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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, 2020

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.)

101 Poor Farm Road
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. ☐

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, 2020 was approximately $196.8 million.

As of February 24, 2021, there were 87,628,904 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2021 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed within 120 days of the registrant's fiscal year ended December 31, 2020, 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, 2020

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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 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, 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 ability to successfully commercialize Twirla, our only approved product;
- the rate and degree of market acceptance of Twirla by physicians, patients, 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 product candidates and our ability to serve those markets;
- the effects of the ongoing COVID-19 pandemic on our commercialization efforts, clinical trials, supply chain, operations and the operations of third parties we rely on for services such as manufacturing, marketing support and sales support, as well as the effects of the COVID-19 pandemic on our potential customer base;
- regulatory and legislative developments in the United States and foreign countries, which could include, among other things, a government shutdown;
- our available cash and our ability to obtain additional funding to fund our business plan without delay and to continue as a going concern;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;

- our inability to timely obtain from our third-party manufacturer, Corium, sufficient quantities or quality of Twirla and our potential product candidates 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 conduct a small post-marketing commitment, or PMC, study to assess the residual drug content of Twirla after use;

- our ability to maintain regulatory approval of Twirla and our ability to obtain regulatory approval of our potential product candidates, 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;

- our plans to develop our other potential product candidates;

- development of unexpected safety or efficacy concerns related to Twirla;

- our ability to continue to develop and maintain successful sales and marketing capabilities, including our ability to maintain an effective sales force or failure to build-out and implement an effective health care compliance program;

- our ability to retain key employees and recruit the additional personnel we will need to support our commercialization plan for Twirla; and

- our ability to successfully implement our strategy.

Risk Factor Summary

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

- We 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 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;

- We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively;
- 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 commercialize Twirla or to complete the development and commercialization of our other potential product candidates;
- 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;
- 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. 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, which would 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 be delayed in obtaining or ultimately not be able to obtain marketing approval for our potential product candidates;
- 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 we fail to develop and commercialize our current pipeline of additional potential product candidates, our prospects for future growth and our ability to reach or sustain profitability may be limited or never achieved;
- In order to establish our sales and marketing infrastructure, we will need to grow the size of our organization, and we may experience difficulties in managing this growth;
- If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of Twirla or our potential product candidates, if approved; and
- We expect that our stock price may fluctuate significantly.

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

statements, you should not regard any of these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all.

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

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

Twirla® is one of our trademarks used in this Form 10-K. This Form 10-K also includes trademarks, tradenames, and service marks that are the property of other organizations. Solely for convenience, our trademarks and tradenames referred to in this Form 10-K may appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

Item 1. Business

Overview

We are a women's healthcare company dedicated to fulfilling the unmet health needs of today's women. We have remained steadfast in our commitment to innovate 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 product, Twirla, which was approved in February 2020 and launched in early December 2020, is a once-weekly prescription combination hormonal contraceptive patch. It delivers a dose of estrogen consistent with commonly prescribed combined hormonal contraceptives, or CHCs, and 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 approximately 30 mcg of estrogen and 120 mcg of progestin in a convenient 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 optimizing patch adhesion and patient comfort and wearability, which may help support compliance.

With the approval of Twirla we are now focused on our advancement as a commercial company. During 2021, we plan to continue implementing our commercialization plan for Twirla, with the goal of becoming a contraceptive market leader, and ultimately, 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 an initial franchise in the multi-billion-dollar U.S. hormonal contraceptive market built on approval of Twirla in the U.S. Our resources are currently focused on the commercialization of Twirla. To that end, we completed the validation of the commercial manufacturing process for Twirla in accordance with our approved marketing application in the fourth quarter of 2020 and commenced shipment of product to wholesalers in early December 2020. During 2020, we also continued efforts to build out our commercial organization with a number of key hires and new contractual relationships. We entered into an agreement with inVentiv Commercial Services, a Syneos Health group company, which we refer to as Syneos Selling Solutions, to provide a contract sales force and related sales services for Twirla. In the third quarter of 2020, we hired and trained an initial sales team of 73 persons who are engaging with health care providers on Twirla through both in-person and virtual meetings. In April 2020, we entered into a commercial supply agreement with Corium for the manufacture and supply of Twirla, which replaced our former

development agreement. We hired a Chief Medical Officer in August 2020, who is leading an evaluation of our existing pipeline including potential development costs and timelines. We also expect to explore possible expansion through business development activities, such as acquiring access to new products through in-licensing, co-promotion or other collabortive arrangements.

Our current priorities are as follows:

- Continue to implement our commercialization plans for Twirla to ensure a successful launch in the United States, including maintaining a sales and marketing team and implementing a healthcare compliance program;
- Expand coverage and reimbursement for Twirla in the United States from private and public third-party payors;
- Expand access to Twirla through multiple business channels including third-party payor contracts, retail and specialty pharmacies, telemedicine and government contracting;
- Maintain and manage the supply chain for Twirla to support commercialization of Twirla across the United States;
- Evaluate the advancement of our existing pipeline and its possible expansion through business development activities; and
- Complete and submit the proposed protocols for the two FDA-required post-marketing commitment studies.

It should be noted that current public health threats could adversely affect our 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 we have taken, such as implementing work-at-home policies, may negatively impact productivity, 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. It is unknown how long these conditions will last and what the complete effect will be on us. 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. Overall, we recognize the challenges of launching in a pandemic, 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 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 approximately 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 comparing the risks for VTE and ATE in new users of Twirla to new users of other CHCs. The final study report for the Twirla post-marketing study is scheduled to be submitted to the FDA in November 2032, with interim safety data reporting to the FDA due in November 2026. We have also agreed to a 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.*

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:

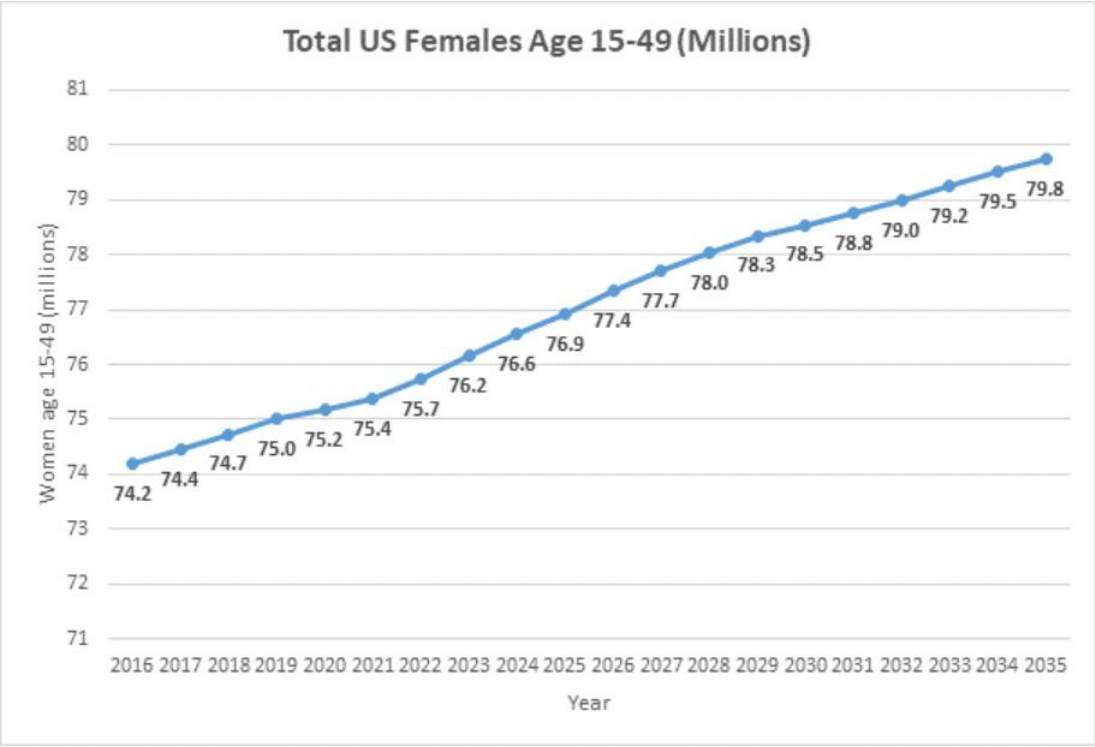
- oral contraceptive;
- vaginal ring;
- transdermal patch;
- hormonal IUD;
- subcutaneous implant; and
- injectable.

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, two 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 $4 billion per year; with a drop in 2020 sales to $3.7 billion, largely due to the introduction of generics to Nuvaring, which was the market leader in 2019. Total prescription volume, or TRx, declined from 2016 to 2020 by 27%, from 90 million to 65 million; however the number of cycles dispensed (1 cycle = 1 month supply) declined by only 6% over the same time period, as the average TRx size (cycles/TRx) grew from 1.4 to 1.8 over the same time period. Therefore, the value of a TRx has grown significantly over the past 5 years, particularly for branded products, where the average revenue per TRx nearly doubled from $144.48 in 2016 to $277.81 in 2020.

Despite the availability of generic contraceptives for over 30 years, branded products have maintained a significant, though declining, share of CHC sales, with 40% of total sales in 2020. In the five years ended December 2020, the average annual price increase among the top branded products was 8.8%. The average price per cycle, referred to as the wholesale acquisition cost, or WAC, for a single 28-day cycle of the top branded products was $131.40 in 2016 and rose to $160.71 by December 2020. The branded CHC transdermal patch (Ortho Evra) was discontinued in October 2014 and the branded generic CHC transdermal patch (Xulane) is currently priced at $122.15 per cycle. We have established a WAC price for Twirla at $159.75. 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 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 75 million women and is estimated to grow to nearly 80 million by 2035.



Source: U.S. Census Bureau, 2017 National Dataset (2016 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 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 1.7% share in 2016 to a 2.8% share in 2020.

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 sales of $331.5 million in 2020. On February 26, 2021, Amneal Pharmaceuticals, Inc. announced that it had received approval by the FDA for Zafemy, a generic version of Ortho Evra.

With its approval on February 14, 2020, Twirla is now 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 the Company's market research, analysis of the current and expected future U.S. contraceptive market, and review of other product launches in the category, the Company estimates that Twirla can potentially achieve a peak market share of 5-8%. As we pursue the commercialization of Twirla, we will continue to analyze the 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. During 2020, we validated our commercial manufacturing process, initiated work with managed care and patient payors to gain market access for Twirla, hired and trained an initial sales team through our contract sales partner, Syneos Selling Solutions, entered into distribution agreements with the three largest wholesalers in the United States and commenced commercial shipments of product to wholesalers in December 2020. In 2021, we intend to continue implementation of our commercial strategy for Twirla with a focus on promotional activities and expanding market access through multiple business channels, including third-party payor contracts, retail and specialty pharmacies, telemedicine, and government contracts.

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 initially focused on Obstetrician-gynecologists in the United States, and we plan to use a significant number of samples in the early stage of commercial launch to gain patient trial and acceptance. We believe that we can deploy a focused sales force effort targeting the ObGyn, NP and PA prescribers who are responsible for approximately 70% of branded CHC prescriptions. In areas of the country where it is not efficient to deploy a sales representative, and/or depending on the evolution of the COVID-19 pandemic, remote promotion can be used to reach prescribers. We plan to complement these efforts by expanding the channels we utilize to drive awareness of Twirla during the pandemic and will focus on promotion with key prescribers and customers groups, including consumers and commercial managed care plans.

We plan to use both branded and unbranded campaigns to create awareness of Twirla and available contraceptive options among consumers. We believe there are cost-effective means to reach our target demographic of females ages 18 to 34 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. Traditional mass-market direct-to-consumer advertising on television may not be required to reach these consumers. 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, potential social media advertising, and other mass-market advertising vehicles will generate consumer awareness and demand for Twirla. In the third quarter of 2020, we launched our unbranded educational awareness campaign, entitled *I'm So Done*. We rolled out our branded campaign in early 2021.

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 formulary access for approximately forty to forty-five percent (40-45%) 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 during 2021 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 halted 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: Twirla line extensions and other transdermal contraceptive product candidates. These potential product candidates are designed to address market needs and offer additional non-daily contraceptive options. Prior market research conducted in December 2016 indicated our potential line extension product candidates may be commercially viable and could garner a share of the contraceptive market. We have conducted an Advisory Board meeting with contraceptive experts and initiated a new market research program to update our previous insights and to advise on the pipeline programs.

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 is to introduce line extensions that will have exclusivity for some time period, either due to our intellectual property estate, or due to Hatch-Waxman exclusivity. The line extensions in our pipeline include using our Skinfusion technology to allow a 28-day regimen where women will experience shorter, lighter withdrawal bleeding, as well as extending the cycle beyond the typical 28-day regimen to allow women to experience fewer withdrawal bleeds each year. In addition, the potential line extension product candidates in our pipeline will utilize a unique aspect in the regimen, where a smaller patch, or SmP, that delivers a lower dose of both EE and LNG will be worn during the final seven days of each cycle, rather than having a patch-free week, to allow for withdrawal bleeding while minimizing hormonal fluctuations and potentially the side effects that accompany changes in hormone levels. These regimens are protected by patents issued to us in 2015.

Our potential Twirla line extensions 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. There are several currently approved oral contraceptives that provide an 84- or 91-day extended cycle regimen, and in 2020, these products totaled 5% of CHC cycles dispensed. However, there is no approved contraceptive patch product offering an extended cycle regimen. AG200-15ER is designed to address the limitations of the currently approved oral contraceptive extended regimens by providing a more convenient, weekly TDS dosing schedule. We are currently evaluating the required development plan required for FDA approval of this regimen.

- 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. 28-day regimen CHCs that use a shortened hormone-free interval, or SHFI, by delivering hormones beyond the traditional 21 days comprised 16% of CHC-TRx volume and 43% of CHC sales in 2020, demonstrating high acceptability among patients and providers. 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 SmP requires additional patch formulation development work on the SmP prior to potentially conducting a pharmacokinetic study.

- 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. AG200-15 ER SmP utilizes the approved Twirla TDS during the 12-week (84-day) active phase of the cycle and the SmP during week 13 of the cycle. AG200-15 ER SmP requires additional patch formulation development work on the SmP prior to potentially conducting a pharmacokinetic study.

Our other potential product candidate is a progestin-only (P-only) contraceptive patch described below:

- AG890 is a P-only contraceptive patch, intended for use by women of reproductive potential to prevent pregnancy. The intended population 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 are obese. Currently, the P-only market consists of pills and several non-oral options, including IUS/IUDs, implants, and injections. AG890 is intended to fulfill an unmet medical need for a non-daily, easily reversible form of contraception in the P-only target population. Previously, we conducted a Phase 1 clinical trial with AG890 containing LNG. In addition, the National Institutes of Health, through a clinical trial agreement with us, conducted a Phase 1/2 trial with LNG-containing AG890. This Phase 1/2 study was a

multicenter study to evaluate the pharmacokinetics, safety, and mechanisms of potential contraceptive efficacy of AG890. We are evaluating our analysis of the data from this trial as well as other potential progestins to be utilized for further development. Additional formulation development work for progestin and dose selection is required, along with additional studies to determine the optimal formulation and dose to advance to Phase 3.

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 these three 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. 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, such as oral contraceptives, injections, implants, hormonal IUDs and vaginal ring and transdermal contraceptive products.

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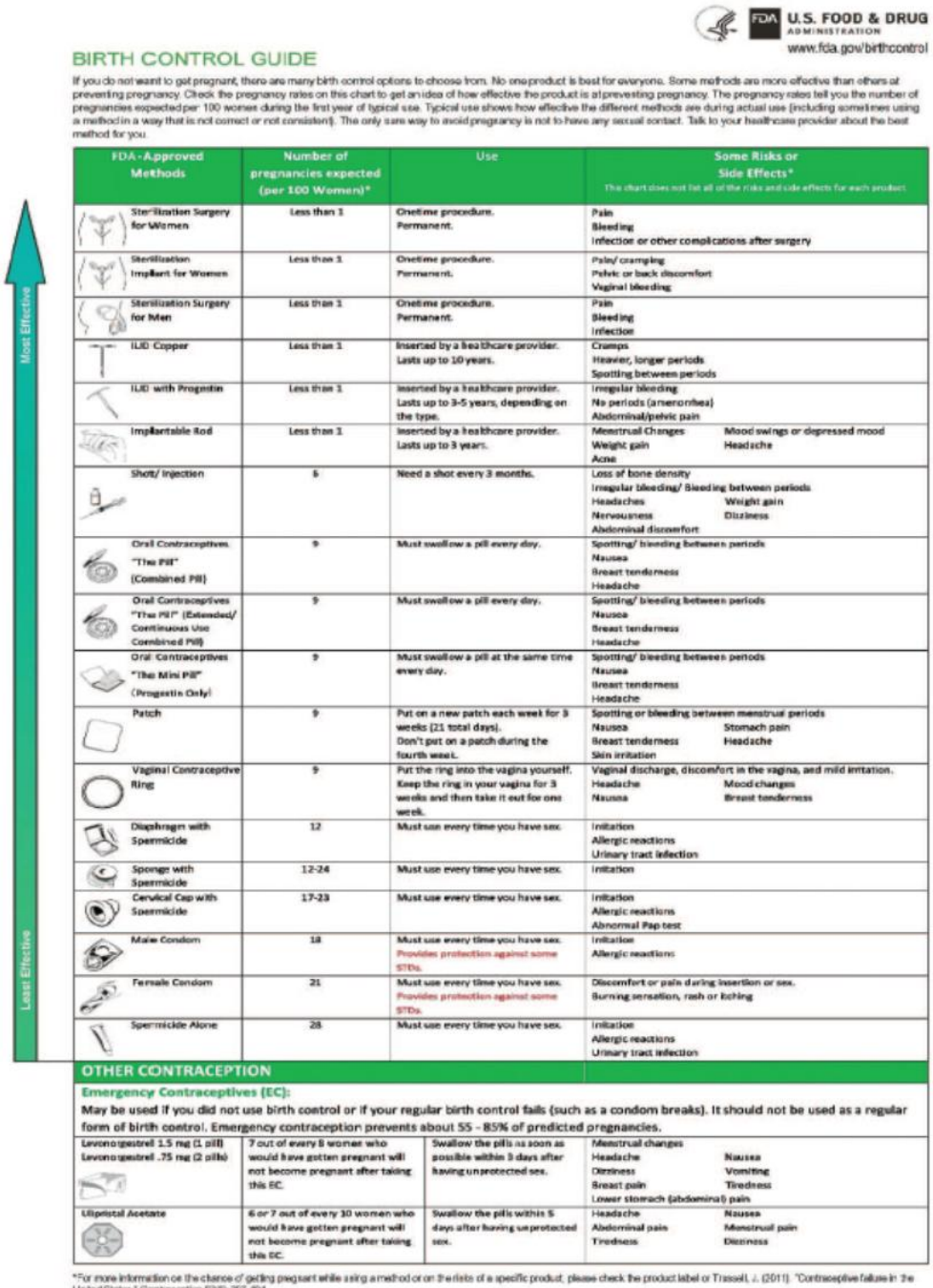
The following table is the FDA Birth Control Chart, which outlines the 18 unique forms of birth control and compares the effectiveness of each method.



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 prevesting 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; Mood swings or depressed mood Weight gain; Headache Acne
Shot/ Injection	6	Need a shot every 3 months.	Loss of bone density Irregular bleeding/ bleeding between periods Headaches; Weight gain Nervousness; Dizziness Abdominal discomfort
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; Stomach pain Breast tenderness; Headache Skin irritation
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; Mood changes Nausea; 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; Nausea Dizziness; Vomiting Breast pain; Tiredness Lower stomach (abdominal) pain
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; Nausea Abdominal pain; Menstrual pain Tiredness; 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

Although there are more than 250 CHC products currently available, including brands and generics, just 14 branded products make up approximately 40% of total market revenue. 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 by Therapeutics MD, 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 $331.5 million in sales for Mylan in 2020. 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. Additionally, several generics manufacturers currently market and continue to introduce new generic contraceptives, including Sandoz, Glenmark, Lupin, Amneal, Mylan, Aurobindo, Xiromed, and Afaxys. 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 other contraceptive products recently approved or in development 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 has indicated they will recruit a new women's health team in the U.S. and expect to launch Nextstellis in the first half 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 only one other CHC transdermal patch, which is not approved in the U.S. Apleek was developed by Luye Pharma and Bayer, and it was approved in the United Kingdom in 2014. Luye acquired the global rights to Apleek from Bayer AG in August 2018. Apleek contains the active ingredients EE and gestodene, a third-generation progestin. There are no contraceptives containing gestodene approved in the U.S. We believe that if this product were to obtain FDA approval, the approved labeling is likely to contain the same language that products containing third generation progestins contain, which language states that these contraceptives have a two-fold increase in risk of VTE as compared with contraceptives containing second generation progestins.

Manufacturing

We do not own any manufacturing facilities and rely on Corium for all aspects of the manufacturing of Twirla. 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 and reproducibility, 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. 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 includes a quarterly minimum purchase commitment and a fixed price per unit for two years depending on annual purchase volume.

The Corium Agreement terminates automatically after ten years, 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.

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.

