underlying facts confidential, such a provision is unenforceable against the Company if the Executive publicly reveals sufficient details of the claim so that the Company is reasonably identifiable. For the avoidance of doubt, the Executive acknowledges that the Executive's right to discuss the underlying facts and details of the Executive's NJLAD claims, subject to the conditions above, does not negate or diminish any other provision of the Agreement, including but not limited to the Executive's general release of claims and the Executive's agreement to protect and not disclose Confidential Information and/or privileged information and to keep the specific terms of any agreement (e.g., settlement payments and other consideration) confidential.

SECTION 6. RESTRICTIVE COVENANT

During the Restricted Period, the Executive shall not engage, directly or indirectly, in any "competitive business." As used in this Agreement, a "competitive business" shall mean any business that is engaged, directly or indirectly, in the research, development, manufacturing, distribution, licensing or sale of technology, products, or services relating to hormonal contraception in the United States and any other geographic region in which the Company conducts business or, at the time of the Executive's termination from employment for any reason, plans to conduct business; provided, however, that a "competitive business" shall not include the acquiring, surviving, or licensing company in a Change of Control transaction if the Executive shall become an employee of or a consultant to such company with the knowledge and consent of the Company. For purposes of this Agreement, the term "Restricted Period" shall mean the period from and after the date of this Agreement and through the twelve (12) month period after the termination of the term of the Executive's employment hereunder, provided that the Restricted Period shall be for a period of eighteen (18) months (instead of twelve (12) months) after the termination of the term of the Executive's employment hereunder if the Executive has a CoC Qualifying Termination.

SECTION 7. NON-SOLICITATION

During the Restricted Period, the Executive shall not, directly or indirectly, solicit, entice or induce any Person to cease doing business (or reduce the scope of business) with the

Company, to alter the scope or nature of any relationship with the Company, or to engage in a competitive business. “Person” for the purposes of this paragraph means an individual, organization, company, association or entity which, at the time of the Executive’s termination of employment for any reason, is doing any business with, or has any employment, contractor, customer, vendor, vendee, or business relationship with, the Company; provided, however, that an individual classified by the Company as an employee and who does not supervise other employees and does not have access to Confidential Information is excluded from the definition of Person. The Executive shall not communicate with any Person for any such purpose or authorize or knowingly approve such communications by any other person or entity.

SECTION 8. REPRESENTATION AND WARRANTY BY THE EXECUTIVE

The Executive hereby represents and warrants to the Company, the same being part of the essence of this Agreement that, as of the date of this Agreement, the Executive is not a party to any agreement, contract, or understanding, and that no facts or circumstances exist, that would in any way restrict or prohibit the Executive in any material way from undertaking or performing any of the Executive’s obligations under this Agreement. The foregoing representation and warranty shall remain in effect throughout the term of the Executive’s employment hereunder.

SECTION 9. REMEDIES

a. Equitable Relief. The parties acknowledge and agree that irreparable harm would result in the event of a breach or threat of a breach by the Executive of Section 5, 6, 7, or 10 or the making of any untrue representation or warranty by the Executive in this Agreement. Therefore, in such an event, and notwithstanding any other provision of this Agreement:

(i) the Company shall be entitled to a restraining order, order of specific performance, or other injunctive relief, without showing actual damage and without bond or other security; and

(ii) the Company’s obligation to make any payment or provide any benefit under this Agreement, including without limitation any severance benefits, shall immediately cease.

b. Remedies Not Exclusive. The Company’s remedies under this Section 9 are not exclusive, and shall not prejudice or prohibit any other rights or remedies under this Agreement or otherwise. To the extent required to be enforceable by applicable law, the cessation of the Company’s obligation to make payments or continue benefits under this Section 9 shall be deemed to be in the nature of liquidated damages.