The Syneos Agreement terminates automatically on the second anniversary of the date of the first activity undertaken by Syneos Selling Solutions to detail Twirla, referred to as the Deployment Date, unless earlier extended upon the mutual written agreement of both parties. We may terminate the Syneos Agreement for any reason upon timely notice after the first anniversary of the Deployment Date; provided, however, that if we terminate the Syneos Agreement prior to the eighteen month anniversary of the Deployment Date, we will be obligated to pay Syneos Selling Solutions a termination fee, the amount of which varies depending on the date of termination.

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 are often a time-consuming and costly process that requires 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.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws, enforcement policies or administrative determinations with respect to the importation of drugs into the United States from other countries where they may be sold at lower prices.

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. Typically, a third-party payor's formulary is organized into between three and six tiers. Each tier is then associated with a set range of co-pay amounts or a percent of the drug costs, with products in the lower tiers having a lower co-pay.

Reimbursement for female contraceptive products was changed by the enactment of the 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.

In May 2015, several government agencies, including the U.S. Department of Health and Human Services, or HHS, the Department of Labor, or DOL, and the U.S. Department of Treasury, or Treasury, jointly issued a clarification in the form of an FAQ which clarified the requirements for coverage of contraceptives under the ACA. This clarifying guidance went into effect in January 2016. The FAQ states that plans and issuers must cover without cost-sharing at least one form of contraception in each of the 18 current methods that the FDA has identified for women in its current Birth Control Guide. The patch is identified as a specific method in the FDA Birth Control Guide, and therefore insurers must cover at least one patch product with no cost-sharing to the patient. Under the FAQ, health plans are allowed to utilize reasonable medical management techniques within a method to control costs, such as covering a generic at no cost but charging a copay for the equivalent brand. However, if using medical management techniques within a method, plans must have a transparent waiver process where, if a provider determines that a particular FDA-approved item, including contraception, is medically necessary for an individual, then the plan must cover that item without cost sharing. While the FAQ is clear that a waiver process is required, plans have implemented the requirement inconsistently on a national basis.

On January 20, 2017, the Trump administration signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of

any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices, among others. The Biden administration revoked the Trump administration Executive Order on January 28, 2021. 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 July 2020, the Supreme Court reversed lower court injunctions applicable to these rules, effectively permitting implementation. However, the Biden administration potentially may elect to exercise its authorities under ACA differently from the previous administration, and it is, therefore, difficult to determine the full effect of the ACA or any other healthcare reform efforts on our business.

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, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products such as those we are developing. 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, the number of guidance documents has increased, as FDA issued a number of guidances, which are continually evolving, to assist companies navigating the COVID-19 pandemic. 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, issuance of Warning, Untitled, or Cyber Letters, requests for product recalls, product seizures or detention, 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 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 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 evaluation 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 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 includes 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. 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 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. We have obtained a waiver from the conduct of a PREA study.

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. A user fee for the Twirla contraceptive patch

was submitted with the original NDA. Application resubmissions by the same applicant do not require a new application fee. Under the 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. These time periods may be extended by the FDA should an applicant submit new information to the agency during the course of the FDA's review of the marketing application. The time period is also only a goal and may not be met by the FDA.

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

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

The FDA may refer a marketing application to an external advisory committee for questions pertaining to issues such as clinical trial design, safety and efficacy, and public health questions. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it typically follows such recommendations and considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will inspect 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 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 reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, 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. If the applicant resubmits the application, the application is subject to an initial FDA review. Within 30 days of receipt, the FDA will review a resubmission to determine whether it constitutes a complete response that addresses all deficiencies identified in a complete response letter. The agency then issues a letter to the applicant, stating whether the agency agrees that the resubmission is a complete response. If the FDA does not agree that the resubmission is a complete response, the review clock will not start until a complete response is received. If the agency agrees that the resubmission is a complete response, the FDA will classify the resubmission as either Class 1 or 2. The FDA aims to review Class 1 resubmissions within two months of receipt or Class 2 resubmissions within six months of receipt. Class 1 resubmissions are resubmissions of an NDA following a complete response letter that include minor updates or data reanalysis. Class 2 resubmissions include more

complex or extensive updates to the NDA. As with the PDUFA timelines for original submissions, these are also subject to extension if the sponsor submits new information. Resubmitted applications may also be subject to FDA inspection 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 medication guides, physician communication plans, assessment plans, 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.

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. 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 Trump administration, and administrative agencies took certain measures to increase drug competition and thus, decrease drug prices. By example, in 2019, the FDA introduced a proposed rule and in 2020 the FDA finalized guidance to facilitate drug importation. Congress also passed a bill requiring 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. 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. These dual requirements 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. Recently, the information that must be submitted to FDA regarding manufactured products was expanded through the Coronavirus Aid, Relief, and Economic Security, or CARES, Act to include the volume of drugs produced during the prior year.

Drug sponsors and manufacturers are subject to periodic announced and unannounced inspections by the FDA and these 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 requirements for 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 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. Manufacturers must also verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this legislation, manufactures have drug product 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. 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, physician payment 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 item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. 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 also amended by the 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. In addition, the ACA provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the 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 on the other. 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 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 Office of Inspector General, or OIG, published further modifications to the federal Anti-Kickback Statute. 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. Pursuant to an order entered by the U.S. District Court for the District of Columbia, 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, 2023. Implementation of the this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed.

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 or 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. A claim includes “any request or demand” for money or property presented to the U.S. government. Claims may be pursued by whistleblowers through qui tam actions, even if the government declines to intervene. Intent to deceive is not necessary to establish civil liability, which may be predicated on reckless disregard for the truth. 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. These investigations have involved, for example, allegations of providing free product to customers with the expectation that the customers would bill federal programs for the free product, as well as the promotion of products for unapproved uses and reporting false pricing information. Potential liability under the federal False Claims Act includes treble damages and significant per claim penalties. The False Claims Act has been used to assert liability on the basis of kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper promotion of off-label uses not expressly approved by the FDA in a drug’s label, and allegations as to misrepresentations with respect to the services rendered. 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. Additionally, the civil monetary penalties statute, which, 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 Affordable Care Act 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. CMS’ final CMP rule went into effect January 1, 2019.

The Affordable Care Act included a provision requiring certain providers and suppliers of items and services to Federal Health Care Programs to report and return overpayments within sixty days after they are “identified” (the “Overpayment Statute”). 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. In 2014 and 2016, the CMS released regulatory guidance (in the form of final rules) to Medicare providers, suppliers and managed care and prescription drug plans regarding how to comply with the

Overpayment Statute. Although these Medicare providers, suppliers and plans have faced federal False Claims Act liability since 2010 for failures to comply with the Overpayment Statute, these final rules interpreting the Overpayment Statute provide guidance regarding how to comply with applicable obligations, and guidance to government regulators and enforcement authorities regarding monitoring and prosecuting suspected violations. These final rules are 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 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 data privacy and security regulation 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, or HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information, known as protected health information. Among other things, HITECH makes security standards and certain privacy standards directly applicable to business associates, defined as persons or organizations of covered entities, other than members of the 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. HITECH also strengthened the civil and criminal penalties 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 regulate the privacy and security of information that we maintain, many of which may differ from each other in significant ways and may not be preempted by HIPAA. Further, a new California privacy law, the California Privacy Rights Act, or CPRA, was passed by California voters on November 3, 2020. The CPRA will create additional obligations with respect to processing and storing personal information that are scheduled to take effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022). Other federal and state laws may govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. For instance, 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. Other states, such as Virginia, also are enacting state specific privacy laws.

Additionally, federal physician payment transparency laws, including the federal Physician Payment Sunshine Act created under Section 6002 of the ACA and its implementing regulations, require that manufacturers of drugs for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, report annually to the government information related to payments or other "transfers of value" made or distributed to or at the request of covered recipients, such as, but not limited to, physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family.Manufacturers must submit reports by the 90th day of each calendar year. Disclosure of such information is made on a publicly available website.

There are also an increasing number of analogous state laws that regulate price increases, require manufacturers to file reports with states on pricing and marketing information, and to track and report gifts, compensation, other remuneration and items of value provided to healthcare professionals and healthcare entities. Many of these laws contain ambiguities as to what is required in order to comply with such laws. For example, several states have enacted legislation requiring pharmaceutical companies to, among other things, establish and implement commercial compliance programs,

file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, or register their sales representatives. 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 administrative and compliance burdens. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions once we commercialize 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, refusal of government contracts, contract debarment 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.

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 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 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.

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. Various portions of the ACA are currently undergoing legal and constitutional challenges in the United States Supreme Court; the former Trump Administration issued various Executive Orders eliminating cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. The United States Supreme Court is expected to rule on a legal challenge to the constitutionality of the ACA in early 2021. The implementation of the ACA is ongoing, 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 and, as amended, will stay in effect through 2030. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, as well as subsequent legislation, these reductions have been suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. Proposed legislation, if passed, would extend this suspension until the end of the pandemic. 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.

On January 20, 2017, the then-new administration signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices among others. Additionally, in October 2017, the Department of Health and Human Services, jointly with the Department of Labor and the Treasury, issued two interim rules outlining exemption processes for employers not wanting to offer contraceptive coverage based on their religious beliefs or sincerely held moral convictions. In July 2020, the Supreme Court reversed lower court injunctions

preventing implementation of these rules. Congress also could consider subsequent legislation to repeal and replace elements of the ACA that are repealed. Therefore, it is difficult to determine the full effect of the ACA or any other healthcare reform efforts on our business.

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 for states to build and submit importation plans for 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. 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, prohibits any U.S. individual or business 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 companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate 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 $13.5 million, $9.9 million, and $9.8 million for the years ended December 31, 2020, 2019, and 2018, respectively. In 2021, we expect to continue to incur research and development expenses as we evaluate the advancement of our existing pipeline and its possible expansion.

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. One of our other potential product candidates, AG890, is similar to Twirla, except that it contains only a single API, LNG.

In both our Twirla product candidate line and in AG890, 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, also called the overlay, comprising three layers 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.

Eight U.S. patents, issuing from two patent families, have been or are being submitted to the FDA for listing in the Orange Book upon approval of Twirla. These patents include claims directed to transdermal delivery systems having an active adhesive matrix and claims directed to methods of controlling fertility by applying such transdermal delivery systems, and in all cases including a skin permeation enhancer. One of our eight issued U.S. patents expired November 22, 2020. Four will expire March 14, 2021. Two will expire July 10, 2028. The eighth will expire August 26, 2028.

U.S. Patent No. 7,045,145 is directed to the adhesive matrix of the transdermal delivery system used in Twirla and expires in March 2021; product-by-process claims cover patches manufactured by drying wet formulations of the active adhesive matrix. U.S. Patent No. 7,384,650, U.S. Patent No. 8,221,784, and U.S. Patent No. 8,221,785 are all directed to the dry final product formulation of the transdermal delivery system used in Twirla and expire in March 2021. U.S. Patent No. 8,221,784 covers both Twirla and AG890. Foreign counterparts to these patents have been granted in China, Hong Kong, India, Israel, and Mexico. U.S. Patent No. 8,883,196 is directed to a method of controlling fertility by applying Twirla or AG890 once each week for three weeks followed by a one-week rest interval, or in an extended regimen without a rest interval for a selected number of weeks and expired November 22, 2020.

U.S. Patent Nos. 8,246,978, 8,747,888, and 9,050,348 are directed to structural features of the transdermal delivery system used in Twirla and AG890 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 and 9,198,920 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 pending or granted in Canada, Europe, Hong Kong, India, Japan and Mexico. We expect this patent to be relevant to at least one product in our pipeline, AG890. 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. The exclusivity prohibits the FDA from approving ANDAs and 505(b)(2) NDAs for the conditions of the Twirla approval. We will consider whether we are going to pursue patent term restoration, however, we do not expect to receive patent term restoration because, as explained above, Twirla is not the first approval of the API.

Employees

As of December 31, 2020, we had 28 full time employees, including nine in research and development and nineteen in selling, general and administrative roles. 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 101 Poor Farm Road, 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, 2020, 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 2020 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, 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 pipeline of potential product candidates are in earlier stages of clinical development and will require additional clinical studies and product development 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. Potential prescribers of Twirla include physicians, nurse practitioners, or NPs, physician’s assistants, or PAs, and

pharmacists. Registered Pharmacists are authorized to prescribe contraceptives in some states, and other states have pending legislation that would allow pharmacists to prescribe contraceptives. 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 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 and ease of administration of Twirla;
- Prevalence and severity of adverse events associated with Twirla;
- Cost of Twirla in relation to alternative treatments, including generic products;
- 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;
- 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. By example, Twirla's label includes the class-wide boxed warning, contraindications, and warnings and precautions applicable to all combined hormonal contraceptives, or CHCs. Twirla also includes a boxed warning that Twirla is contraindicated in women with a BMI $\geq$ 30 kg/m^2, and that compared to women with a lower BMI, women with a BMI $\geq$ 30 kg/m^2 had reduced effectiveness and may have a higher risk for venous thromboembolic events. Twirla's label also contains a limitation of use to consider Twirla's reduced effectiveness in women with a BMI of $\geq$25 to $\leq$30 kg/m^2 before prescribing.

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. In addition, even though we believe Twirla has advantages over other treatment options, because no adequate head-to-head trials comparing the safety and efficacy of Twirla to the competing approved patch or other contraceptive products have been conducted, we cannot make claims that Twirla is safer or more effective than the currently approved patch product, or other contraceptive products, without conducting a supportive head-to-head postmarketing study. Moreover, we will not be able to make any other Twirla marketing or promotional claims to the extent that they are inconsistent with the Twirla FDA-approved label or are not otherwise supported. The availability of numerous inexpensive generic forms of contraceptive products may also limit acceptance of Twirla among prescribers, patients and third-party payors. If Twirla does not achieve an adequate level of acceptance among prescribers, patients and third-party payors, we may not generate significant product revenues or become profitable, and the value of our common stock may suffer.

We may not be able to successfully commercialize Twirla, and the revenue that we generate from its sales, if any, may be limited.

The commercial success of Twirla will depend upon the contraceptive market landscape as well as acceptance and uptake of Twirla by prescribers, patients and third-party payors.

Risks related to the 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 from third party payors, including managed care organizations and government-sponsored health systems, could limit our revenue;
- The proportion of the contraceptive market comprised of generic products could continue to increase, making the introduction of a branded contraceptive difficult and expensive;
- 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 contraceptive market could increase, with the introduction of new contraceptives, including the potential of a new generic or branded competitive contraceptive patch;
- Competition from generic contraceptive products could increase as additional generic contraceptives receive FDA approval;
- 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;
- Access to the prescriber universe, particularly obstetrics and gynecology physicians, could be limited, decreasing our ability to promote Twirla efficiently; and
- Our ability to access pharmacists in states where they are authorized by law to prescribe contraceptives could be limited, decreasing our ability to promote Twirla.

The degree of acceptance and uptake of Twirla by prescribers, patients and third-party payors will depend upon a number of factors, including:

- The level of contraceptive effectiveness of Twirla demonstrated in our clinical trials;
- The incidence and severity of adverse effects associated with Twirla;
- 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;
- Acceptability to patients of the appearance and feel of Twirla;
- Willingness of prescribers to prescribe a contraceptive patch based on the labeling and prior experience with the generic contraceptive patch already on the market;
- Willingness of prescribers to prescribe a contraceptive patch in light of safety issues and restrictive labeling of the generic contraceptive patch already on the market;
- The cost of Twirla to the patient, as compared to other contraceptive products and methods;

- Our ability to obtain and maintain sufficient third-party coverage or reimbursement for Twirla from private health insurers, government healthcare programs (including Medicare, Medicaid and 340B Clinics) and other third-party payors; and

- The effectiveness of our or any future collaborators' sales and marketing strategies.

In addition, we may face additional generic or other drug product competition sooner than we anticipate for Twirla or our potential product candidates, which would potentially limit their commercial success. For example, on February 26, 2021, Amneal Pharmaceuticals, Inc. announced that it had received approval by the FDA for Zafemy, a generic version of Ortho Evra, a combined contraceptive patch previously marketed by Johnson & Johnson. Zafemy represents the second generic version of Orth Evra after Xulan, which is marketed by Mylan. Because Zafemy was just approved, it is not possible to predict what the effect of its commercial availability will be on our efforst to market Twirla. Upon approval by the FDA, we received three years of FDA marketing exclusivity for Twirla. The FDCA provides a period of three years of marketing exclusivity for an NDA, Section 505(b)(2) NDA or supplement to an existing NDA for a drug product that contains a previously approved active moiety, if new clinical investigations, other than bioavailability or bioequivalence studies, were conducted or sponsored by the applicant and are determined by the FDA to be essential to the approval of the application. This three-year marketing exclusivity, however, does not protect drug products from all competition. For instance, it does not protect against the approval of a full NDA. It also would only protect against the approval of a product that contains the same conditions of approval as Twirla. Therefore, the three-year exclusivity for Twirla may not adequately protect us from competition. 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 and we may not be able to achieve or sustain profitability. 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 coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize Twirla, which could adversely impact our business, financial condition, results of operations and prospects and the value of our common stock. Increasingly, third party-payors attempt to contain healthcare costs in ways that are likely to impact our development of products, including:

- Failing to approve or challenging the prices charged for healthcare products;
- Introducing reimportation schemes from lower-priced jurisdictions;
- Limiting both coverage and the amount of reimbursement for new therapeutic products; for example, Express Scripts has excluded most branded and all newly approved hormonal contraceptive products, including Twirla, from its national preferred formulary;
- Denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third party-payors; and
- Refusing to provide coverage when an approved product is used for off-label indications.

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 in the United States. In April 2020, we entered into an agreement with inVentiv Commercial Services, a Syneos Health group company, which we refer to as Syneos Selling Solutions, to provide a contract sales force and related sales services for Twirla. In the third quarter of 2020, we hired and trained an initial sales team of 73 persons and they have commenced detailing Twirla to health care providers through both live and virtual meetings. At the time of the commercial launch of Twirla, our sales and marketing team have worked together for only a limited period of time. 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 inability of sales personnel to obtain access to or persuade adequate numbers of prescribers to prescribe Twirla;
- 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; and
- Unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization.

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 and financial condition.

If we intend to commercialize Twirla outside the United States, we will likely enter into collaboration agreements with pharmaceutical partners, and we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend on the success of the efforts of these third parties.

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 in the United States, internationally or both.

If estimates of the size of the potential market for Twirla are overstated or data we have used to identify physicians is inaccurate, our ability to earn revenue to support our business could be materially adversely affected.

We have relied on a number of external sources, as well as market research funded by us and internal analyses and calculations, to estimate the potential market opportunity for Twirla in the United States. We have not independently verified the externally sourced information used to develop the estimates for the potential market for Twirla, and their accuracy and completeness cannot be assured. Similarly, our internal analyses and calculations are based upon analysis of the current and expected future U.S. contraceptive market and management's understanding and assessment of numerous inputs and market conditions, including, but not limited to, the addressable market segment for CHCs and the reimbursement status of contraceptives under the federal Affordable Care Act and similar state laws. These understandings and assessments necessarily require assumptions subject to significant judgment and may prove to be inaccurate. As a result, our estimates of the size of the potential market for Twirla could prove to be overstated, perhaps materially.

In addition, we are relying on third party data to identify the healthcare providers who prescribe contraception in the U.S. and to determine how to deploy resources to market to those healthcare providers; however, we may not be marketing to the appropriate physicians and may therefore be limiting our market opportunity.

We may develop estimates with respect to market opportunities for potential product candidates in the future, and such estimates would be subject to similar risks. Even if we obtain regulatory approval for one or more potential product candidates, we may be unable to commercialize the product on a scale sufficient to generate significant revenue, which could have a material adverse effect on our business, financial condition, results of operations and prospects and the value of our common stock.

The proportion of the contraceptive market that is made up of generic products could continue to increase, making introduction of a branded contraceptive difficult and expensive.

The proportion of the U.S. market that is made up of generic products has been increasing over time. For example, in 2005, generic contraceptive products held 49% of prescription volume and 36% of sales and, by 2019, those values had risen to 88% and 43%, respectively. Recently, Congress and the FDA have taken steps to increase generic competition in the market. A primary trend in the U.S. healthcare industry is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications including branded innovator products. If this trend continues, it may be more difficult to commercialize Twirla as a branded contraceptive at a price that will maximize our revenue and profits. Also, there may be additional marketing costs to commercialize Twirla in order to overcome the trend towards generics and to gain access to reimbursement by payors. If we are unable to introduce Twirla at a price that is commensurate with that of current branded contraceptive products, or we are unable to gain reimbursement from payors for Twirla, or if patients are unwilling to pay any price differential between Twirla and a generic contraceptive, our revenues will be limited. For example, in light of the introduction of the branded generic version of the Ortho Evra product by Mylan Inc. in April 2014, and the subsequent discontinuation of distribution of Ortho Evra in October 2014 by Janssen we may have to take additional measures in order to be competitive and gain market share. We may increase the rebates available to commercial payors or we may provide incentives to consumers covered by non-governmental payors, such as coupons or rebates, in order to make up for the difference in the co-payment for Twirla and the generic patch product.

Prescribers, patients and payors may not adopt a new contraceptive patch due to concerns based upon the prior experience with or perception of the previously marketed contraceptive patch and its currently marketed generic equivalent product.

The Ortho Evra® contraceptive patch, or Evra, was introduced in early 2002 and was the first FDA-approved contraceptive patch. The following is a brief history of the Evra market experience:

- Evra had rapid uptake in the contraceptive market, achieving a 10% share of the CHC market by September 2003. The initial approved labeling for Evra indicated that it delivered a daily EE dose of 20 micrograms.

- Following the approval of Evra, the manufacturer of Evra and the FDA began receiving reports of thrombotic and thromboembolic events.

- A pharmacokinetic study was conducted in 2005 and later published in the Journal of Clinical Pharmacology comparing Evra to an oral contraceptive, which demonstrated that Evra was delivering higher serum concentrations of EE compared to an oral contraceptive with an EE dose of 35 micrograms. A pharmacokinetic study evaluates how the body handles a given drug over time; these studies are conducted by measuring the amount of time it takes for the drug to be absorbed, distributed and eliminated throughout the body.

- 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 a unique boxed warning and bolded warning in the Evra labeling.

- The FDA held a Joint Meeting of the Advisory Committees for Reproductive Health Drugs and Drug Safety and Risk Management on December 9, 2011. The Committees concluded that users of Evra have an increased risk of venous thromboembolism, or VTE compared to users of second-generation contraceptives, such as those containing LNG. The Committees, through a vote, concluded that the benefits of Evra outweighed the risks, but that the current package insert did not adequately reflect the risk/benefit profile.

- A subsequent change to the labeling for Evra was implemented in August 2012.

- The Evra market share declined rapidly following the 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.

- In April 2014, the Evra label was revised to provide revised dosage form and strength information. However, this revision did not affect the unique boxed warning and bolded warning in the Evra label.

- The approval of a generic equivalent to Evra, Xulane was announced by Mylan Inc. in April 2014. Subsequently, in October 2014, Janssen discontinued distribution of Evra and currently over 99% of patch prescriptions are filled with the generic.

We have conducted pharmacokinetic studies of Twirla to demonstrate that it delivers a daily EE dose of approximately 30 micrograms, which is less than that delivered by Xulane, according to its FDA approved label. However, because none of our completed Phase 3 clinical trials studied Twirla in a head-to-head comparison with Xulane, we will not be able to make comparative claims regarding the EE exposure, safety, or efficacy of Twirla as compared to Xulane without conducting a supportive head-to-head post-marketing study. As a result, uptake and usage of Twirla and our related revenues could ultimately 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 a long-term post marketing safety study required by the FDA to compare the risks for venous thromboembolism (VTE) and arterial thromboembolism (ATE) in new users of Twirla to new users of oral CHCs and new users of Xulane in U.S. women of reproductive age. Further, we may conduct additional trials in connection with lifecycle management programs for Twirla. New safety or efficacy 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 or efficacy 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.

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive. We have significant competition with contraceptive products already in the marketplace, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. Any new product that competes with a previously approved product may need to demonstrate compelling advantages in efficacy, convenience, tolerability or safety to be commercially successful. In addition, new products developed by others could emerge as competitors to Twirla. If we are not able to compete effectively against our current and future competitors, our business may not grow, and our financial condition and operations may suffer.

Our potential competitors include, but are not limited to, large, well-established pharmaceutical companies, and specialty pharmaceutical sales and marketing companies. These companies include Organon & CO., a new company created by Merck & Co., Inc., or Merck, which markets Nuvaring®, TherapeuticsMD, Inc., or TherapeuticsMD, which has licensed and markets Annovera®, a recently approved contraceptive ring, Allergan, Inc., or Allergan, which markets

several branded and generic contraceptives including Minastrin® 24, LoLoestrin®, and Taytulla®, Bayer AG, or Bayer, which markets Beyaz®, Yaz®, Yasmin®, and Natazia®, and Mylan N.V., which markets Xulane®, a generic version of Ortho Evra. 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. Additionally, several generic manufacturers currently market and continue to introduce new generic contraceptives, including Sandoz International GmbH, Glenmark Pharmaceuticals Ltd., Lupin Pharmaceuticals, Inc., and Amneal Pharmaceuticals, Inc.

There are other contraceptive product candidates in development that, if approved, would potentially compete with Twirla. Specifically, Bayer has a contraceptive patch approved in the European Union, or E.U. Bayer entered into a license and distribution agreement for the sale of this contraceptive patch in Europe with Gedeon Richter Ltd. Other companies that have new hormonal contraceptive product candidates in various stages of development include Allergan (progestin-only vaginal ring for which they received a CRL from the FDA), The Population Council in collaboration with Antares Pharma, Inc. (transdermal gel contraceptive in Phase 2), Mithra Pharmaceuticals SA (combination oral contraceptive in Phase 3), and Panterhei Bioscience (combination oral contraceptive in Phase 2).

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 2018, three companies generated about 95% of all revenues from drug distribution in the United States, and in 2019, the top five chain pharmacy companies owned about 35% 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.

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 of Twirla may be.

In March 2010, President Obama signed into law the ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the healthcare industry and impose additional healthcare policy reforms. The ACA, among other things, increased the Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program for both branded and generic drugs, extended the rebate program to certain individuals enrolled in Medicaid managed care organizations, addressed new methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are line extension products and expanded the 340B drug discount program (excluding orphan drugs) to other entities. Further, the ACA imposed a significant annual tax on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with regard to healthcare practitioners.

Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies or new drug products. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in

2010, the ACA, among other things, subjected biologic products to potential competition by lower-cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

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. Contraceptive methods and counseling, including all FDA-approved contraceptive methods as prescribed, are included in the ACA mandate, and this has come to be known as the "contraceptive mandate." Under the ACA, payors are only required to cover one favored product within each contraceptive "method" without imposing any cost-sharing obligations on the patient. For example, the introduction of a generic contraceptive patch product with a price that will likely be lower than the price of Twirla makes it less clear that Twirla would have a preferred position, such as coverage without a co-insurance payment, under the ACA contraceptive mandate. Other products within the same method may also be covered, but payors are allowed to use reasonable medical management techniques, such as the application of cost-sharing obligations. An amendment was issued that provided an exemption to the contraceptive mandate for group health plans established or maintained by religious employers. However, the contraceptive mandate has remained controversial, with several legal challenges filed around the country. In June 2014, the U.S. Supreme Court ruled that owners of certain private companies can object to the contraceptive mandate on religious grounds and in November 2015, the Court agreed to hear arguments from non-profit organizations requesting similar treatment. In October 2017, the U.S. Department of Health and Human Services announced it will seek to issue regulations that will allow all companies to qualify for the exemption from the contraceptive mandate on the basis of religious and moral grounds. While there is an injunction against the administration prohibiting it from implementing these rules, the ultimate outcome of that litigation, which is currently in front of the Supreme Court, cannot be predicted. 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. Further, on January 20, 2017, the Trump administration signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices, among others; this Executive Order was overturned by President Biden on January 28, 2021. 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.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction in funding to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2030 unless additional Congressional action is taken. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, as well as subsequent legislation, these cuts have been suspended from May 1, 2020 through March 31, 2021. Proposed legislation, if passed, would extend this suspension until the end of the pandemic. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. 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.

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. Various portions of the ACA are currently undergoing legal and constitutional challenges in the United States Supreme Court; the former Trump Administration issued various Executive Orders eliminating cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. The United States Supreme Court is expected to rule on a legal challenge to the constitutionality of the ACA in early 2021. The implementation of the ACA is ongoing, 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.

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 the 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 required to be done electronically. Manufacturers must also verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this legislation, manufacturers have drug product 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 measures have also been taken by Congress, the previous administration, and administrative agencies to increase drug competition and thus, decrease drug prices. By example, the Medicare Modernization Act contains provisions that call for the promulgation of regulations that expand pharmacists' and wholesalers' ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. Further, the Medicare Modernization Act provides that these changes to U.S. importation laws will not take effect unless and until the Secretary of HHS certifies that the changes will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of products to consumers. On September 23, 2020, the Secretary of HHS made such certification to Congress, and on October 1, 2020, the FDA published a final rule that allows for the importation of certain prescription drugs from Canada. Under the final rule, States and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the FDA for review and authorization. Since the issuance of the final rule, several industry groups have filed federal lawsuits challenging multiple aspects of the final rule, and authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. On September 25, 2020, CMS stated drugs imported by States under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Separately, the FDA also issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code (NDC) for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. Since the issuance of the final rule, on November 23, 2020, several industry groups filed federal lawsuits in the U.S. District Court for the District of Columbia, requesting injunctive relief to prevent certification from the Secretary of HHS from taking effect and challenging multiple aspects of the final rule. This litigation has not progressed. If implemented, drug importation may materially and adversely affect the price we receive for any of our products or future product candidates. The market implications of these rules and guidance are unknown at this time. Additionally, a law was enacted in 2019 requiring 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. New legislative and regulatory efforts could ultimately have an adverse impact on our business and results of operation.

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.

Third-party coverage and reimbursement and healthcare cost containment initiatives and treatment guidelines may constrain our future revenues.

Our ability to successfully market Twirla will depend in part on the level of coverage and reimbursement that government authorities, private health insurers and other organizations provide for Twirla and contraceptives in general. Countries in which Twirla is sold through reimbursement schemes under national health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the United States, government-funded and private medical care plans can exert significant indirect pressure on prices. We may not be able to sell Twirla profitably if adequate prices are not approved or coverage and reimbursement are unavailable or limited in scope. Increasingly, third party payors attempt to contain healthcare costs in ways that are likely to impact our development of products including:

- Failing to approve or challenging the prices charged for healthcare products;
- Introducing reimportation schemes from lower-priced jurisdictions;
- Limiting both coverage and the amount of reimbursement for new therapeutic products;
- Denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third party payors; and
- Refusing to provide coverage when an approved product is used for off-label indications.

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 $51.9 million, $18.6 million and $19.8 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of approximately $312.2 million. Based on our current business plan and on-going commercialization of Twirla, we believe that our cash, cash equivalents and marketbale securities as of December 31, 2020 will be sufficient to meet our projected operating requirements through the end of 2021. Our cash, cash equivalents and marketable securities will not be sufficient to fund our current and planned operations through the 12 months following the date on which this Annual Report on Form 10-K is filed, which raises substantial doubt about our ability to continue as a going concern. Substantial doubt about our ability to continue as a going concern may create negative reactions to the price of our common stock and we may have a more difficult time obtaining financing in the future.

Specialty pharmaceutical product development is a speculative undertaking, involves a substantial degree of risk and is a capital-intensive business. We expect to incur expenses without corresponding revenues until we are able to sell Twirla in significant quantities, which may not happen. We have devoted most of our financial resources to research and development, including our non-clinical development activities and clinical trials. We will require additional capital to fund our operating needs beyond 2021, 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. Our potential product candidates will

also require the completion of regulatory review, significant marketing efforts and substantial investment before they can provide us with any revenue.

We expect that our expenses will increase as we 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 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 or even if we are able to commercialize any other potential product candidate, 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 our ability to:

- Maintain an acceptable price for Twirla, and our other potential product candidates, if approved, and obtain adequate coverage and reimbursement from third party payors;
- Obtain commercial quantities of Twirla, and our other potential product candidates, if approved, at acceptable cost levels from our third-party manufacturer;
- Successfully market and sell Twirla, and our other potential product candidates, if approved, in the United States and abroad; and
- Successfully receive regulatory approval for our other potential product candidates.

In addition, because of the numerous risks and uncertainties associated with product commercialization and product candidate 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 and our other potential product candidates, if approved.

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, and our other potential product candidates, if approved, 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. 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 for a senior secured term loan facility of up to $35.0 million, which was amended in February 2021 to add a fourth tranche of $10.0 million, which is subject to the same interest rate and 1% fee payable upon the drawing of a tranche as set forth in the 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 $25.0 million will be available in two separate tranches upon the achievement of certain revenue milestones. The facility will be interest only until the third anniversary of the closing date.

The Perceptive Credit Agreement subjects us to various customary affirmative and negative covenants, including requirements as to financial reporting and insurance, and restrictions on our ability to dispose of our business or property, change our line of business, liquidate or dissolve, enter into any change in control transaction, merge or consolidate with any other entity or acquire all or substantially all the capital stock or property of another entity, incur additional indebtedness, incur certain types of liens on our property, including our intellectual property, pay any dividends or other distributions on our capital stock other than dividends payable solely in capital stock or redeem our capital stock. 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. We are currently required to make interest-only payments through February 2023. Loans under the Perceptive Credit Agreement currently bear interest at rate of 10.25% per annum plus one-month LIBOR, and mature on February 10, 2024.

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. In that case, we may be required to delay, limit, reduce or terminate our potential product candidate 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.

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 to complete the development and commercialization of our other potential product candidates.

Our operations have consumed substantial amounts of cash since our inception. From our inception to December 31, 2020, we have cumulative net cash flows used by operating activities of $274.6 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 develop and commercialize our other potential product candidates and to complete the development of any additional product candidates we might acquire. 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, and our other potential product candidates, if approved;
- Our ability to have commercial product successfully manufactured consistent with FDA regulations;

- Amount of sales and other revenues from Twirla and our other potential product candidates that we may commercialize, if any, including the selling prices for such products and the availability of adequate third-party coverage and reimbursement;
- Sales and marketing costs associated with commercializing Twirla, and our other potential product candidates, if approved, including the cost and timing of expanding our marketing and sales capabilities;
- 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, including the ability to timely enroll subjects in our ongoing, planned and any other clinical trials;
- Terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- Cash requirements of any future acquisitions or the development of other potential product candidates;
- 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 expansion of our commercial manufacturing process for Twirla and/or the establishment of a backup supplier;
- Costs associated with the hiring of new employees and maintaining our contract sales force; and
- Costs associated with the leasing of additional office space.

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. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay or reduce the scope of our commercialization efforts or one or more of our research or development programs. 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. In addition, if we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have 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.

Our ability to fund our operations through the period of time necessary to successfully commercialize Twirla could be adversely affected based on our inability to manufacture sufficient quantities of Twirla, the failure of Twirla to gain acceptance in the marketplace, our inability to successfully compete with other contraceptive products, our inability to receive reimbursement coverage from third-party payors, and the need to provide higher rebates in order to gain a competitive formulary status. 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 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.

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

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

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 example, as part of the FDA's approval of Twirla, the FDA has required us to conduct a long-term post-marketing safety study to assess and describe the risks of Twirla, including the risk of VTE and ATE compared to oral CHCs and Xulane. This study is similar to one recently required by FDA for another contraceptive product. We will also conduct a second small post-marketing study, required by FDA, to assess Twirla's residual drug content, strength, and adhesion. 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 enforcement action or FDA removal of the product from the market.

Other 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, the FDA and other government authorities may issue a Warning Letter or Untitled Letter, or take other regulatory action such as a product seizure and detention, withdrawal of product approval, requests for a recall, refusal to allow the import or export of the product, criminal or civil penalties, injunction against or restriction of product manufacture or distribution, consent decrees, disgorgement, restitution, clinical holds or terminations of clinical trials, FDA debarment, debarment from government contracts or refusal of orders under existing contracts, exclusion from federal healthcare programs, corporate integrity agreements, or imprisonment.

The FDA has the authority to require a REMS after approval, which may impose further requirements or restrictions on the information that patients must be provided, distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring treated patients to enroll in a registry.

With respect to sales and marketing activities by us and our contracted sales force or any future collaborative partner, advertising and promotional materials must comply with the FDA's rules in addition to other applicable federal and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act and is subject to certain requirements. 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. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

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. 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. Physicians may nevertheless prescribe the products to their patients in a manner that is inconsistent with the approved label. 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 and government fines. 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. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

In the United States, 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, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute drug products through, for example, corporate integrity agreements, and debarment, suspension or exclusion from participation in federal and state healthcare programs. These false claims statutes include the federal civil False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims or causing others to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. 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. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations and prospects.

If we or a regulatory agency discover previously unknown problems with Twirla or with a potential product candidate, once approved, 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 the following administrative or judicial sanctions:

- Restrictions on the marketing, distribution or manufacturing of the product, withdrawal of the product from the market, or requests for product recalls;
- Issuance of Warning Letters, Cyber Letters or Untitled Letters;
- Mandated modification to promotional materials and labeling requirements or provision of corrective information to healthcare providers;
- FDA or regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings and other safety information about the product;
- Entry into a consent decree or corporate integrity agreement, which can include imposition of various fines, reimbursement for inspection costs, required due dates for specific actions and penalties for noncompliance;
- Clinical holds or termination of clinical trials;
- Injunctions or the imposition of civil or criminal penalties, imprisonment, monetary fines disgorgement or restitution;
- Suspension or withdrawal of regulatory approval;
- Suspension of any ongoing clinical trials;
- Refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- Debarment;
- Exclusion from participation in federal healthcare programs or refusal of government contracts;
- Suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or
- Product seizure or detention or refusal to permit the import or export of product.

The occurrence of any event or penalty described above may inhibit our ability to commercialize Twirla, or our potential product candidates, if approved, 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.

Moreover, the FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay the sale and promotion of Twirla, or marketing approval and the sale and promotion of our potential product candidates, if approved. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any obtained marketing approval, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Our relationships with physicians, customers and payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products that we commercialize. Our arrangements with third-party payors, including government healthcare programs, and customers will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute Twirla. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- The federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

- The federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;

- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, impose obligations on covered healthcare providers, health plans and healthcare clearinghouses, as well as their business associates that create receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- The federal physician payment transparency requirements and applicable regulations require manufacturers of drugs, devices, biologics and medical supplies to report certain information to the Department of Health and Human Services including information related to payments and other transfers of value made to physicians and teaching hospitals and the ownership and investment interests held by physicians and their immediate family members; and

- Analogous state laws and regulations, such as state anti-kickback and false claims laws that 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 HIPAA, thus complicating compliance efforts.

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. Additionally, the risk of our being found in violation of these laws and regulations is increased by the fact that many of them have not been fully interpreted by the relevant government or regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Moreover, healthcare reform legislation has strengthened these laws. For example, the ACA, among other things, amended the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes; such that a person or entity no longer needs to have actual knowledge of these statutes or

specific intent to violate them. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations are costly. 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. If our operations, including anticipated activities conducted by our sales team in the sale of Twirla are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to a variety of different consequences, depending upon which law we are found to have violated, including significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, corporate integrity agreements, refusal of government contracts, contract debarment and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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, which could materially harm our business.

Corium is a biopharmaceutical company that focuses on the development, manufacture, and commercialization of specialty transdermal products. In addition to partnering with other companies to manufacture transdermal products, Corium also engages in the research and development of its own proprietary transdermal drug delivery products. We rely on Corium, our third-party manufacturer, to produce commercial supplies and samples of Twirla. We have not back-up or alternative manufacturer of Twirla. We may also rely on them for clinical and commercial supplies and samples of our potential product candidates, if approved. We do not own or operate, and have no plans to establish, any manufacturing facilities for Twirla or our potential product candidates. We lack the resources and the capabilities to manufacture Twirla or any of our potential product candidates on a clinical or commercial 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. For example, in 2018 Corium was acquired by Gurnet Holding Company, or GHC. Following completion of the transaction, Corium became a private company, wholly owned by GHC. Corium has announced that it plans to continue its operations in Grand Rapids, Michigan, where commercial supplies of Twirla are being manufactured.

Furthermore, we do not control the manufacturing process of Twirla, and are completely dependent on Corium for compliance with the FDA's manufacturing regulatory requirements for the manufacture of Twirla, our potential product candidates and our other future products, if and when approved. As a manufacturer, Corium or other contract manufacturers that we may use are subject to routine inspection by regulatory authorities, including the FDA. If Corium or other contract manufacturers that we may use 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.

In addition, while our contracts with our manufacturers generally contain provisions to help ensure that quality standards and compliance with laws and regulations are maintained, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If in the future, 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 and to develop, and obtain, regulatory approval for and market our potential product candidates, if approved. Moreover, if our contract manufacturer

cannot successfully manufacture materials that conform to our specifications and the strict regulatory requirements of the FDA, we may be subject to regulatory enforcement actions such as adverse inspectional findings, Warning Letters, Untitled Letters, recall requests, withdrawal of product or investigational approvals, clinical holds or termination of clinical trials, refusals to approve pending applications, disgorgement, restitution, exclusion from federal healthcare programs, product seizures and detention, consent decrees, corporate integrity agreements, criminal and civil penalties, including imprisonment, refusal to permit import or export of the product and injunction against or restriction of manufacture or distribution. If our contract manufacturer experiences issues in its manufacturing process or is unable to produce commercial supplies in adequate quantity and quality, our commercialization of Twirla could be delayed. An inability of our contract manufacturer to produce supplies in adequate quantity and quality of Twirla and our potential product candidates could also delay our ability to conduct clinical trials. This may adversely impact our ability to fulfil our post-marketing study requirements for Twirla and obtain regulatory approval of our potential product candidates.

The machinery and process to produce the commercial supply of Twirla is located within one manufacturing site and is customized to the particular manufacturing specifications of Twirla. If this customized equipment malfunctions at any time during the production process, the time it may take Corium to secure replacement parts, to undertake repairs and to revalidate the equipment and process or to identify new third-party manufacturers could limit our ability to meet the commercial demand for Twirla. Similar manufacturing conditions may also apply to our potential product candidates. This may increase the risk that the third-party manufacturer may not manufacture Twirla in accordance with the applicable regulatory requirements, that we may not have sufficient quantities of Twirla or our potential product candidates or that we may not have such quantities at an acceptable cost, any of which could delay, prevent, or impair the commercialization of Twirla and the development of our potential product candidates.