SECTION 10. RETURN OF COMPANY PROPERTY

Immediately upon termination of the term of the Executive’s employment or upon the Company’s earlier request, the Executive shall return to the Company all Confidential Information and other items described in Section 5 and all originals and copies of any other property or information owned by the Company or relating to its business, that the Executive has in the Executive’s possession or under the Executive’s control, including all credit cards, papers,

books, equipment, files, and samples. To the extent that the Executive made use of the Executive's own personal device(s) (e.g., smartphone, laptop, iPad, thumbdrive, etc.) during and in connection with the term of the Executive's employment, the Executive agrees to deliver such personal device(s) to the Company for review and permit the Company to delete and permanently erase all of the Company's Confidential Information from such personal device(s). The Executive understands that personal information contained on such devices will be subject to the Company's or the Company's designee's review for the purposes of identifying and removing Confidential Information.

SECTION 11. MISCELLANEOUS PROVISIONS

a. Notices. Unless otherwise agreed in writing by a party entitled to notice, all notices required by this Agreement shall be in writing and shall be deemed given when physically delivered to and acknowledged by receipt by a party or its duly authorized attorney or legal representative, or when deposited postage paid, registered or certified mail, addressed to the party at its principal business or residence as set forth in the Company's records or as known to or reasonably ascertainable by the party required to give notice.

b. General Rules of Construction. The parties have participated jointly in negotiating and drafting of this Agreement. If a question concerning intent or interpretation arises, no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of authorship. Any reference to any federal, state, local, or foreign statute or law shall be deemed also to refer to all related rules and regulations unless the context requires otherwise.

c. Meaning of Certain Words. The word "including" shall mean "including without limitation."

d. Waivers. No assent, express or implied, by any party to any breach or default under this Agreement shall constitute a waiver of or assent to any breach or default of any other provision of this Agreement or any breach or default of the same provision on any other occasion.

e. Binding Effect; No Third Party Beneficiaries. This Agreement shall bind and benefit the parties and their respective heirs, devisees, beneficiaries, grantees, donees, legal representatives, successors, and assigns. Nothing in this Agreement shall be construed to confer any rights or benefits on third party beneficiaries.

f. Assignment. Neither party may assign this Agreement or any interest herein without the other's prior written consent; provided that the Company may assign its interest to another entity that it controls, is controlled by, or is under common control with or to a successor in interest upon a Change of Control.

g. Captions. Titles or captions contained in this Agreement are for convenience and are not intended to affect the substantive meaning of any provision.

h. Severability. If any provision of this Agreement, including the Confidential Information provision of this Agreement, is found in binding arbitration or by a court or other

tribunal of competent jurisdiction to be invalid or unenforceable, the attempt shall first be made to read that provision in such a way as to make it valid and enforceable in light of the parties' apparent intent as evidenced by this Agreement. If such a reading is impossible, the tribunal having jurisdiction may revise the provision in any reasonable manner, to the extent necessary to make it binding and enforceable. If no such revision is possible, the offending provision shall be deemed stricken from the Agreement, and every other provision shall remain in full force and effect.

i. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

j. Survival. The provisions of this Agreement that by their terms are intended to continue beyond the termination of the term of the Executive's employment shall survive such termination of employment and shall continue in effect for the respective periods therein provided or contemplated.

k. Tax Withholding. All payments under this Agreement shall be made subject to applicable tax withholding, and the Company shall withhold from any payments under this Agreement all federal, state, and local taxes as the Company is required to withhold pursuant to any law or governmental rule or regulation. The Executive shall be solely responsible for all federal, state, and local taxes due with respect to any payment received under this Agreement or otherwise in connection with the Executive's employment.