Additionally, if Corium or any third-party manufacturer with whom we contract fails to perform its obligations, 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 so 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 some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original contract manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change contract manufacturers for any reason, we will be required to verify that the new contract manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our products or product candidates according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new contract manufacturer could negatively affect our ability to commercialize our products, including Twirla, and develop our other potential product candidates in a timely manner or within budget. Furthermore, a contract manufacturer may possess technology related to the manufacture of our products or product candidates that such contract manufacturer owns independently. This would increase our reliance on such contract manufacturer or require us to obtain a license from such contract manufacturer in order to have another contract manufacturer manufacture our products or product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging or comparability studies between our prior clinical or commercial supply and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of newly manufactured products or product candidates to prior manufactured products or product candidates which could require the conduct of additional clinical trials.

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. While, to date, Corium has not experienced any disruption to its supply chain for the raw materials needed to manufacture Twirla, 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. Although Corium intends to enter into agreements with critical manufacturers, component fabricators and secondary service providers to secure commercial supply of Twirla, not all of such suppliers and service providers will be under contract. Any delays in obtaining adequate supplies of our potential product candidates, including on account of the COVID-19 pandemic or U.S. government utilization of its Defense Production Act authorities, could limit our ability to meet clinical and commercial demand for Twirla.

In addition, in the event Twirla achieves significant market share, Corium may not possess adequate manufacturing capabilities to meet market demand for Twirla. 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.

Reliance on a third-party manufacturer subjects us to risks that would not affect us if we manufactured Twirla and our potential product candidates ourselves, including:

- Reliance on the third party for regulatory compliance and quality assurance;
- Reduced control over the manufacturing process for Twirla and our potential product candidates;
- The possible breach of the manufacturing agreements by the third party because of factors beyond our control;
- The possibility of termination or nonrenewal of the agreements by the third party because of our breach of the manufacturing agreement or based on their own business priorities;

Twirla and our potential product candidates may compete with other products and product candidates for access to manufacturing resources and facilities. There are a limited number of manufacturers that operate in compliance with the FDA's manufacturing requirements and that are both capable of manufacturing for us and willing to do so. If our existing third-party manufacturer, or the third parties that we may engage in the future to manufacture a product for commercial sale or for our clinical trials, should cease to continue to manufacture our products or potential product candidates for any reason, we likely would experience delays in obtaining sufficient quantities of our products or potential product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify alternative suppliers. If for any reason we are unable to obtain adequate supplies of our products or potential product candidates or the components used to manufacture them, it will be more difficult for us to develop our potential product candidates and compete effectively.

Our third-party manufacturer is subject to regulatory requirements, covering manufacturing, testing, quality control and record keeping relating to Twirla and our potential product candidates, and is subject to ongoing inspections by various regulatory agencies. In addition to the above-described regulatory actions, failures by our third-party manufacturer to comply with applicable regulations may result in long delays and interruptions to our manufacturing capacity while we seek to secure another third-party manufacturer that meets all applicable regulatory requirements.

If the manufacturing facilities of Corium are not maintained in a manner that is compliant with FDA's manufacturing requirements, we may need to find alternative manufacturers and suppliers, which could result in supply interruptions of Twirla and our potential product candidates, additional costs and lost revenues.

Corium's facilities used for the manufacture of Twirla and our potential product candidates must be maintained in a manner compliant with the FDA's manufacturing requirements, including obtaining favorable inspection reports. We do not control the manufacturing process and are dependent on Corium for compliance with the FDA's requirements for manufacture of Twirla and our potential product candidates. If Corium cannot successfully manufacture material components and finished products that conform to our specifications and the FDA's strict regulatory requirements, they and we may be subject to regulatory action, including adverse inspectional findings, Warning Letters, Untitled Letters, product recall requests, withdrawal of product or investigational approvals, non-approval of marketing applications,

clinical holds or termination of clinical trials, disgorgement, restitution, exclusion from federal healthcare programs, detentions or seizures, refusal to allow the import or export of a product, injunction against or restriction of manufacture or distribution, consent decrees, corporate integrity agreements, criminal and civil penalties, including imprisonment, and Corium may not be able to maintain FDA approval for its manufacturing facilities or acceptance of its manufacturing data in regulatory filings. If Corium's facilities cannot maintain compliance with FDA requirements, we may need to find and successfully qualify alternative manufacturing facilities, which could result in supply interruptions of Twirla and our potential product candidates and substantial additional costs as a result of such delays, including costs with respect to finding alternative manufacturing facilities, and lost revenues. There is further no guarantee that the FDA would approve these alternative facilities.

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 be delayed in obtaining or ultimately not be able to obtain marketing approval for our potential product candidates.

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. Entering into relationships with CROs and clinical trial sites involves substantial cost and requires extensive management time and focus. In addition, typically there is a transition period between engagement of a CRO and clinical trial sites and the time the CRO and sites commences work. As a result, 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, as part of Twirla's approval, the FDA is requiring that we conduct a post-marketing study comparing the risks for venous thromboembolism (VTE) and arterial thromboembolism (ATE) in new users of Twirla to new users of oral CHCs and new users of Xulane in U.S. women of reproductive age. The FDA has also required a second small post-marketing study to assess Twirla's residual drug content, strength, and adhesion. We plan to engage the services of a CRO to design, enroll, and complete this study, which will likely involve thousands of subjects and hundreds of clinical trial sites and will require substantial time and resources. If the CRO cannot enroll subjects and complete the trial in a timely manner, we may be unable 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, known as Current Good Clinical Practices, or cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our products and potential product candidates in clinical trials, which include requirements related to the conduct of the study, subject informed consent, and IRB approval. Regulatory authorities enforce these cGCPs through routine inspections of trial sponsors, principal investigators and trial sites. Although we may rely on third parties for the execution of our trials, we are nevertheless responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on CROs and clinical trial sites does not relieve us of our regulatory responsibilities. If we, any of our CROs, or clinical trial sites fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, European Medicines Agency or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications for potential product candidates in development, or to perform additional post marketing studies for approved products or determine that data from the post marketing study is not sufficient to support maintaining marketing authorization for the product at issue. We cannot assure you that, upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials or post marketing studies complies with cGCP regulations.

In addition, our clinical trials must be conducted with product and potential product candidates' materials produced in compliance with the FDA's manufacturing regulations. Our failure to comply with these regulations may require us to discontinue or repeat clinical trials, which could delay the regulatory approval process for our potential product candidates or impact our ability to meet our post-market study requirements. 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 regulatory action, including Warning Letters, Untitled Letters, adverse inspectional findings, clinical holds or termination of clinical trials, non-approval of marketing applications, criminal and civil penalties, including imprisonment, injunction against manufacture or distribution and debarment. 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, and cash collection. If we retain a service provider, we would substantially rely on it as well as other third-party providers that perform services for us. 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 regulatory enforcement action.

In addition, we may engage third parties to perform various other services for us relating to pharmacovigilance and adverse event reporting, safety database management, fulfillment of requests for medical information regarding Twirla and related services. If the quality or accuracy of the data maintained by these service providers is insufficient, or these third parties otherwise fail to comply with regulatory requirements, we could be subject to regulatory sanctions.

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 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. We believe we will be able to obtain, through prosecution of our pending patent applications, additional patent protection for our proprietary technology. 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. 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 potential product candidates and potential products may prevent us from obtaining or enforcing patents relating to this product and potential product candidates and potential products, including without limitation transdermal delivery systems and methods of using such transdermal delivery systems. Our product and potential product candidates contain generically available active pharmaceutical ingredients. As a result, new chemical entity patents directed to the active pharmaceutical ingredients in our product and potential product candidates, which are generally believed to offer the strongest form of patent protection, are not available for our potential product candidates.

Patents that we own or may license in the future do not necessarily ensure the protection of our intellectual property for a number of reasons, including without limitation the following:

- The active pharmaceutical ingredients in Twirla and our potential product candidates are generic and therefore our patents do not include claims directed solely to the active pharmaceutical ingredients;
- Our patents may not be broad or strong enough to prevent competition from other products that are identical or similar to Twirla or our potential product candidates using the same active pharmaceutical ingredients;
- There can be no assurance that the term of patent protection will be long enough for our company to realize sufficient economic value under the patents following commercialization of Twirla, or our potential product candidates, if approved;
- Our issued patents and pending patent applications that may issue as patents in the future may not prevent entry into the U.S. market or other markets of generic versions of Twirla or our other potential product candidates;
- Our patents may face paragraph IV challenges from potential generic or 505(b)(2) applicants, asserting that our applicable patents are invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the competitive drug product;
- We do not at this time own or control issued foreign patents in all markets that would prevent generic entry into some markets for Twirla or our potential product candidates;
- We may be required to disclaim part of the term of one or more patents;
- There may be prior art of which we are not aware that may affect the validity or enforceability of one or more patent claims;
- There may be prior art of which we are aware, which we do not believe affects the validity or enforceability of a patent claim, but which, nonetheless, ultimately may be found to affect the validity or enforceability of a patent claim;
- There may be other patents issued to others that will affect our freedom to operate;

- If our patents are challenged, a patent office or a court could determine that they are invalid or unenforceable;
- There might be changes in the law that governs patentability, validity and infringement of our patents that adversely affects the scope or enforceability of our patent rights;
- A court could determine that a competitor's technology or product that is the same as or similar to, Twirla or our potential product candidates does not infringe our patents; and
- Our patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations or could be subject to compulsory licensing.

Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic, similar or strength modified versions of any approved products by submitting abbreviated new drug or 505(b)(2) NDA applications to the FDA in which our competitors claim that our patents are invalid, unenforceable or not infringed. Alternatively, our competitors may seek approval to market their own products that are the same as, similar to or otherwise competitive with Twirla or our potential product candidates. In these circumstances, we may need to defend or assert our patents, by means including filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or government agency with jurisdiction may find our patents invalid, unenforceable or not infringed. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

The issuance of a patent is not conclusive as to its inventorship, scope, ownership, priority, validity or enforceability. In that regard, third parties may challenge our patents in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and potential products. In addition, given the amount of time required for the development, testing and regulatory review, and commercial launch of new products, patents protecting any approved product we may have might expire or be held invalid or unenforceable before our company can realize sufficient economic value following commercialization.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application will be entitled to that patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO and may become involved in post-grant proceedings including reexamination, post-grant review, *inter partes* review, or derivation or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

The USPTO has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, did not become effective until March 16, 2013. However, the full impact of the Leahy-Smith Act, as well as the courts' treatment of any appeals to related proceedings, remain unclear. Accordingly, the full impact that the Leahy-Smith Act will have on the operation of our business is not clear. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, as well as our ability to bring about timely favorable resolution of any disputes involving our patents and the patents of others.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in unenforceability, invalidity, abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in unenforceability, invalidity, abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or any future licensors fail to maintain the patents and patent applications covering Twirla or our potential product candidates, our competitive position would be adversely affected.

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.

Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. There may be currently pending applications of which we are unaware that may later result in issued patents that Twirla or our current or future potential product candidates infringe. For example, pending applications may exist that claim or can be amended to claim subject matter that Twirla or our current or future potential product candidates infringe. Competitors may file continuing patent applications claiming priority to already issued patents in the form of continuation, divisional or continuation-in-part applications, in order to maintain the pendency of a patent family and attempt to cover Twirla or our potential product candidates.

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. 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, and we may not be able to do this. Proving invalidity or unenforceability is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If a court holds that any third-party patents are valid, enforceable and cover our product, potential product candidates, or their use, the holders of any of these patents may be able to block our ability to commercialize Twirla or our potential product candidates unless we acquire or obtain a license under the applicable patents or until the patents expire. We may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of our product or potential product candidates or lead to prohibition of the manufacture or sale of our product or potential product candidates by us. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from

commercializing our product or potential product candidates or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated their confidential information, know-how or trade secrets could have a similar negative impact on our business. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

We may be subject to claims that we or our employees have misappropriated the intellectual property, including know-how or trade secrets, of a third party, or that claim ownership of what we regard as our own intellectual property.

Many of our employees, consultants and contractors were previously employed at or engaged by biotechnology companies or other pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and contractors do not use the intellectual property and other proprietary information or know-how or trade secrets of others in their work for us, we may be subject to claims that we or these employees, consultants and contractors have used or disclosed such intellectual property, including know-how, trade secrets or other proprietary information. Litigation may be necessary to defend against these claims. We are not aware of any threatened or pending claims related to these matters or concerning agreements with our senior management, or other of our employees, consultants and contractors, but litigation may be necessary in the future to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, or personnel or access to consultants and contractors. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets to protect our proprietary technological advances and know-how, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, contractors, outside scientific collaborators, sponsored researchers and other advisors, including the third parties we rely on to manufacture Twirla and our potential product candidates, to protect our trade secrets and other proprietary information. However, any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets. Accordingly, these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. In addition, others may independently discover our trade secrets and proprietary information. Further, the FDA, as part of its Transparency Initiative, previously took steps to increase the public disclosure of information regarding FDA-regulated products, including information that we may consider to be trade secrets or other proprietary information. It is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position and financial results.

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 could substantially increase our operating expenses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

In infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information and trade secrets could be compromised by disclosure during litigation. Moreover, 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, our patents and patent applications in the United States and other jurisdictions could face other challenges, such as derivation or interference proceedings, opposition proceedings, *inter partes* review, reexamination proceedings, third party submissions of prior art, and other forms of post-grant challenges. In the United States, for example, post-grant review, which is similar to opposition proceedings available in many countries other than the U.S., was newly established by the Leahy-Smith Act. Any of these challenges, if successful, could result in the invalidation of, or in a narrowing of the scope or preventing the issuance of, any of our patents and patent applications subject to challenge. Any of these challenges, regardless of their success, would likely be time consuming and expensive to defend and resolve and would divert our management and scientific personnel's time and attention.

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 the Development of Our Additional Potential Product Candidates

If we fail to develop and commercialize our current pipeline of additional potential product candidates, our prospects for future growth and our ability to reach or sustain profitability may be limited or never achieved.

A key element of our long-term strategy is to develop, obtain regulatory approval for and commercialize our portfolio of potential product candidates in addition to Twirla. To do so, we plan to utilize our proprietary transdermal delivery technology, Skinfusion®, to develop additional potential product candidates. We may not be successful in our efforts to develop our portfolio of additional potential product candidates, and any potential product candidates we do develop may not produce commercially viable products that safely and effectively treat their indicated conditions. To date, our efforts have identified additional potential product candidates, including AG200 15 Extended Regimen (ER), 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, AG200 15 SmP, a 28 day regimen designed to provide users with shorter, lighter withdrawal bleeds and potentially improve contraceptive efficacy, AG200 15 ER SmP, 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, and AG890, which is a progestin-only contraceptive patch intended for use by women who are unable or unwilling to take estrogen. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or emergence of unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our future clinical trials will ultimately be successful or support further clinical development of any of our product candidates. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- preclinical studies or clinical trials may show the product candidates to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have unacceptable side effects or toxicities;
- failure to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- failure to receive the necessary regulatory approvals;
- manufacturing issues, formulation issues, pricing or reimbursement issues or other factors that make a product candidate uneconomical; and
- the proprietary rights of others and their competing products and technologies that may prevent one of our product candidates from being commercialized.

In addition, differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products.

Additionally, from time to time, we may publish interim or preliminary data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Material adverse changes between preliminary or interim data and final data could significantly harm our business prospects.

Moreover, in the past we have and in the future we may conduct clinical trials that utilize an "open-label" trial design. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

The potential product candidates in our pipeline will require additional product development efforts to optimize patch formulations and dosing. In addition, we will need to conduct additional clinical trials to establish the safety and efficacy of these potential product candidates, which will be expensive and potentially require additional capital.

Our development programs may initially show promise in identifying potential product leads yet fail to produce potential product candidates for clinical development. In addition, identifying new treatment needs and potential product candidates requires substantial technical, financial and human resources on our part. If we are unable to obtain development partners or additional development program funding, or to continue to devote substantial technical and human resources to such programs, we may have to delay or abandon these programs. Any potential product candidate that we successfully identify may require substantial additional development efforts prior to commercial sale, including preclinical studies, extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All potential product candidates are susceptible to the risks of failure that are inherent in pharmaceutical product development.

If we experience any of a number of possible unforeseen events in connection with clinical trials related to our potential product candidates, or Twirla, any potential marketing authorization or commercialization of our potential product candidates could be delayed or prevented or we may not be able to meet our post-marketing study requirements for Twirla.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing authorization or commercialize our potential product candidates, may prevent us from meeting our Twirla post-marketing study requirements, or which may adversely impact our commercialization of Twirla including:

- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs, or we may be required to modify the Twirla label, or regulators may withdraw Twirla approval or impose other conditions or restrictions, such as REMS;

- the number of patients required for clinical trials of our product and potential product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;

- we may enroll patients at clinical trial sites in countries that are inexperienced with clinical trials in general;

- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- regulators, institutional review boards or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or may require us

to submit additional data, conduct additional studies or amend our investigational new drug application, or IND, or comparable application prior to commencing a clinical trial;

- we may have delays in reaching or may fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- we may have to suspend or terminate clinical trials of our potential product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulators, institutional review boards or independent ethics committees may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials may be greater than we anticipate;
- regulators may determine that our studies, study design, or data analyses do not meet their regulatory requirements;
- the supply or quality of our potential product candidates, Twirla, or other materials necessary to conduct clinical trials may be insufficient or inadequate; or
- Twirla or our potential product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, institutional review boards or independent ethics committees to suspend or terminate the trials.

Our costs will increase if we experience delays in testing, completion of post-marketing studies, or, for our potential product candidate marketing authorizations. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all.

For Twirla, failure to complete post-marketing studies may also result in enforcement actions or removal of the product from the market. Adverse post-marketing study results may also result in withdrawal or limitations on marketing applications, label changes, or other restrictions or requirements, such as REMS or additional study requirements.

For our potential product candidates, we cannot commercialize any potential product candidates in the U.S. without first obtaining FDA approval. Before obtaining regulatory approvals for commercial sale, however, we must demonstrate in, or rely on data from preclinical studies and well controlled clinical trials that the potential product candidate is safe and effective for use in the target indication and that the manufacturing processes, facilities, and controls are adequate. Obtaining marketing approval in the U.S. is a lengthy, expensive and uncertain process, and approval may not be obtained or may be subject to significant restrictions. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our potential product candidates, allow our competitors to bring products to market before we do, or impair our ability to successfully commercialize our potential product candidates, and so may harm our business, results of operations and financial condition. Delays in regulatory approvals or failure to obtain regulatory approval for a potential product candidate may result from many factors, including:

- Regulatory requests for additional analyses, reports, data, nonclinical and preclinical studies, product design work and testing, and manufacturing development work;
- Regulatory questions regarding interpretation of data or new information regarding the potential product candidate or other products;
- Regulators may not agree with the design of our studies or our statistical analysis, may interpret our data differently than we do, or may find that our study results are not supportive of approval;

- Our studies may reveal unfavorable or inconclusive results, including unfavorable results regarding the potential product candidate's safety or efficacy;
- Regulators may determine that our potential product candidates present an unacceptable health risk or that the product's candidate's risks outweigh any benefits;
- Regulators may not approve our manufacturing facilities or processes following a facility inspection;
- Regulators may determine that our studies were not properly conducted or did not comply with regulatory requirements;
- We and regulators may not come to an agreement on product labeling;
- We may have insufficient funds to pay the FDA's significant application user fees;
- We may not be able to use FDA's 505(b)(2) NDA pathway due to changes in the FDA's interpretation of the law; and
- We may face patent challenges that may result in stays on the FDA's ability to approve our potential product candidates.

Delays or failure to receive regulatory approval for any additional potential product candidates may materially impact our business.

Risks Related to Our Business Operations and Industry

The ongoing outbreak of the novel strain of coronavirus, or COVID-19, or other similar public health crises, 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®.

In December 2019, a novel strain of coronavirus (SARS-CoV-2), now referred to as COVID-19, surfaced in Wuhan, China. Since then, the virus has spread globally to multiple countries, including the United States. The impact of this pandemic has been and will likely continue to be extensive, affecting many aspects of society, and it has resulted in and will likely continue to result in significant disruptions to global business activities and capital markets around the world, including as emerging variants of the virus are detected and continue to spread.

As a result of the COVID-19 pandemic, or similar pandemics, we may experience disruptions that could severely affect our business, including our plans to clinically develop and commercialize our products. We may not be able to meet expectations with respect to our anticipated commercial launch of Twirla, our first approved product, which we plan to begin manufacturing on a commercial scale in the second half of 2020.

Global business interruptions resulting from COVID-19 may adversely impact our third-party manufacturer, Corium, whom we rely upon for the manufacture of Twirla, as well as its suppliers of raw materials. If Corium or any of its suppliers of raw materials are adversely impacted by the COVID-19 pandemic or the restrictions resulting from the pandemic, if they cannot obtain the necessary supplies, or if such third parties need to prioritize other products or customers over us, including under the Defense Production Act, we may experience delays or disruptions in our supply chain, which could have a material and adverse impact on our business. Third party manufacturers may also need to implement measures and changes, or deviate from typical requirements because of the COVID-19 pandemic that may otherwise adversely impact our supply chains or the quality of the resulting products or supplies. Depending on the change, we may need to obtain FDA pre-approval or otherwise provide FDA with a notification of the change. As a result, we may not be able to obtain sufficient quantities of Twirla, which could impair our ability to commercialize Twirla and conduct the post-marketing studies requested by the U.S. Food and Drug Administration, or the FDA, in connection with the approval of Twirla. In addition, if there are continued or future disruptions, our third-party

manufacturers may not be able to supply our other potential product candidates, which would adversely affect our research and development activities.

Further, many jurisdictions have implemented travel restrictions and expansive social distancing orders. These measures may have a material adverse impact on the third-party consultants who assist us with our sales and marketing functions, as well as on our ability to develop our own sales and marketing infrastructure. For example, such social distancing orders could limit the ability of sales representatives to interact with healthcare providers and also restrict 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 Twirla prescriptions during the COVID-19 pandemic. This could negatively affect our ability to commercialize Twirla as well as market our other potential product candidates.

Delays in the ability to manufacture commercial supplies of Twirla and to implement a sales force for Twirla could also adversely affect our financial position. Based on our current business plan and ability to get Twirla launched, we believe that our cash, cash equivalents and marketable securities as of September 30, 2020 will be sufficient to meet our projected operating requirements through the end of 2021. However, two vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020, and more are likely to be authorized in the coming months. While, to date, we have not encountered any delays or interruptions to our supply due to the pandemic, the resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials and/or commercial product, which could lead to delays in these trials and/or issues with our commercial supply. If the COVID-19 pandemic or other factors impact our current business plan or our ability to generate revenue from the launch 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. However, 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 the revisions to our commercial plans are inadequate or management determines that it is necessary.

Additionally, certain of our clinical activities, including the post-marketing studies requested by the FDA in connection with the approval of Twirla, as well as any product development activities that we have planned, may be delayed or interrupted, compromising our ability to maintain regulatory approval for Twirla and our future ability to obtain marketing approval for our other potential product candidates. By example, the pandemic may result in slower enrollment than we anticipated, the need to suspend enrollment into studies, patient withdrawals, postponement of planned clinical or preclinical studies, redirection of site resources from studies, study modification, suspension, or termination, the introduction of remote study procedures and modified informed consent procedures, study site changes, direct delivery of investigational products to patient homes requiring state licensing, study deviations or noncompliance, and changes or delays in site monitoring. The foregoing may require that we consult with relevant review and ethics committees, IRBs, and the FDA. The foregoing may also impact the integrity of our study data. The effects of the COVID-19 pandemic may also increase the need for clinical trial patient monitoring and regulatory reporting of adverse effects. The pandemic could further impact our ability to interact with the FDA or other regulatory authorities, and may result in delays in the conduct of inspections or review of pending applications or submissions. Since March 2020, foreign and domestic inspections by the FDA have largely been on hold with FDA announcing plans in July 2020 to resume prioritized domestic inspections. Should FDA determine that an inspection is necessary for approval of a marketing application and an inspection cannot be completed during the review cycle due to restrictions on travel, FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. In 2020, FDA noted it was continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals; however, FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions FDA is unable to complete such required inspections during the review period. Due to the potential impact of the COVID-19 pandemic on clinical trials,

drug development, and manufacturing, FDA issued a number of guidances concerning how sponsors and investigators may address these challenges. FDA's guidance is continually evolving. Any of these factors could significantly impair our ability to generate revenue in the future and to attain and maintain profitability.

The COVID-19 pandemic may result in changes in laws and regulations. For example, in March 2020, the CARES Act, includes 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. This and any future changes in law may require that we change our internal processes and procedures to ensure continued compliance.

In order to establish our sales and marketing infrastructure, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2020, we had a total of 28 full-time employees reflecting a resumption of hiring to advance the commercialization of Twirla. We use third-party consultants to assist with our sales and marketing functions. As our commercialization of Twirla advances, we expect to need to expand the size of our employee base for managerial, operational, commercial, sales, marketing, compliance, regulatory, finance and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize Twirla and any other future potential product candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth.

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. 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.

Our management team has expertise in many different aspects of drug development and commercialization. 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. 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. 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.

Other pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than those that we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate of and success with which we can commercialize Twirla, as well as our potential product candidates, would be limited.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of Twirla, or our potential product candidates, if approved.

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:

- Decreased demand for Twirla or any future potential product candidates that we may develop;
- Injury to our reputation;
- Withdrawal of clinical trial participants;
- Costs to defend any related litigation;
- A diversion of management's time and our resources;
- Substantial monetary awards to trial participants or patients;
- Product recalls, withdrawals or labeling, marketing or promotional restrictions;
- Regulatory authority withdrawal of product approvals or refusal to approve pending applications;
- Loss of revenue;
- The inability to commercialize Twirla, or our potential product candidates, if approved;
- A decline in our stock price; and
- Exposure to adverse publicity.

We have obtained limited product liability insurance coverage for Twirla and our clinical trials with a $10.0 million annual aggregate coverage limit. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization Twirla or of potential product candidates we develop. 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 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. Any losses or damages we incur could have a material adverse effect on our business operations.

Our business and operations would suffer in the event of system failures.

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, natural disasters, 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. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. 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 regulatory enforcement actions, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, corporate integrity agreements, 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 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:

- Our failure to commercialize Twirla or develop and commercialize additional potential product candidates;
- Unanticipated efficacy, safety or tolerability concerns related to the use of Twirla;
- Regulatory actions with respect to Twirla;
- Inability to obtain adequate product supply of Twirla or inability to do so at acceptable prices;
- Adverse results or delays in our clinical trials for our potential product candidates;
- Changes in laws or regulations applicable to Twirla or any future potential product candidates, including but not limited to clinical trial requirements for approvals, post-approval requirements, and product marketing, advertising, and promotional requirements and limitations;
- Actual or anticipated fluctuations in our financial condition and operating results;
- Actual or anticipated changes in our growth rate relative to our competitors;
- Competition from existing products or new products that may emerge;
- 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;
- 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;

- Additions or departures of key personnel;
- Disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- 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 (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 March 1, 2021, we had 1,850,000 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 December 31, 2022 (collectively "Price Protection Warrants"). The current exercise prices of the Price Protection Warrants are: 700,000 Price Protection Warrants - $3.74, 700,000 Price Protection Warrants - $4.67 and 450,000 Price Protection Warrants - $2.87. 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 December 31, 2022, their exercise prices will be reduced pursuant to a weighted-average anti-dilution formula. 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 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. Litigation of this type 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.

If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

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. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or require us to identify other areas for further attention or improvement. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm conducts its Section 404 reviews, we could lose investor confidence in the accuracy

and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the Nasdaq Capital Market, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

We have never paid 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 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. Consequently, in the foreseeable future, you will likely only experience a gain from your investment in our common stock if the price of our common stock increases.

If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our common stock, the price of our common stock could decline.

The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our common stock could decline if one or more equity analysts downgrade our common stock or if analysts issue other unfavorable commentary or cease publishing reports about us or our business.

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;
- 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 5,750 square feet of leased office space in Princeton, New Jersey pursuant to a lease agreement that expires in December 2021. We believe that our current facilities are suitable and adequate to meet our current needs. We are currently seeking new facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

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".

	High	Low
Year Ended December 31, 2020		
Fourth Quarter	$ 3.30	$ 2.68
Third Quarter	$ 3.89	$ 2.32
Second Quarter	$ 3.35	$ 1.75
First Quarter	$ 4.77	$ 1.35
Year Ended December 31, 2019		
Fourth Quarter	$ 2.97	$ 0.35
Third Quarter	$ 1.64	$ 0.95
Second Quarter	$ 1.56	$ 1.02
First Quarter	$ 1.70	$ 0.66

As of February 24, 2021, we had 23 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 February 24, 2021 was $3.13.

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 gurantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, 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.

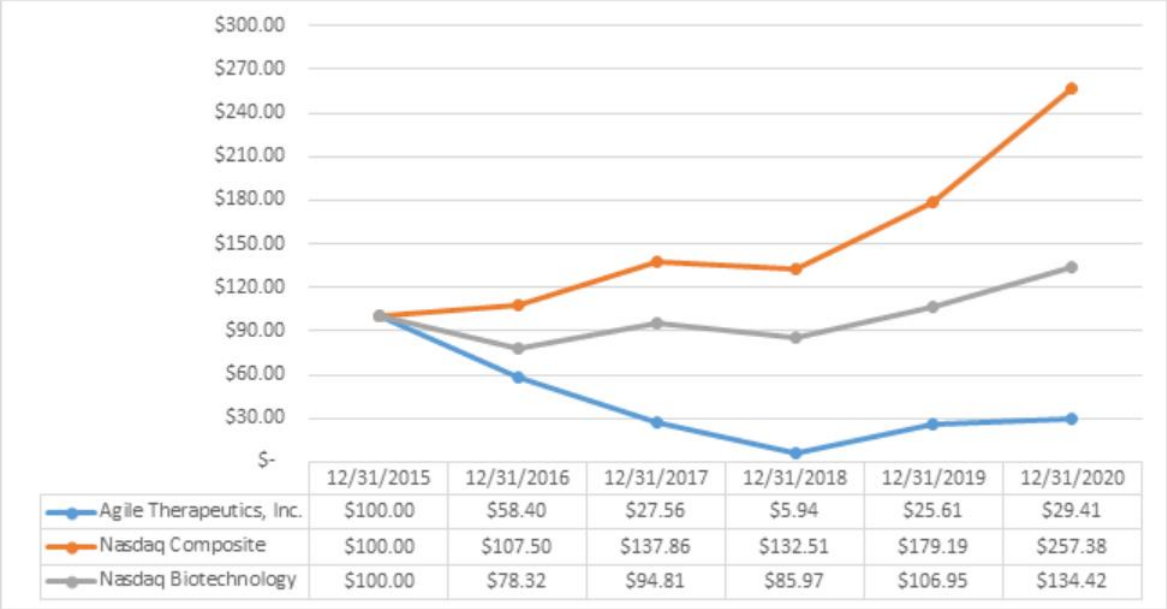
Stock Performance Graph

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, 2015 through December 31, 2020 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, 2015 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, 2020



	12/31/2015	12/31/2016	12/31/2017	12/31/2018	12/31/2019	12/31/2020
Agile Therapeutics, Inc.	$100.00	$58.40	$27.56	$5.94	$25.61	$29.41
Nasdaq Composite	$100.00	$107.50	$137.86	$132.51	$179.19	$257.38
Nasdaq Biotechnology	$100.00	$78.32	$94.81	$85.97	$106.95	$134.42

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 have remained steadfast in our commitment to innovate 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 product, Twirla, which was approved in February 2020 and launched in early December 2020, is a once-weekly prescription combination hormonal contraceptive patch. It delivers a dose of estrogen consistent with commonly prescribed combined hormonal contraceptives, or CHCs, and 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 approximately 30 mcg of estrogen and 120 mcg of progestin in a convenient 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 optimizing patch adhesion and patient comfort and wearability, which may help support compliance.

With the approval of Twirla we are now focused on our advancement as a commercial company. During 2021, we plan to continue implementing our commercialization plan for Twirla, with the goal of becoming a contraceptive market leader, and ultimately, pursuing opportunities to broaden our portfolio to address areas of unmet medical need in women's health.

It should be noted that current public health threats could adversely affect our 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 we have taken, such as implementing work-at-home policies, may negatively impact productivity, 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. It is unknown how long these conditions will last and what the complete effect will be on us. 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. Overall, we recognize the challenges of launching in a pandemic, will continue to closely monitor events as they develop and plan for alternative and mitigating measures that we can implement if needed.

For more information about Twirla, please see *Part 1, Item 1, "Business"*

Financial Overview

Since our inception in 1997, we have devoted substantial resources to developing and seeking regulatory approval for Twirla, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. We incurred research and development expenses of $13.5 million, $9.9 million and $9.8 million during the years ended December 31, 2020, 2019 and 2018, respectively. While we anticipate that a portion of our operating expenses will continue to be related to research and development as we plan our post marketing studies, which include both our post marketing requirement and post marketing commitment to the FDA, and evaluate the development of our pipeline, we expect our operating expenses to substantially shift towards commercialization. A substantial amount of our current resources have been dedicated to completing manufacturing validation and commercializing Twirla.

We have funded our operations primarily through sales of common stock, convertible preferred stock, convertible promissory notes and term loans. As of December 31, 2020, and 2019, respectively, we had $54.5 million and $34.5 million in cash and cash equivalents.

In January 2019, we entered into a common stock sales agreement or the "2019 ATM Agreement," under which we were authorized to sell up to an aggregate of $10.0 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). We agreed to pay a commission of 3% of the gross proceeds of any common stock sold under this agreement. During the year ended December 31, 2019, we issued and sold a total of 1,801,528 shares of common stock under the 2019 ATM Agreement resulting in net proceeds of approximately $2.5 million. We terminated the 2019 ATM Agreement on July 31, 2019.

In March 2019, we completed a private placement of 8,426,750 shares of common stock at $0.93 per share. Proceeds from the private placement, net of offering costs, were approximately $7.8 million.

In August 2019, we completed a public offering of 14,526,315 shares of common stock at a price of $0.95 per share. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses, were approximately $12.7 million.

In November 2019, we entered into a second ATM Agreement, or the "Second 2019 ATM Agreement," under which we were authorized to issue and sell shares of our common stock having aggregate sales proceeds of up to $20.0 million from time to time. We paid a commission of 3% of the gross proceeds from the sales of our common stock under the Second 2019 ATM Agreement. In the year ended December 31, 2019, we issued and sold 10,440,908 shares of common stock under the Second 2019 ATM Agreement, representing all of the capacity of the Second ATM Agreement, resulting in net proceeds of approximately $19.3 million.

In February 2020, we entered into the Perceptive Credit Agreement for a senior secured term loan facility of up to $35.0 million, which was amended in February 2021 ("Amended Perceptive Credit Agreement") to add a fourth tranche of $10.0 million, which is subject to the same interest rate and 1% fee payable upon the drawing of a tranche as set forth in the 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 $25.0 million will be available in two separate tranches upon the achievement of certain revenue milestones. The facility will be interest only until the third anniversary of the closing date.

In February 2020, we completed a public offering of 17,250,000 shares of our common stock at a price of $3.00 per share. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses, were approximately $48.4 million.

We have generated minimal revenue and have never been profitable for any year. Our net loss was $51.9 million, $18.6 million and $19.8 million for the years ended December 31, 2020, 2019 and 2018, respectively. We expect to incur increased expenses and increasing operating losses for the foreseeable future as we commercialize Twirla. This includes commercially launching Twirla, advancing our other potential product candidates and expanding our research and development programs.

Going Concern

As of December 31, 2020, we had cash, cash equivalents and marketable securities of $54.5 million. We believe that our cash, cash equivalents and marketable securities as of December 31, 2020 will be sufficient to meet our projected operating requirements through the end of 2021. We will require additional capital to fund our operating needs beyond 2021, which primarily will include commercializing Twirla, and exploring the advancement of our existing pipeline and its possible expansion through business development activities.

Our future success depends on our ability to raise additional capital and/or implement various strategic alternatives. Our ability to continue operations beyond 2021 will depend on our ability to obtain additional capital, 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.

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 complete 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, 2020 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 successfully launch 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 expect to incur 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.

Research and Development Expenses

Since our inception, we have 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.

Research and development activities are 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.

For the years ended December 31, 2020, 2019 and 2018, our research and development expenses were approximately $13.5 million, $9.9 million and $9.8 million, respectively. The following table summarizes our research and development expenses by functional area.

	Year ended December 31,		
	2020	2019	2018
		(In thousands)	
Clinical development	$ 2,022	$ 1,781	$ 1,318
Regulatory	951	2,990	562
Personnel related	2,086	1,669	2,162
Manufacturing—commercialization	7,790	2,896	4,461
Stock-based compensation	651	522	1,274
Total research and development expenses	$ 13,500	$ 9,858	$ 9,777

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 Twirla or 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 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 commercializing 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, 2020, 2019 and 2018, our selling and marketing expenses totaled approximately $23.3 million, $1.1 million and $0.9 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 increase in the future as our commercialization efforts continue. These increases will likely include increased payroll and operating costs, including brand building, advocacy, market research and consulting, and the costs of maintaining our contract sales force.

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, 2020, 2019 and 2018, our general and administrative expenses totaled approximately $12.7 million, $7.9 million and $7.8 million, respectively. We anticipate that our general and administrative expenses will increase in the future as our recently added administrative positions are maintained on a full-year basis. These increases will likely include legal and accounting services, stock registration and printing fees, addition of new personnel to support compliance and communication needs, increased insurance premiums, outside consultants and investor relations.

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 2- Summary of Significant Accounting Polieies.

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

We began to capitalize inventory costs associated with Twirla in December 2020 with the commercial launch of Twirla. Inventory costs consist of direct and indirect costs related to the manufacturing of Twirla sold, including third-party manufacturing costs, packaging services, freight, and allocation of overhead costs. There was no cost associated with the validation batches from Corium, our third party manufacturer, since the cost of validation was previously expensed as research and development. Once the supply of validation batches is exhausted, we will capitalize product cost using a weighted average costing method, which approximates actual cost.

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, 2020, we did not have any ongoing clinical trials.

Warrant Liability

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 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.

In connection with the completion of our initial public offering in May 2014, the warrants to purchase shares of Series A-1 and Series A-2 preferred stock expired unexercised and the warrants to purchase shares of Series C preferred stock automatically converted into warrants to purchase shares of common stock. Prior to January 1, 2019, warrants with non-standard anti-dilution provisions (referred to as down round protection) were classified as liabilities and re-measured each reporting period. On January 1, 2019, we adopted the provisions of Accounting Standards Update ("ASU") 2017-11 *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part 1) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Non-controlling Interests with a Scope Exception*, which indicates that a down round feature no longer precludes equity classification when assessing whether an investment is indexed to an entity's own stock. We used a modified retrospective approach for adoption, which did not restate our financial statements as of the prior year end (December 31, 2018). The cumulative effect of adoption of ASU 2017-11 resulted in an adjustment to accumulated deficit as of January 1, 2019 of $0.2 million with a corresponding adjustment to additional paid-in capital. Warrants to purchase 62,505 shares of common stock at $6.00 per share expired on December 14, 2019, and none of these warrants were outstanding as of December 31, 2020.

The warrants issued in connection with our debt financing completed in February 2015 are classified as a component of stockholders' equity. The value of such warrants was determined using the Black-Scholes option-pricing model. These warrants expired without being exercised on February 24, 2020.

As part of the February 2020 Perceptive Credit Agreement, we issued Perceptive warrants to purchase 1,400,000 shares of Agile common stock, all of which expire on February 27, 2027. The per share exercise price for 700,000 shares is $3.74, which is equal to the 5-day volume weighted average exercise price ("5 Day VWAP") as of the trading day immediately prior to closing. The per share exercise price for the remaining 700,000 shares of our common stock is $4.67, which is 1.25 times the 5 Day VWAP. In connection with entering into the Amended Perceptive Credit Agreement, we issued Perceptive a warrant to purchase 450,000 shares of Agile common stock.

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 restricted stock units 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, 2020 and 2019

	Year Ended December 31,		
	2020	2019	Change
Revenues, net	$ 749	$ —	$ 749
Cost of product revenues	282	—	282
Gross profit	467	—	467
Operating expenses:			
Research and development	$ 13,500	$ 9,858	$ 3,642
Selling and marketing	23,285	1,085	22,200
General and administrative	12,735	7,915	4,820
Total operating expenses	49,520	18,858	30,662
Loss from operations	$ (49,053)	$ (18,858)	(30,195)
Other income (expense)			
Interest income	309	252	57
Interest expense	(3,109)	—	(3,109)
Total other income (expense), net	(2,800)	252	(3,052)
Loss before benefit from income taxes	(51,853)	(18,606)	(33,247)
Net loss	$ (51,853)	$ (18,606)	$ (33,247)

Revenues. 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 initial 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 totaled $0.3 million and consist of direct and indirect costs related to the manufacturing of Twirla sold, including third-party manufacturing costs, packaging services, freight, and allocation of overhead costs. For the year ended December 31, 2020, there was no third-party manufacturing cost related to Twirla sold since the units sold were validation product and the costs associated with validation had previously been expensed as research and development. Once the supply of validation batches is exhausted, the cost of product from our third-party manufacturer will be determined using the weighted average costing method, which approximates actual cost.

Research and development expenses. Research and development expenses increased by $3.6 million, or 37%, from $9.9 million for the year ended December 31, 2019 to $13.5 million for the year ended December 31, 2020. This overall increase in research and development expenses was primarily due to the following:

- an increase in manufacturing commercialization expenses of $4.9 million for the year ended December 31, 2020 as compared to the year ended December 31, 2019. This increase reflects costs to complete manufacturing development, process improvements, and pre-validation and validation work for the commercial manufacturing of Twirla by Corium, our contract manufacturer;

- an increase in clinical development expenses of $0.2 million for the year ended December 31, 2020 as compared to the year ended December 31, 2019. This increase primarily relates to costs for medical education and consulting partially offset by costs associated with the comparative wear study of Twirla and Xulane which was initiated and completed during 2019;

- an increase in personnel-related expenses of $0.5 million for the year ended December 31, 2020 as compared to the year ended December 31, 2019. This increase reflects higher headcount for the year ended December 31, 2020; and

- a decrease in regulatory expenses of $2.0 million for the year ended December 31, 2020 as compared to the year ended December 31, 2019. This decrease is primarily related to decreased costs associated with preparation for the FDA advisory committee meeting in the fourth quarter of 2019;

Selling and marketing expenses. Selling and marketing expenses increased by $22.2 million, from $1.1 million for the year ended December 31, 2019 to $23.3 million for the year ended December 31, 2020. This overall increase in selling and marketing expenses was primarily due to an increase related to the resumption of our pre-commercialization activities such as brand building, advocacy, market research and consulting, and the costs of establishing and maintaining our contract sales force.