l. Section 409A. This Agreement is intended to comply with the requirements of Section 409A of the Code and the regulations thereunder ("Section 409A"), and shall in all respects be administered in accordance with Section 409A. Notwithstanding anything in this Agreement to the contrary, distributions may only be made under this Agreement upon an event and in a manner permitted by Section 409A or an applicable exemption. If the payment of severance benefits would otherwise be accelerated under this Agreement and paid in a lump sum upon a Change of Control, and such Change of Control is not a "change in control event" under Section 409A, such severance payments shall not be accelerated and shall instead be paid on the regularly scheduled payment date. Severance benefits provided under this Agreement are intended to be exempt from Section 409A under the "separation pay exception" to the maximum extent applicable. Further, any payments that qualify for the "short-term deferral" exception or another exception under Section 409A shall be paid under the applicable exception. All separation payments to be made upon a termination of employment under this Agreement may only be made upon a "separation from service" under Section 409A. For purposes of Section 409A, each payment hereunder shall be treated as a separate payment and the right to a series of payments under this Agreement shall be treated as a right to a series of separate payments. With respect to payments that are subject to Section 409A, in no event may the Executive, directly or indirectly, designate the calendar year of a payment, and if a payment that is subject to execution of a Release Agreement could be made in more than one taxable year, payment will be made in the later taxable year. If and to the extent that reimbursements or other in-kind benefits under this Agreement constitute "nonqualified deferred compensation" for purposes of Section 409A, such reimbursements or other in-kind benefits shall be made or provided in accordance with the

requirements of Section 409A. Notwithstanding the foregoing, although the Company has made every effort to ensure that the payments and benefits provided under this Agreement comply with Section 409A, in no event shall the Company be liable for all or any portion of any taxes, penalties, interest, or other expenses that may be incurred by the Executive on account of non-compliance with Section 409A.

m. Governing Law. This Agreement shall be governed by and construed under the laws of the United States and the State of New Jersey.

n. Board Information. The Executive shall at all times promptly give to the Board (in writing if so requested) all such information as it may require in connection with matters relating to the Executive's employment or with the Company or the business of the Company.

o. Effective Date. This Agreement shall be effective immediately on the date duly executed by both parties.

p. Full Agreement; Modification. This Agreement supersedes the Prior Agreement and all other consulting and employment arrangements between the Executive and the Company. This Agreement constitutes the entire agreement of the parties concerning its subject matter and supersedes all other oral or written understandings, discussions, and agreements, and may be modified only in a writing signed by both parties. The parties acknowledge that they have read and fully understand the contents of this Agreement and execute it after having an opportunity to consult with legal counsel.

q. Counterparts; Delivery. This Agreement may be executed by the parties in separate counterparts and may be delivered by either or both parties by facsimile or electronic transmission.

(Signature page follows.)

IN WITNESS WHEREOF, and intending to be legally bound hereby, the parties have executed this Agreement to be effective as of the date specified above.

AGILE THERAPEUTICS, INC.

/s/ Paul Korner, M.D.
Name:Paul Korner, M.D.

By: /s/ Al Altomari
Name:Al Altomari
Title: Chairman and Chief Executive Officer

SCHEDULE A

Permitted Activities

Description of Activity	**Nature of Work**	**Hours Per Week**	**Anticipated Compensation**
Voltron Therapeutics Board of Directors (Private)	Voltron Therapeutics high level support of HPV related cancers Immuno-oncology therapeutic vaccine development	• 1 hour per quarter BoD calls • 1 hours per week for regular Voltron/LVP Team calls (Tuesdays 4-5 pm EST) • 5 hours per week (evenings and weekends only and will not interfere with Agile responsibilities)	$30,000/year $400/hour $400/hour
Pretzel Therapeutics (Private)	Advisory consulting for pipeline indications and TPPs for small molecule an ASOs to treat rare mitochondrial disorders	1-8 hours per week	$425/hour
HeraLife Medical (Private)	SAB for fetal pulse oximeter device in development to measure fetal oxygenation status during labor	0 - 1 hour per week (all off work hours)	Equity

NeuralPositivity.com (Private)	SAB for music streaming service for well-being conditions (from Cornell Tech transfer office)	0 - 1 0 - 1 hour per week (all off work hours)	Equity

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. and

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

of our report dated March 22, 2023, 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, 2022.

/s/ Ernst & Young LLP
Iselin, New Jersey
March 22, 2023

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 22, 2023

/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, Jason Butch, 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 22, 2023

/s/ JASON BUTCH
Jason Butch
Chief Accounting 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, 2022 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 22, 2023

/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, 2022 as filed with the Securities and Exchange Commission (the "Report"), I, Jason Butch, Chief Accounting 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 22, 2023

/s/ JASON BUTCH
Jason Butch
Chief Accounting Officer
(Principal Financial Officer)