General and administrative expenses. General and administrative expenses increased by $4.8 million, or 61%, from $7.9 million for the year ended December 31, 2019 to $12.7 million for the year ended December 31, 2020. This overall increase in general and administrative expenses was primarily due to the following:

- an increase in salaries and wages of $1.5 million, due to increased headcount and retention bonuses expensed and paid during the year ended December 31, 2020;

- an increase in professional fee expense of $1.9 million primarily related to legal fees, accounting fees, recruiting fees and increased use of financial consultants;

- an increase in stock compensation expense of $0.9 million for the year ended December 31, 2020 compared to the year ended December 31, 2019. This increase is primarily the result of new hires and higher stock prices associated with 2020 stock option grants as compared to 2019 stock option grants; and

- an increase in D&O insurance of $0.3 million for the year ended December 31, 2020 as compared to the year ended December 31, 2019.

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 for the year ended December 31, 2020. Interest expense also 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 increased by $3.1 million, from $0 for the year ended December 31, 2019 to $3.1 million for the year ended December 31, 2020.

Net Operating Losses and Tax Carryforwards

As of December 31, 2020, we had approximately $ 281.7 million of federal and $107.2 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, 2020, all of our net operating losses were fully offset by a valuation allowance.

Liquidity and Capital Resources

At December 31, 2020, we had cash, cash equivalents and marketable securities totaling $54.5 million. We invest our cash equivalents and marketable securities in short-term highly liquid, interest-bearing investment-grade and government securities in order to preserve principal.

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

	Year Ended December 31,		
	2020	2019	2018
	(In thousands)		
Net cash used in operating activities	$ (47,311)	$ (15,689)	$ (16,895)
Net cash used in investing activities	(40,690)	(98)	(318)
Net cash provided by financing activities	67,985	42,415	(10,888)
Net (decrease) increase in cash and cash equivalents	$ (20,016)	$ 26,628	$ (28,101)

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 $47.3 million for the year ended December 31, 2020 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. Net cash used in operating activities was $15.7 million for the year ended December 31, 2019 and consisted of a net loss of $18.6 million and an increase in prepaid expenses of $0.2 million, which was offset by non-cash stock-based compensation expense of $1.8 million and depreciation and amortization of $0.2 million as well as an increase in accounts payable, accrued expenses and other liabilities of $1.1 million which reflects increased commercial development and commercial manufacturing expenses related to the initialization of pre-commercialization activities for Twirla. Net cash used in operating activities was $16.9 million for the year ended December 31, 2018 and consisted of a net loss of $19.8 million which was offset, in part, by non-cash stock-based compensation expense of $3.6 million and non-cash interest expense of $0.3 million as well as a decrease in accounts payable and accrued liabilities of $1.2 million which reflects higher manufacturing commercialization expenses and the accrued loan fee which were both paid in 2018.

Investing Activities

Net cash used in investing activities for the years ended December 31, 2020, 2019 and 2018 was $40.7 million, $0.1 million and $0.3 million, respectively. 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, 2020 was $68.0 million, which primarily represents net proceeds of $48.4 million received from the issuance of 17,250,000 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. Net cash provided by financing activities for the year ended December 31, 2019 was $42.4 million which primarily represented net proceeds of $7.8 million received from the issuance of 8,426,750 shares of our common stock in a private placement, net proceeds of $12.7 million from the sale of 14,526,315 shares of common stock through a public offering, and net proceeds of approximately $21.8 million from the sale of a total of 12,242,436 shares of our common stock through two at-the-market, or ATM, sales programs. Net cash used in financing activities for the year ended December 31, 2018 was $10.9 million which represented principal payments under the Hercules Loan Agreement which began on February 1, 2017 and were completed on December 1, 2018.

Funding Requirements and Other Liquidity Matters

Based on our current business plan and ability to get Twirla launched, we believe that our cash, cash equivalents and marketable securities as of December 31, 2020 will be sufficient to meet our projected operating requirements through the end of 2021. We will require additional capital to fund our operating needs beyond 2021, including, among other

items, the commercialization of Twirla, and advancing the development of our other potential product candidates. 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. If the COVID-19 pandemic or other factors impact our current business plan or our ability to generate revenue from the launch 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.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially as we:

- maintain a sales and marketing infrastructure to commercialize 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
- add 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 sooner if we choose to accelerate 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.

Except for the remaining two tranches under the Amended Perceptive Credit Agreement, which are contingent upon achieving certain revenue milestones, 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, 2020, we had cash, cash equivalents and marketable securities of $54.5 million. We believe that our cash and cash equivalents as of December 31, 2020 will be sufficient to meet our projected operating requirements through the end of 2021. We will require additional capital to fund our operating needs beyond 2021,

which we expect primarily will consist of commercializing Twirla, and exploring the advancement of our existing pipeline and its possible expansion through business development activities.

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

The financial statements as of December 31, 2020 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, 2020 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. (“the Corium Agreement”) for the manufacture and supply of Twirla. Under the terms of the Coriumn Agreement, Corium is to be the exclusive supplier of Twirla for ten years. The Corium Agreement includes a fixed price per unit for two years depending on annual purchase volume and quarterly minimum purchase amounts. As of December 31, 2020, the amount committed for purchases into the first quarter of 2021 is $7.0 million.

In April 2020, we entered into a project agreement (the “Project Agreement”) with inVentiv Commercial Services, LLC (“inVentiv”) under which inVentiv 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 the Company in exchange for an up-front implementation fee and a fixed annual fee. The Project Agreement has an initial term of two years from August 24, 2020, the date of the first activity undertaken by inVentiv to detail Twirla (the “Deployment Date”), unless earlier extended upon the mutual written agreement of the Parties. We may terminate the Project Agreement for any reason upon timely notice after the first anniversary of the Deployment Date; provided, however, that if we terminate the Project Agreement prior to the eighteen month anniversary of the Deployment Date, we will be obligated to pay inVentiv a termination fee, the amount of which varies depending on the date of termination. As of December 31, 2020, the minimum amount committed totals $9.3 million.

The following table summarizes our contractual obligations and commitments as of December 31, 2020 that will affect our future liquidity:

	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
			(In thousands)		
Long-term Debt Obligations	$ 20,000	$ —	$ 3,300	$ 16,700	$ —
Operating Lease Obligations	150	150	—	—	—
Purchase Obligations	16,257	16,257	—	—	—
Total	$ 36,407	$ 16,407	$ 3,300	$ 16,700	$ —

Our operating lease commitment relates to our lease of office space in Princeton, New Jersey. In November 2020, we entered into an extension for this location through December 31, 2021, and simultaneously reduced the amount of space we are leasing. We are currently seeking new facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

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. Prior to the 2020 Shelf Registration Statement, we had filed a universal shelf registration statement in November 2018 for the issuance of up to $100.0 million of securities, which we refer to as the 2018 Shelf Registration Statement, which was declared effective by the SEC on November 14, 2018.

Recent Accounting Pronouncements

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

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

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 $54.5 million and $34.5 million at December 31, 2020 and December 31, 2019, respectively, consisting primarily of funds in cash, money market accounts and corporate and government debt securities. 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 $75.1 million for the year ended December 31, 2020, a 1% increase or decrease in interest rates would have increased or decreased interest income by $0.8 million for the year ended December 31, 2020. Based on average debt outstanding of $16.7 million for the year ended December 31, 2020, a 1% increase or decrease in interest rates would have increased or decreased interest expense by $0.2 million for the year ended December 31, 2020.

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, 2020.

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, 2020 and 2019, the related statements of operations and comprehensive loss, statements of changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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 and requires additional capital to fund its operating needs beyond 2021. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty

Basis for Opinion

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

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

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

Critical Audit Matter

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

Product Revenue -Net

Description of the Matter	The Company sells approved product to a limited number of distributors. As discussed in Note 2, product sales are recorded net of estimated rebates and chargebacks, estimated product returns and other deductions at the time revenue is recorded. 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 rebates, chargebacks, product returns and other deductions 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 product sales 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 rebates, chargebacks, product returns and other deductions 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 and tested the underlying sales data by confirming a sample of receivable balances directly with the Company's customers.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2010.
Iselin, New Jersey
March 1, 2021

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

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 14,463	$ 34,479
Marketable securities	40,008	—
Accounts receivable, net	865	—
Prepaid expenses	1,449	840
Total current assets	56,785	35,319
Property and equipment, net	14,243	14,044
Right of use asset	138	158
Other non-current assets	1,896	19
Total assets	$ 73,062	$ 49,540
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,867	$ 1,819
Accrued expenses	3,348	1,804
Lease liability, current portion	138	172
Total current liabilities	7,353	3,795
Long-term debt	16,381	—
Total liabilities	23,734	3,795
Commitments and contingencies (Note 15)		
Stockholders' equity		
Common stock, $.0001 par value, 150,000,000 shares authorized, 87,563,753 and 69,810,305 issued and outstanding at December 31, 2020 and December 31, 2019, respectively	9	7
Additional paid-in capital	361,539	306,108
Accumulated other comprehensive income	3	—
Accumulated deficit	(312,223)	(260,370)
Total stockholders' equity	49,328	45,745
Total liabilities and stockholders' equity	$ 73,062	$ 49,540

See accompanying notes.

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

	Year ended December 31,		
	2020	2019	2018
Revenues, net	$ 749	$ —	$ —
Cost of product revenues	282	—	—
Gross profit	467	—	—
Operating expenses:			
Research and development	$ 13,500	$ 9,858	$ 9,777
Selling and marketing	23,285	1,085	942
General and administrative	12,735	7,915	7,797
Restructuring costs	—	—	1,019
Total operating expenses	49,520	18,858	19,535
Loss from operations	(49,053)	(18,858)	(19,535)
Other income (expense)			
Interest income	309	252	366
Interest expense	(3,109)	—	(1,116)
Change in fair value of warrants	—	—	29
Total other income (expense), net	(2,800)	252	(721)
Loss before benefit from income taxes	(51,853)	(18,606)	(20,256)
Benefit from income taxes	—	—	477
Net loss	$ (51,853)	$ (18,606)	$ (19,779)
Net loss per share (basic and diluted)	$ (0.61)	$ (0.38)	$ (0.58)
Weighted-average common shares (basic and diluted)	84,683,084	49,432,487	34,315,931
Comprehensive loss:			
Net loss	$ (51,853)	$ (18,606)	$ (19,779)
Other comprehensive income:			
Unrealized gain on marketable securities	3	—	—
Comprehensive loss	$ (51,850)	$ (18,606)	$ (19,779)

See accompanying notes.

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Net Stockholders' Equity
	Number of Shares	Amount				
Balance December 31, 2017	34,186,342	$ 3	$ 258,092	$ —	$ (221,772)	$ 36,323
Share-based compensation—stock options and RSUs	—	—	3,630	—	—	3,630
Vesting of RSUs	190,987	—	—	—	—	—
Net loss	—	—	—	—	(19,779)	(19,779)
Balance December 31, 2018	34,377,329	$ 3	$ 261,722	$ —	$ (241,551)	$ 20,174
Adjustment to derivitive liabilities upon adoption of ASU 2017-11	—	—	213	—	(213)	—
Share-based compensation— stock options and RSUs	—	—	1,762	—	—	1,762
Issuance of common stock in private placement, net of expenses	8,426,750	1	7,809	—	—	7,810
Issuance of common stock pursuant to at-the-market stock sales, net of expenses	12,242,436	1	21,753	—	—	21,754
Issuance of common stock upon exercise of stock options	92,271	—	164	—	—	164
Proceeds from issuance of common stock in public offering, net of expenses	14,526,315	2	12,685	—	—	12,687
Vesting of RSUs	145,204	—	—	—	—	—
Net loss	—	—	—	—	(18,606)	(18,606)
Balance December 31, 2019	69,810,305	$ 7	$ 306,108	$ —	$ (260,370)	$ 45,745
Share-based compensation - stock options and RSUs	—	—	2,818	—	—	2,818
Issuance of common stock in public offering, net of expenses	17,250,000	2	48,433	—	—	48,435
Issuance of common stock upon exercise of stock options	503,448	—	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	87,563,753	$ 9	$ 361,539	$ 3	$ (312,223)	$ 49,328

See accompanying notes.

Agile Therapeutics, Inc.
Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2020	2019	2018
Cash flows from operating activities:			
Net loss	$ (51,853)	$ (18,606)	$ (19,779)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	105	18	23
Amortization	171	145	—
Noncash stock-based compensation	2,818	1,762	3,630
Noncash interest	1,341	—	282
Change in fair value of warrants	—	—	(29)
Changes in operating assets and liabilities:			
Accounts receivable	(865)	—	—
Prepaid expenses and other assets	(2,485)	(233)	155
Accounts payable and accrued expenses	3,641	1,377	(1,177)
Lease liability	(184)	(152)	—
Net cash used in operating activities	(47,311)	(15,689)	(16,895)
Cash flows from investing activities:			
Purchases of marketable securities	(54,837)	—	—
Sales and maturities of marketable securities	14,500	—	—
Acquisition of property and equipment	(353)	(98)	(318)
Net cash used in investing activities	(40,690)	(98)	(318)
Cash flows from financing activities:			
Proceeds from issuance of common stock in public offering, net of offering costs	48,434	12,687	—
Proceeds from issuance of long-term debt	20,000	—	—
Principal payments of long-term debt	—	—	(10,888)
Debt financing costs paid	(1,059)	—	—
Proceeds from issuance of common stock in private placement, net of offering costs	—	7,810	—
Proceeds from At-the-Market sales of common stock, net of offering costs	—	21,754	—
Proceeds from exercise of stock options	610	164	—
Net cash provided by (used in) financing activities	67,985	42,415	(10,888)
Net (decrease) increase in cash and cash equivalents	(20,016)	26,628	(28,101)
Cash and cash equivalents, beginning of period	34,479	7,851	35,952
Cash and cash equivalents, end of period	$ 14,463	$ 34,479	$ 7,851
Supplemental disclosure of noncash financing activities			
Warrants issued in connection with long-term debt	$ 3,570	$ —	$ —
Supplemental cash flow information			
Interest paid	$ 2,099	$ —	$ 1,370
Cash paid for income taxes	$ —	$ —	$ —
Non-cash transactions			
Property and equipment purchases included in accounts payable	$ —	$ 49	$ —

See accompanying notes.

Agile Therapeutics, Inc.
Notes to Financial Statements
December 31, 2020
(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 and performing research and development, including development of the Company's lead product, Twirla. The Company is headquartered in Princeton, New Jersey.

The Company's sole approved product, Twirla®, also known 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. 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 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, competition from larger companies and compliance with FDA and other government regulations. If the Company does not successfully commercialize any product candidates, 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, 2020, the Company had an accumulated deficit of approximately $312 million.

The Company expects to continue to incur significant expenses and increased operating losses for the foreseeable future and that its operating expenses will increase substantially in connection with its ongoing activities, as the Company:

- maintains a sales and marketing infrastructure to commercialize 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
- adds 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, 2020, the Company had cash, cash equivalents and marketable securities of $54.5 million. The Company believes that its cash, cash equivalents and marketable securities as of December 31, 2020 will be sufficient to meet its projected operating requirements through the end of 2021. The Company will require additional capital to fund its operating needs beyond 2021, which primarily will include commercializing 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 and anticipates it will continue to incur net losses for the foreseeable future. The Company's ability to continue operations beyond 2021 will

Agile Therapeutics, Inc.
Notes to Financial Statements (Continued)
December 31, 2020
(in thousands, except share and per share data)

depend on its ability to obtain additional capital, 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 complete 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, 2020 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, 2020 do not include any adjustments that might result from the outcome of this uncertainty. If the Company is unable to continue as a going concern, it may have to liquidate its assets and may receive less than the value at which those assets are carried on the financial statements.

2. Summary of Significant Accounting Polices

Basis of Presentation

The accompanying financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented. Certain reclassifications have been made to prior periods to conform with current reporting. On the balance sheet, our right of use asset has been stated separately from other non-current assets. On the statement of operations, the Company has separated the presentation of selling and marketing expenses from the total general and administrative expenses in the current period. To conform prior year amounts to the current period presentation, totals of $1.1 million and $0.9 million were reclassified from general and administrative expenses to selling and marketing expenses for the years ended December 31, 2019 and 2018, respectively.

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, the accounting for common stock warrants, stock-based compensation, income taxes, 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.

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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. While it is unknown how long these conditions will last and what the complete effect will be on the Company, to date, the Company has been able to continue to execute on its plans according to the related timelines. 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.

Marketable Securities

The Company invests a portion of its excess cash balances in marketable securities, including U.S. government agency securities, and highly rated corporate bonds. The Company classifies all of its marketable securities as current assets on the balance sheet because they are available-for-sale and available to fund current operations. Marketable securities are stated at fair value with unrealized gains and losses included as a component of accumulated other comprehensive income (loss), which is a separate component of stockholders' equity, until such gains and losses are realized. If a decline in the fair value is considered other-than-temporary, based on available evidence, the unrealized loss is reclassified from accumulated other comprehensive income (loss) to the statements of operations. Realized gains and losses are determined on the specific identification method and are included in other income.

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

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determine the allowance for credit losses, as Twirla was commercially launched in December 2020 and historical data is not yet available. The credit loss reserves are reviewed and adjusted periodically.

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, cash equivalents, and marketable securities 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 and planned production. Management does not believe the Company's inventory is subject to significant risk of obsolescence in the near term.

The Company's third-party manufacturer, Corium, has completed the validation of the commercial manufacturing process for Twirla. The costs associated with validation batches were expensed as research and development expenses during the period the costs were incurred. The Company is using this validation product for commercial supplies and samples of Twirla. Since the Company did not capitalize any validation product, all sales of this validation product will have no product cost associated with it. During the year ended December 31, 2020, the cost basis of product sold that had a carrying value of zero was approximately $0.1 million. Had such inventory been valued at acquisition cost, it would have resulted in an increase in cost of goods sold and a decrease in gross profit. The Company expects inventories with a carrying value of zero to be utilized in 2021. All future production of commercial supplies will be capitalized as inventory.

Property and Equipment

Property and equipment, consisting of 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. Currently, all fixed assets pertain to production equipment at the Company's third party manufacturing partner and have an estimated useful life of 7 years.

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.

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, 2020.

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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 $5.5 million and $0 for the years ended December 31, 2020 and 2019, 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 $231, $0 and $133 for the years ended December 31, 2020, 2019 and 2018, 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 2020, the Company had sales to three customers that individually accounted for more than 10% of our total revenue. These customers had sales of $0.3 million, $0.2 million, and $0.2 million, respectively, which represented 97% of total revenues in the aggregate. Accounts receivable related to these major customers comprised 35%, 32%, and 30%, 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.

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

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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. 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.

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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 there were no returns as of December 31, 2020. As time passes and historical data becomes available, the Company will begin to use historical sales and return data to estimate future product returns.

Chargebacks – Certain government entities and covered entities will be able to purchase the product at a price discounted below WAC. The Company is currently in the process of finalizing agreements with these types of entities. 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 Company is currently in the process of finalizing these agreements with Medicaid and Tricare. 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 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 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, 2020 which have been deducted in arriving at revenues, net.

	December 31, 2019	Allowances for current period sales	Payments & credits	December 31, 2020
Customer credits, discounts and allowances	$ —	$ 187	$ —	$ 187
Rebates and co-pay assistance	—	116	—	116
Total	$ —	$ 303	$ —	$ 303

Warrants

The Company accounts for its warrants to purchase common stock in accordance with ASC 480, *Distinguishing Liabilities from Equity*. On January 1, 2019, the Company adopted the provisions of Accounting Standards Update ("ASU") 2017-11 *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II)*

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Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Non-controlling Interests with a Scope Exception, which indicate that a down round feature no longer precludes equity classification when assessing whether an investment is indexed to an entity's own stock. The Company used a modified retrospective approach to adoption, which does not restate its financial statements as of the prior year end (December 31, 2018). The cumulative effect of adoption of ASU 2017-11 resulted in an adjustment to accumulated deficit as of January 1, 2019 of $213 with a corresponding adjustment to additional paid-in capital.

Warrants to purchase 62,505 shares of common stock at $6.00 per share expired on December 14, 2019, and none of these warrants are outstanding as of December 31, 2020.

The warrants issued in connection with the Company's debt financing completed in February 2015 are classified as a component of stockholders' equity. The value of such warrants was determined using the Black-Scholes option-pricing model. These warrants expired without being exercised on February 24, 2020.

In connection with entering into a senior secured term loan facility in February 2020, the Company issued warrants to purchase 1,400,000 shares of its common stock. These warrant instruments qualify for equity classification and have been allocated based upon the relative fair value of the base instrument and the warrant. See Note 9 for additional information.

Income Taxes

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

The Company has adopted the authoritative guidance on accounting for and disclosure of uncertainty in tax positions which prescribes a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. The Company has no uncertain tax positions as of December 31, 2020 that qualify for either recognition or disclosure in the financial statements under this guidance.

Stock-Based Compensation

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

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

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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, 2020, 2019 and 2018, respectively, because to do so would be anti-dilutive (in common equivalent shares):

	Year Ended December 31,		
	2020	2019	2018
Common stock warrants	1,400,000	180,274	242,779
Unvested restricted stock units	159,795	—	147,554
Common stock options	8,519,086	7,192,357	5,687,901
Total	10,078,881	7,372,631	6,078,234

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 July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part 1) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception.* This ASU eliminates the requirement to consider "down round" features when determining whether certain equity-linked financial instruments or embedded features are indexed to an entity's own stock. On January 1, 2019, the Company adopted the provisions of ASU No. 2017-11 using a modified retrospective approach, which does not restate its financial statements as of the prior year end (December 31, 2018). The cumulative effect of adoption of ASU 2017-11 resulted in an adjustment to accumulated deficit as of January 1, 2019 of $213 with a corresponding adjustment to

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additional paid-in capital. As a result of the adoption of ASU 2017-11, effective January 1, 2019, the Company no longer measures these warrants at fair value.

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. In December 2020, the Company recognized its first sales of Twirla resulting in a receivable of $0.9 million at December 31, 2020. The Company applied the new credit standard to these transactions resulting in an immaterial allowance for credit losses at December 31, 2020.

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 guidance is effective for the Company on January 1, 2021. The Company is currently evaluating the impact of adopting this standard and does not expect the guidance to have a material impact on its 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.

3. Fair Value Measurements

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

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

- Level 1—Quoted prices in active markets for identical assets 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.

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

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The following tables set forth the Company's financial instruments measured at fair value by level within the fair value hierarchy as of December 31, 2020 and 2019:

	Level 1	Level 2	Level 3
December 31, 2020			
Assets:			
Cash and cash equivalents	$ 14,463	$ —	$ —
Marketable securities	—	40,008	—
Total assets at fair value	$ 14,463	$ 40,008	$ —

	Level 1	Level 2	Level 3
December 31, 2019			
Assets:			
Cash and cash equivalents	$ 34,479	$ —	$ —
Total assets at fair value	$ 34,479	$ —	$ —

There were no transfers between Level 1, 2 or 3 during 2020 or 2019.

4. Marketable Securities

The following is a summary of marketable securities, classified as available-for-sale:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2020				
U.S. government obligations (maturing in one year or less)	$ 7,035	$ 2	$ —	$ 7,037
Corporate debt securities (maturing in one year or less)	32,970	1		32,971
Total marketable securities	$ 40,005	$ 3	$ —	$ 40,008

The Company holds investment-grade marketable securities. There were no continuous unrealized loss positions in excess of twelve months as of December 31, 2020. Marketable securities include $0.1 million of accrued interest income at December 31, 2020.

5. Prepaid Expenses

Prepaid expenses consist of the following:

	December 31, 2020	December 31, 2019
Prepaid insurance	$ 680	$ 656
Other	769	184
Total prepaid expenses	$ 1,449	$ 840

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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, 2020	December 31, 2019	Estimated Life
Office equipment	$ —	$ 49	
Computer equipment	—	179	
Manufacturing equipment	14,328	14,203	7 years
	14,328	14,431	
Less: accumulated depreciation	(85)	(387)	
Property and equipment	$ 14,243	$ 14,044	

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.

7. Accrued Liabilities

Accrued liabilities consist of the following:

	December 31, 2020	December 31, 2019
Employee bonuses	$ 1,697	$ 1,437
Accrued professional fees and other	1,651	367
Total accrued liabilities	$ 3,348	$ 1,804

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 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 recorded a lease asset and lease liability of approximately $0.3 million on its balance sheet as of January 1, 2019, with no impact on its statement of operations.

The Company has no finance leases and one operating lease for office space in Princeton, NJ. On November 11, 2020, the Company entered into an extension for this location through December 31, 2021 and simultaneously reduced the amount of space it was leasing. Operating lease expense was $190 and $193 for the years ended December 31, 2020 and 2019, respectively.

Operating cash flows used for operating leases during the years ended December 31, 2020 and 2019 were $184 and $152, respectively. As of December 31, 2020, the weighted-average remaining lease term was 1.0 years and the weighted average discount rate was 15.2%.

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Future minimum lease payments under non-cancellable leases as of December 31, 2020 were as follows:

2021	$	150
Total	$	150
Less: Interest		(12)
Present value of lease liability	$	138

9. Credit Agreement and Guaranty

On February 10, 2020 (the "Closing Date"), the Company entered into a Credit Agreement and Guaranty with Perceptive Credit Holdings III, LP, a related party ("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 will be available to the Company based on the achievement of certain revenue milestones. On February 26, 2021 the Perceptive Credit Agreement was amended ("Amended Perceptive Credit Agreement") to increase the total amount available to the Company to $45.0 million by creating a fourth tranche of $10.0 million that will be available based on the achievement of a revenue milestone.

The facility will mature on February 10, 2024 ("Maturity Date"). The Company is scheduled to make interest-only payments on the loans under the Perceptive Credit Agreement until February 10, 2023. Thereafter, the Company is required to make monthly principal payments in an amount equal to 1.50% of the principal amount of the outstanding loans until February 10, 2024.

Borrowings under the Amended Perceptive Credit Agreement 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 the Closing Date and at December 31, 2020 was 11.75%. Upon the occurrence and during the continuance of any event of default under the Amended Perceptive Credit Agreement, 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 fee of 10.0% if such prepayment occurs on or prior to February 10, 2021; 8.0% if such prepayment occurs after February 10, 2021 and on or prior to February 10, 2022; 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 February 10, 2024.

All of the Company's obligations under the Amended Perceptive Credit Agreement are secured by a first-priority lien and security interest in substantially all of the Company's tangible and intangible assets, including intellectual property.

The Amended Perceptive Credit Agreement contains certain representations and warranties, affirmative covenants, negative covenants and conditions that are customary for similar financings. The negative covenants restrict or limit the ability of the Company to, among other things and subject to certain exceptions contained in the Perceptive Credit Agreement, incur new indebtedness; create liens on assets; engage in certain fundamental corporate changes, such as mergers or acquisitions, or changes to the Company's business activities; make certain investments or restricted payments (each as defined in the 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 June 30, 2021, report revenues for the trailing 12-month period that exceed the amounts set forth in the

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Amended Perceptive Credit Agreement, which range from $3.8 million for the fiscal quarter ending June 30, 2021 to $87.1 million for the fiscal quarter ending December 31, 2023. The Company received a covenant waiver pertaining to the existence of substantial doubt about the Company's ability to continue as a going concern as disclosed in Note 1. The Company was in compliance with the remaining covenants under the Amended Perceptive Credit Agreement as of December 31, 2020.

In connection with the Perceptive Credit Agreement, the Company issued to Perceptive two warrants to purchase an aggregate of 1,400,000 shares of the Company's common stock (together, the "Perceptive Warrants"). The first warrant is exercisable for 700,000 shares of common stock at an exercise price of $3.74 per share. The second warrant is exercisable for 700,000 shares of common stock at an exercise price of $4.67 per share. The Perceptive Warrants contain anti-dilution provisions and other warrant holder protections. The Perceptive Warrants 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. The Perceptive Warrants expire on February 10, 2027. In connection with the Amended Perceptive Credit Agreement, the Company issued to Perceptive a warrant to purchase 450,000 shares of the Company's common stock.

The Company allocated the proceeds of $20.0 million in accordance with ASC 470 based on the relative fair values of the debt and warrants. The relative fair value of the 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 preparing the option pricing model for valuing the Company's warrants issued to Perceptive include (i) volatility (70.0%), (ii) risk free interest rate of 1.47% (estimated using treasury bonds with a 3-year life), (iii) strike prices of $3.74 and $4.67 for the common stock warrants, (iv) fair value of common stock ($4.01) 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.

	December 31, 2020
Notes payable	$ 20,000
Debt issuance costs	(828)
Warrant discount	(2,791)
Long-term debt	$ 16,381

10. Stockholders' Equity

The Company's Certificate of Incorporation, among other things: (i) authorizes 150,000,000 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.

Shelf Registration Statements

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

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effective by the SEC. Prior to the 2020 Shelf Registration Statement, the Company had filed a universal shelf registration statement in November 2018 for the issuance of up to $100.0 million of securities, ("the 2018 Shelf Registration Statement"), which was declared effective by the SEC on November 14, 2018.

On January 23, 2019, the Company filed a prospectus supplement to the 2018 Shelf Registration Statement registering an at-the-market offering program entered into for the sale of up to $10.0 million of shares of the Company's common stock. In the year ended December 31, 2019, the Company sold a total of 1,801,528 shares of the Company's common stock under the ATM program resulting in net proceeds of approximately $2.5 million.

In August 2019, the Company filed a prospectus supplement to the 2018 Shelf Registration Statement registering a public offering of 14,526,315 shares of common stock at a price of $0.95 per share. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses, were approximately $12.7 million.

On November 8, 2019, the Company filed a prospectus supplement to the 2018 Shelf Registration Statement registering an at-the-market offering program entered into for the sale of up to $20.0 million of shares of the Company's common stock. In the year ended December 31, 2019, the Company sold a total of 10,440,908 shares of common stock under this ATM program, representing all of the capacity, resulting in net proceeds of approximately $19.3 million.

On February 21, 2020, the Company filed a prospectus supplement to the 2018 Shelf Registration Statement registering a public offering of 17,250,000 shares of common stock at a price of $3.00 per share. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses were approximately $48.4 million.

Private Placement

In March 2019, the Company completed a private placement of 8,426,750 shares of common stock at $0.93 per share. Proceeds from the Company's private placement, net of offering costs were approximately $7.8 million.

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, 2020, there were 1,980,203 shares available for future grant under the Amended 2014 Plan.

Through December 31, 2020, the Company granted options to certain employees and nonemployees to purchase shares of common stock at exercise prices ranging from $0.60 to $10.75 per share. The Company recorded noncash

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stock-based compensation expense for the years ended December 31, 2020, 2019 and 2018 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,		
	2020	2019	2018
Cost of goods sold	$ 14	$ —	$ —
Research and development	651	522	1,274
General and administrative	2,153	1,240	2,356
Total	$ 2,818	$ 1,762	$ 3,630

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

	2020	2019	2018
Risk-free interest rate	.40% - 1.68 %	1.74% - 2.61 %	2.57 %
Expective volatility	65% - 106 %	65 %	70 %
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.

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, 2020, the unrecorded deferred stock-based compensation balance related to stock options was approximately $4.0 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, 2020 was $1.70.

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The following table summarizes the options outstanding, options vested and the options exercisable as of December 31, 2020, 2019 and 2018:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2018	5,687,901	4.34	7.4	
Options granted	2,805,600	1.18		
Options exercised	(92,271)	1.78		
Options cancelled/forfeited	(1,208,873)	2.70		
Options outstanding at December 31, 2019	7,192,357	3.42	7.2	
Options granted	2,539,403	2.80		
Options exercised	(503,448)	1.21		
Options cancelled/forfeited	(709,226)	6.20		
Options outstanding at December 31, 2020	8,519,086	3.13	7.3	$ 6,153
Options exercisable at December 31, 2020	5,300,428	3.46	6.3	$ 5,086
Vested and expected to vest at December 31, 2020	8,519,086			$ 6,153

Intrinsic value in the tables was calculated as the difference between the Company's stock price at December 31, 2020, of $2.87 per share, and the exercise price, multiplied by the number of options.

Restricted Stock Units

During the year ended December 31, 2017, the Company granted a total of 247,694 RSUs to executive officers and directors of the Company. These RSUs vested ratably over a two-year period for the executive officers and on the one-year anniversary of the grant date for the directors.

During the year ended December 31, 2018, the Company granted a total of 108,254 RSUs to executive officers of the Company representing payment for 2017 target bonuses. These RSUs vested on the one-year anniversary of the grant date.

During the year ended December 31, 2020, the Company granted a total of 52,651 RSUs to executive officers of the Company. These RSUs vest on the one-year anniversary of the grant date. During the year ended December 31, 2020, the Company granted a total of 107,144 RSUs to directors of the Company. These RSUs vest ratably over one and three years.

As of December 31, 2020, the unrecorded deferred stock-based compensation balance related to RSUs was approximately $0.2 million and will be recognized over an estimated weighted-average amortization period of 1.0 years.

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The following table shows the Company's restricted stock unit activity during the years ended December 31, 2020, and 2019:

	Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Restricted stock units outstanding at December 31, 2018	147,554	3.03	
Vested	(147,554)	3.03	$ 129
Restricted stock units outstanding at December 31, 2019	—	—	
Granted	159,795	2.81	
Restricted stock units outstanding at December 31, 2020	159,795		$ 458

Performance Based Restricted Stock Awards

In January 2018, the Company granted up to 365,000 shares of performance-based restricted stock units ("Performance Units") under the 2014 Plan primarily to executive officers, which were largely contingent upon the achievement of performance goals during the performance period beginning on the date of grant and ending on December 31, 2019 as set forth in each individual's Performance Unit agreement. Performance Units granted in January 2018 replaced Performance Units granted in April 2017 which expired. During 2018, 50,000 Performance Units were cancelled and as of December 31, 2018 315,000 Performance Units remained outstanding. The remaining 315,000 Performance Units expired in December 2019 as the performance goals were not achieved, and there are no Performance Units outstanding as of December 31, 2020.

12. Accumulated Other Comprehensive Income

The change in accumulated other comprehensive income, which is reported as a component of stockholders' equity, for the year ended December 31, 2020 is summarized below:

	Unrealized Gain on Marketable Securities
Balance December 31, 2019	$ —
Other comprehensive income	3
Balance December 31, 2020	$ 3

13. Income Taxes

On December 22, 2017, the then President of the United States signed into law an Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018 (commonly known as "the Tax Cuts and Jobs Act or the "TCJA"), which introduced a comprehensive set of tax reforms. The Tax Cuts and Jobs Act significantly revises U.S. tax law by, among other provisions, lowering the Company's corporate tax rate from 34% to 21% and eliminating or reducing certain income tax deductions.

In December 2017, in accordance with the SEC Staff Accounting Bulletin ("SAB") 118–Income Tax Accounting Implications of the TCJA, the Company recorded tax effects on a provisional basis based on a reasonable estimate. The TCJA did not have a material impact on the Company's financial statements because its deferred temporary differences are fully offset by a valuation allowance and the Company does not have any offshore earnings from which to record the

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mandatory transition tax. During 2018, the Company completed its analysis under SAB 118 and no additional tax effects due to rate-remeasurement were required to be recorded.

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, 2020, the Company had available net operating loss carryforwards ("NOLs") of approximately $281.7 million for federal and $107.2 million for state income tax reporting purposes. Under the TCJA, the federal NOLs generated after 2017, approximately $84.0 million, can be carried forward indefinitely, while the NOLs generated through taxable years ending December 31, 2017, approximately $197.7 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 $6.5 million and $1.8 million for federal and state income tax reporting purposes, respectively, which are available to reduce federal income taxes, if any, through 2040 and state income taxes, if any, through 2035.

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, 2020, the Company has not accrued interest or penalties related to uncertain tax positions. The Company's tax returns for the years ended December 31, 2017 through December 31, 2019 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, 2020, 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,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 66,907	$ 55,216
Research credit carryforward	7,909	7,609
Stock options and other	1,962	3,225
Total gross deferred tax assets	76,778	66,050
Valuation allowance for deferred tax assets	(76,778)	(66,050)
Net deferred tax assets	$ —	$ —

The net change in the valuation allowance for the years ended December 31, 2020 and 2019 was an increase of $10.6 million and an increase of $5.3 million, respectively.

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

	December 31,		
	2020	2019	2018
Federal income tax at statutory rate	21.0 %	21.0 %	21.0 %
State income tax benefit, net of federal benefit	1.0 %	7.0 %	6.0 %
Research and development tax credits	0.7 %	4.0 %	3.0 %
Other	(2.0)%	(4.0)%	(4.0)%
Increase to valuation allowance	(20.7)%	(28.0)%	(24.0)%
Effective income tax rate	0.0 %	0.0 %	2.0 %

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. In January 2018, the Company completed the sale of NOLs totaling approximately $0.5 million. This amount is a current state tax benefit and is reflected in the statement of operations for the year ended December 31, 2018. 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. The Company is currently evaluating the potential sale of NJ NOLs under this new threshold.

14. 2019 Retention Plan

In July 2019, the Company adopted a retention plan (the "2019 Retention Plan") for all employees (with the exception of the Chairman and Chief Executive Officer) in order to induce such employees to remain employed by the Company through at least the extended PDUFA goal date of February 14, 2020.

Each employee who participated in the 2019 Retention Plan and remained continuously employed by the Company through the approval of Twirla was to be paid a lump-sum cash payment in an amount determined for each eligible employee by the Compensation Committee at the time of the adoption of the 2019 Retention Plan. If an eligible employee terminated employment prior to the approval for any reason, no such retention payment was payable to the

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eligible employee. With the approval of Twirla in February 2020, the cash portion of the 2019 Retention Plan in the amount of approximately $0.3 million was expensed and paid to eligible employees in February 2020.

All employees (with the exception of the Chairman and Chief Executive Officer) who were employed by the Company as of July 3, 2019 were also granted a stock option to purchase the number of shares of common stock as approved by the Compensation Committee, with a per share exercise price of $1.48, representing the closing price of the Company's common stock as reported by Nasdaq on the date of grant. For each option, 50% of the option vested on July 3, 2020 and the remaining 50% vested on December 31, 2020.

In addition, the vesting schedule for the stock options granted in January 2019 was amended for all employees (with the exception of the Chairman and Chief Executive Officer) holding such options who were employed on July 3, 2019 as follows: 50% of the option vested on January 29, 2020, 25% vested on June 30, 2020 and the remaining 25% vested on December 31, 2020. The change in vesting schedule was approved by the Compensation Committee and did not have a material impact on the Company's statement of operations.

15. 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 2030, total $16.3 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 2021 or termination amounts. Additionally, the Company purchases products and services as needed with no firm commitment.

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, 2020, the Company has not recorded a provision for any contingent losses.

16. Subsequent Event

On February26, 2021, the Company entered into the Amended Perceptive Credit Agreement, which amends the Credit Agreement and Guarantee dated February 10, 2020 between the Company and Perceptive. The Amended Perceptive Credit Agreement increases the total amount of credit available to the Company under the Credit Agreement to $45.0 million by creating a fourth tranche of $10.0 million that will be available based on the achievement of a revenue milestone. The interest rate and 1% fee payable upon the drawing of a tranche set forth in the Credit Agreement will also apply to the fourth tranche created by the Amended Perceptive Credit Agreement. Perceptive will receive an additional warrant to purchase 450,000 shares of common stock in connection with entering into the Amended Perceptive Credit Agreement.

17. Quarterly Data (Unaudited)

The following tables summarize the quarterly results of operations for each of the quarters in 2020 and 2019. These quarterly results are unaudited, but in the opinion of management, have been prepared on the same basis as our audited

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financial information and include all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of the information set forth herein (in thousands, except per share amounts).

	March 31, 2020	June 30, 2020	September 30, 2020	December 31, 2020
Total revenue	$ —	$ —	$ —	$ 749
Gross profit	$ —	$ —	$ —	$ 467
Operating expenses	$ 7,617	$ 10,039	$ 14,656	$ 17,208
Net loss	$ (7,883)	$ (10,826)	$ (15,524)	$ (17,620)
Basic and diluted net loss per common share	$ (0.10)	$ (0.12)	$ (0.18)	$ (0.20)

	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
Total revenue	$ —	$ —	$ —	$ —
Operating expenses	$ 4,707	$ 3,547	$ 4,499	$ 6,105
Net loss	$ (4,669)	$ (3,484)	$ (4,432)	$ (6,021)
Basic and diluted net loss per common share	$ (0.13)	$ (0.08)	$ (0.08)	$ (0.10)

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, 2020. 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, 2020, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable level.

Management's Annual Report on Internal Controls Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act and is a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel, to:

- Provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

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

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Our management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2020. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework.

Based on its evaluation, our management has concluded that, as of December 31, 2020, our internal control over financial reporting was effective.

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.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting occurred during the quarter ended December 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item 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	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.)
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	Warrant Agreement between Agile Therapeutics, Inc. and Perceptive Credit Holdings III, LP, dated as of February 10, 2020 (Incorporated by reference, Exhibit 4.1 to Company’s Current Report on Form 8-K, file number 001-36464, filed on February 12, 2020.)
4.3	Warrant Agreement between Agile Therapeutics, Inc. and Perceptive Credit Holdings III, LP, dated as of February 10, 2020 (Incorporated by reference, Exhibit 4.2 to Company’s Current Report on Form 8-K, file number 001-36464, filed on February 12, 2020.)
4.4	Warrant Agreement between Agile Therapeutics, Inc. and Perceptive Credit Holdings III, LP, dated as of February 26, 2021.
4.5	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.)

Exhibit Number	
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.)
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 November 19, 2010, by and between the Registrant and Bunn Farm Associates, LLC, as modified by the Lease Amendment, dated November 20, 2012, by and between the Registrant and Bunn Farm Associates, LLC, and the Second Lease Amendment, dated July 24, 2013, by and between the Registrant and Bunn Farm Associates, LLC, (Incorporated by reference, Exhibit 10.11 to Company's Registration Statement on Form S-1, file number 333-194621, filed on March 17, 2014.)
10.6	Third Lease Amendment, dated August 20, 2015, by and between the Registrant and Bunn Farm Associates, LLC. (Incorporated by reference, Exhibit 10.1 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on November 9, 2015.)
10.7	Fourth Lease Amendment, dated April 22, 2016, by and between the Registrant and Bunn Farm Associates, LLC and Fifth Lease Amendment dated December 1, 2016, by and between the Registrant and Bunn Farm Associates, LLC. (Incorporated by reference, Exhibit 10.15 to Company's Annual Report on Form 10-K, file number 001-36464, filed on March 12, 2018.)
10.8	Sixth Lease Amendment, dated November 11, 2020, by and between the Registrant and Bunn Farm Associates, LLC (Incorporated by reference, Exhibit 10.5 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on November 12, 2020.)
10.9	Common Stock Sales Agreement dated November 8, 2019 by and between the Registrant 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.)
10.10	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.)
10.11	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.
10.12*	Project Agreement, dated April 30, 2020, by and between the Registrant 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.)
10.13*	First Amendment to Project Agreement, dated June 1, 2020, by and between the Registrant and inVentiv Commercial Services, LLC

Exhibit Number	
10.14*	Master Service Agreement, dated October 11. 2017, by and between the Registrant and inVentiv Commercial Services, LLC (Incorporated by reference, Exhibit 10.2 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on August 11, 2020.)
10.15*	First Amendment to Master Service Agreement, dated April 30, 2020, by and between the Registrant 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.)
10.16*	Manufacturing and Commercialization Agreement, dated April 30, 2020, by and between the Registrant 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.)
10.17+	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.)
10.18	Clinical Research Agreement, dated October 26, 2018, by and between the Registrant and TKL Research, Inc. (Incorporated by reference, Exhibit 10.24 to Company's Annual Report on Form 10-K, file number 001-36464, filed on March 12, 2019.)
10.19	Amended and Restated Employment Agreement, dated August 14, 2020 by and between the Registrant and Alfred Altomari (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, file number 001-36464, filed on August 17, 2020).
10.20	Amended and Restated Employment Agreement, dated August 14, 2020 by and between the Registrant and Robert Conway (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, file number 001-36464, filed on August 17, 2020).
10.21	Amended and Restated Employment Agreement, dated August 14, 2020 by and between the Registrant and Geoffrey Gilmore (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, file number 001-36464, filed on August 17, 2020).
10.22	Amended and Restated Employment Agreement, dated August 14, 2020 by and between the Registrant and Dennis Reilly (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K, file number 001-36464, filed on August 17, 2020).
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, dated March 12, 2019.
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, dated March 12, 2019.
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, dated March 12, 2019 (furnished herewith).
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, dated March 12, 2019 (furnished herewith).
101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Balance Sheets, (ii) Statements of Operations and Comprehensive Loss, (iii) Consolidated Statements of Stockholders' Equity, (iv) Statements of Cash Flows, and (v) the Notes to Financial Statements.

+ 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).

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 1, 2021.

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 1, 2021
/s/ DENNIS P. REILLY Dennis P. Reilly	Chief Financial Officer (Principal Financial Officer)	March 1, 2021
/s/ JASON BUTCH Jason Butch	Chief Accounting Officer (Principal Accounting Officer)	March 1, 2021
/s/ SHARON BARBARI Sharon Barbari	Director	March 1, 2021
/s/ SANDRA CARSON Sandra Carson, M.D., FACOG	Director	March 1, 2021
/s/ SETH H.Z. FISCHER Seth H.Z. Fischer	Director	March 1, 2021
/s/ JOHN HUBBARD John Hubbard, Ph.D.	Director	March 1, 2021
/s/ AJIT S. SHETTY Ajit S. Shetty, Ph.D.	Director	March 1, 2021
/s/ JAMES TURSI James Tursi, M.D.	Director	March 1, 2021

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.

COMMON STOCK PURCHASE WARRANT

AGILE THERAPEUTICS, INC.

Common Stock Warrant Shares: 450,000 Dated: February 26, 2021

THIS COMMON STOCK PURCHASE WARRANT (this "Warrant") certifies that, for value received, Perceptive Credit Holdings III, LP or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date hereof, 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 Agile Therapeutics, Inc., a Delaware corporation (the "Company"), up to four hundred and fifty thousand (450,000) shares (as subject to adjustment hereunder, the "Warrant Shares") of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

This Warrant is issued pursuant to 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 the date hereof.

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), 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 under this Warrant shall be $2.87, subject to adjustment hereunder (the "Exercise Price").

(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. Notwithstanding anything herein to the contrary, the provisions of Section 3(a), 3(c) and 3(g) (solely as it relates to transactions or events of the type contemplated by the provisions of Section 3(a) and 3(c)) shall only be applicable during the period commencing on the date hereof and ending on December 31, 2022.

(a) Adjustment to Exercise Price Upon Issuance of Common Stock. Subject to Section 3(c), if the Company shall, at any time after the date hereof (the "Issue Date"), issue or sell any shares of Common Stock, whether directly or indirectly by way of Options or Convertible Securities (other than in an Excluded Issuance or any event described in Section 3(d) or (e)), without consideration or for consideration per share less than the Exercise Price in effect immediately prior to such issuance or sale, then immediately upon such issuance or sale, the Exercise Price in effect immediately prior to such issuance or sale shall be reduced (and in no event increased) to an Exercise Price equal to the quotient obtained by dividing:

(i) the sum of (A) the product obtained by multiplying the Common Stock Deemed Outstanding immediately prior to such issuance or sale (or deemed issuance or sale) by the Exercise Price then in effect plus (B) the aggregate consideration, if any, received by the Company upon such issuance or sale (or deemed issuance or sale); by

(ii) the sum of (A) the Common Stock Deemed Outstanding immediately prior to such issuance or sale (or deemed issuance or sale) plus (B) the aggregate number of shares of Common Stock issued or sold (or deemed issued or sold) by the Company in such issuance or sale (or deemed issuance or sale);

provided, for the avoidance of doubt, the number of Warrant Shares issued pursuant to this Warrant Certificate will not be adjusted in the event that the Exercise Price is adjusted under Section 3(a).

(b) *Intentionally Omitted*.

(c) Effect of Certain Events on Adjustment to Exercise Price. For purposes of determining the adjusted Exercise Price under Section 3(a), the following shall be applicable:

(i) Issuance of Options. If the Company shall, at any time or from time to time after the date hereof, in any manner grant or sell (whether directly or by assumption in a merger or otherwise) any Options, whether or not such Options or the right to convert or exchange any Convertible Securities issuable upon the exercise of such Options are immediately exercisable, and the price per share (determined as provided in this Section 3(c)(i) and in Section 3(c)(v)) for which Common Stock is issuable upon the exercise of such Options or upon the conversion or exchange of Convertible Securities issuable upon the exercise of such Options is less than the Exercise Price in effect immediately prior to the time of the granting or sale of such Options, then the total maximum number of shares of Common Stock issuable upon the exercise of such Options or upon conversion or exchange of the total maximum amount of Convertible Securities issuable upon the exercise of such Options shall be deemed to have been issued as of the date of granting or sale of such Options (and thereafter shall be deemed to be outstanding for purposes of adjusting the Exercise Price under Section 3(a)), at a price per share equal to the quotient obtained by dividing:

(A) the sum (which sum shall constitute the applicable consideration received for purposes of Section 3(a)) of (1) the total amount, if any, received or receivable by the Company as consideration for the granting or sale of all such Options, plus (2) the minimum aggregate amount of additional consideration payable to the Company upon the exercise of all such Options, plus (3), in the case of such Options which relate to Convertible Securities, the minimum aggregate amount of additional consideration, if any, payable to the Company upon the issuance or sale of all such Convertible Securities and the conversion or exchange of all such Convertible Securities, by

(B) the total maximum number of shares of Common Stock issuable upon the exercise of all such Options or upon the conversion or exchange of all Convertible Securities issuable upon the exercise of all such Options.

Except as otherwise provided in Section 3(c)(iii), no further adjustment of the Exercise Price shall be made upon the actual issuance of Common Stock or of Convertible Securities upon exercise of such Options or upon the actual issuance of Common Stock upon conversion or exchange of Convertible Securities issuable upon exercise of such Options.

(ii) Issuance of Convertible Securities. If the Company shall, at any time or from time to time after the Issue Date, in any manner grant or sell (whether directly or by assumption in a merger or otherwise) any Convertible Securities, whether or not the right to convert or exchange any such Convertible Securities is immediately exercisable, and the price per share (determined as provided in this Section 3(c)(ii) and in Section 3(c)(v)) for which Common Stock is issuable upon the conversion or exchange of such Convertible Securities is less than the Exercise Price in effect immediately prior to the time of the granting or sale of such

Convertible Securities, then the total maximum number of shares of Common Stock issuable upon conversion or exchange of the total maximum amount of such Convertible Securities shall be deemed to have been issued as of the date of granting or sale of such Convertible Securities (and thereafter shall be deemed to be outstanding for purposes of adjusting the Exercise Price pursuant to Section 3(a)), at a price per share equal to the quotient obtained by dividing:

(A) the sum (which sum shall constitute the applicable consideration received for purposes of Section 3(a)) of (1) the total amount, if any, received or receivable by the Company as consideration for the granting or sale of such Convertible Securities, plus (2) the minimum aggregate amount of additional consideration, if any, payable to the Company upon the conversion or exchange of all such Convertible Securities, by

(B) the total maximum number of shares of Common Stock issuable upon the conversion or exchange of all such Convertible Securities.

Except as otherwise provided in Section 3(c)(iii), (A) no further adjustment of the Exercise Price shall be made upon the actual issuance of Common Stock upon conversion or exchange of such Convertible Securities and (B) no further adjustment of the Exercise Price shall be made by reason of the issue or sale of Convertible Securities upon exercise of any Options to purchase any such Convertible Securities for which adjustments of the Exercise Price have been made pursuant to the other provisions of this Section 3(c).

(iii) Change in Terms of Options or Convertible Securities. Upon any change in any of (A) the total amount received or receivable by the Company as consideration for the granting or sale of any Options or Convertible Securities referred to in Section 3(c)(i) or (ii), (B) the minimum aggregate amount of additional consideration, if any, payable to the Company upon the exercise of any Options or upon the issuance, conversion or exchange of any Convertible Securities referred to in Section 3(c)(i) or (ii), (C) the rate at which Convertible Securities referred to in Section 3(c)(i) or (ii) are convertible into or exchangeable for Common Stock, or (D) the maximum number of shares of Common Stock issuable in connection with any Options referred to in Section 3(c)(i) or any Convertible Securities referred to in Section 3(c)(ii) (in each case, other than in connection with an Excluded Issuance), then (whether or not the original issuance or sale of such Options or Convertible Securities resulted in an adjustment to the Exercise Price pursuant to this Section 3) the Exercise Price in effect at the time of such change shall be adjusted or readjusted, as applicable, to the Exercise Price which would have been in effect at such time pursuant to the provisions of this Section 3 had such Options or Convertible Securities still outstanding provided for such changed consideration, conversion rate or maximum number of shares, as the case may be, at the time initially granted, issued or sold, but only if as a result of such adjustment or readjustment the Exercise Price then in effect is reduced.

(iv) Treatment of Expired or Terminated Options or Convertible Securities. Upon the expiration or termination of any unexercised Option (or portion thereof) or any unconverted or unexchanged Convertible Security (or portion thereof) for which any adjustment (either upon its original issuance or upon a revision of its terms) was made pursuant to this Section 3 (including without limitation upon the redemption or purchase for consideration of all or any portion of such Option or Convertible Security by the Company), the Exercise Price then in effect hereunder automatically shall be changed to the Exercise Price which would have been in effect at the time of such expiration or termination had such unexercised Option (or portion thereof) or unconverted or unexchanged Convertible Security (or portion thereof), to the extent outstanding immediately prior to such expiration or termination, never been issued.

(v) Calculation of Consideration Received. If the Company shall, at any time or from time to time after the Issue Date, issue or sell, or pursuant to Section 3(c) be deemed to have issued or sold, any shares of Common Stock, Options or Convertible Securities: (A) for cash, the consideration received therefor shall be deemed to be the net amount received by the Company therefor; (B) for Marketable Securities, the amount of consideration received therefor shall be deemed to be the market price (as reflected on any securities exchange, quotation system or association or similar pricing system covering such security) for such securities as of the end of business on the date of receipt of such securities; (C) for consideration other than cash or Marketable Securities, the amount of consideration received therefor shall be deemed to be the fair value of such consideration; (D) for no specifically allocated consideration in connection with an issuance or sale of other securities of the Company, together comprising one integrated transaction, the amount of consideration received therefor shall be deemed to be to be the fair value of such portion of the aggregate consideration received by the Company in such transaction as is attributable to such shares of Common Stock, Options or Convertible Securities, as the case may be, issued in such transaction; or (E) to the owners of the non-surviving entity in connection with any merger in which the Company is the surviving corporation, the amount of consideration received therefor shall be deemed to be the fair value of such portion of the net assets and business of the non-surviving entity as is attributable to such shares of Common Stock, Options or Convertible Securities, as the case may be, issued to such owners. The net amount of any cash consideration and the fair value of any consideration other than cash or Marketable Securities shall be determined in good faith jointly by the Board of Directors of the Company and the Holder.

(vi) Record Date. For purposes of any adjustment to the Exercise Price or the number of Warrant Shares in accordance with this Section 3, or any adjustment to the Number of Warrant Shares pursuant to Section 3(d) or 3(e), in case the Company shall take a record of the holders of its Common Stock for the purpose of entitling them (A) to receive a dividend or other distribution payable in Common Stock, Options or Convertible Securities or (B) to subscribe for or purchase Common Stock, Options or Convertible Securities, then such record date shall be deemed to be the date of the issue or sale of the shares of Common Stock

deemed to have been issued or sold upon the declaration of such dividend or the making of such other distribution or the date of the granting of such right of subscription or purchase, as the case may be.

(vii) Treasury Shares. The number of shares of Common Stock 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, and the disposition of any such shares (other than the cancellation or retirement thereof or the transfer of such shares among the Company and its wholly-owned subsidiaries) shall be considered an issue or sale of Common Stock for the purpose of this Section 3.

(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 Issue Date, (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 Issue Date, 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 the Issue Date 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. 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).

(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/ Alfred Altomari
Name: /s/ Alfred Altomari
Title: Chairman and Chief Executive Officer

Address for Notices:

Agile Therapeutics, Inc.
101 Poor Farm Road
3rd Floor
Princeton, New Jersey 08540
Attention: Dennis Reilly

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

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

[Signature Page to Warrant dated February 26, 2021]

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

[Signature Page to Warrant dated February 26, 2021]

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: _____

EXHIBIT 10.11

WAIVER AND FIRST AMENDMENT TO CREDIT AGREEMENT AND GUARANTY

This Waiver and First Amendment to Credit Agreement and Guaranty (herein, this "*Agreement*") is entered into as of February 26, 2021 (the "*First Amendment Effective Date*"), by and among Agile Therapeutics, Inc., a Delaware corporation (the "*Borrower*"), the Lenders party hereto (each a "*Lender*" and collectively, the "*Lenders*") and Perceptive Credit Holdings III, LP, a Delaware limited partnership, as a lender and as administrative agent for the Lenders (in such capacity, together with its successors and assigns, the "*Administrative Agent*").

RECITALS:

A. The Lenders have extended credit to the Borrower on the terms and conditions set forth in that certain Credit Agreement and Guaranty, dated as of February 10, 2020 (the "*Existing Credit Agreement*"; the Existing Credit Agreement as amended by this Agreement, the "*Credit Agreement*").

B. The Borrower has advised the Administrative Agent that its Annual Report on Form 10-K, which will be delivered to the Administrative Agent via the SEC's EDGAR system pursuant to Section 8.01(b) of the Existing Credit Agreement, will be subject to a "going concern" qualification in the accompanying opinion of Ernst & Young LLP (the "*Specified Event of Default*").

C. The Borrower has requested that the Administrative Agent and the Lenders agree to waive the Specified Event of Default

D. The Administrative Agent and the Lenders are willing to grant such waiver in accordance with and subject to the terms and conditions of this Agreement.

E. The Borrower has requested that the Administrative Agent and the Lenders agree to amend certain provisions of the Existing Credit Agreement.

F. The parties hereto agree to amend the Existing Credit Agreement pursuant to the terms of this Agreement.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

1. *Incorporation of Recitals; Defined Terms.* The parties hereto acknowledge that the Recitals set forth above are true and correct in all material respects. The defined terms in the Recitals set forth above are hereby incorporated into this Agreement by reference. All other capitalized terms used herein without definition shall have the same meanings herein as such terms have in the Credit Agreement.

2. *Limited Waiver*. Upon satisfaction of the conditions set forth in Section 6 hereof, pursuant to Section 13.04 of the Credit Agreement and subject to the terms and conditions hereof, the Administrative Agent and the Lenders hereby waive the Specified Event of Default. For the avoidance of doubt, this waiver is effective solely as a waiver of the Specified Event of Default and does not constitute a waiver or any other Default or Event of Default.

3. *First Amendment to Existing Credit Agreement*. Upon satisfaction of the conditions set forth in Section 6 hereof, the Borrower, the Lenders and the Administrative Agent hereby agree that the Existing Credit Agreement is hereby amended by incorporating the changes shown on the marked copy of the Existing Credit Agreement attached hereto as Annex C. Deletions of text in the Existing Credit Agreement as amended hereby are indicated by struck-through red text, and insertions of text as amended hereby are indicated by underlined blue text. Attached hereto as Annex D is a clean copy of the Credit Agreement conformed through the First Amendment. Schedule 1 to the Existing Credit Agreement is hereby amended and replaced in its entirety with the Schedule 1 attached hereto as Annex A. Exhibit H to the Existing Credit Agreement is hereby amended and replaced in its entirety with the Exhibit H attached hereto as Annex B.

4. *Acknowledgement of Liens*. The Borrower hereby acknowledges and agrees that the Obligations owing to the Administrative Agent and the Lenders arising out of or in any manner relating to the Loan Documents shall continue to be secured by the Liens granted as security therefor in the Loan Documents, to the extent provided for in the Loan Documents heretofore executed and delivered by the Borrower; and nothing herein contained shall in any manner affect or impair the priority of the Liens created and provided for thereby as to the indebtedness, obligations, and liabilities which would be secured thereby prior to giving effect to this Agreement.

5. *Representations And Warranties.* In order to induce the Administrative Agent and the Lenders to enter into this Agreement, the Borrower hereby represents and warrants to the Administrative Agent and the Lenders as follows:

(A) After giving effect to this Agreement, the representations and warranties of the Borrower contained in Article 7 of the Credit Agreement and in each other Loan Document shall be true and correct in all material respects on and as of the date hereof; provided that to the extent that such representations and warranties specifically refer to an earlier date, they shall be true and correct in all material respects as of such earlier date; provided further that any representation and warranty that is qualified as to "materiality", "Material Adverse Effect" or similar language shall be true and correct (after giving effect to any qualification therein) in all respects on such respective dates.

(B) The execution, delivery and performance of this Agreement has been duly authorized by all necessary corporate action on the part of, and duly executed and delivered by, the Borrower.

(C) No Default or Event of Default has occurred and is continuing or shall occur and be continuing immediately after giving effect to this Agreement.

6. *Conditions Precedent.* The effectiveness of this Agreement is subject to the satisfaction of the following conditions precedent:

(A) The Agent and the Lenders shall have received executed counterparts of this Agreement duly executed and delivered by the Borrower.

(B) The Borrower shall have issued to the Administrative Agent a warrant that, among other things, grants the holder thereof the right to purchase 450,000 shares of unrestricted common stock of the Borrower.

(C) The Administrative Agent and the Lenders shall have received a favorable opinion, dated as of the First Amendment Effective Date, of Morgan, Lewis & Bockius LLP, counsel to the Borrower in form reasonably acceptable to the Lenders and their counsel.

(D) The Administrative Agent and the Lenders shall have been reimbursed by the Borrower for all fees and expenses (including attorneys' fees and expenses) incurred by the Agent and its counsel outstanding as of the date hereof.

(E) The Administrative Agent and the Lenders shall have received (i) certified copies of the Organizational Documents of the Borrower and of resolutions of the board of directors (or similar governing body or committee of the board of directors, as applicable) of the Borrower approving and authorizing the execution, delivery and performance of this Agreement, certified as of the First Amendment Effective Date by its secretary or assistant secretary as being in full force and effect without modification or amendment and (ii) a good standing certificate and/or compliance certificate from the applicable Governmental Authority of the Borrower's jurisdiction of incorporation, dated a recent date prior to the First Amendment Effective Date.

7. *Reference to and Effect on the Loan Documents; No Novation.*

(A) This Agreement constitutes a Loan Document. On and after the date hereof, words of like import referring to the Credit Agreement, and each reference in the other Loan Documents to the "Credit Agreement", "thereunder", "thereof" or words of like import referring to the Credit Agreement shall mean and be a reference to the Credit Agreement after giving effect to this Agreement.

(B) Except as specifically set forth in this Agreement, the Credit Agreement and the other Loan Documents shall remain in full force and effect and are hereby ratified and confirmed.

(C) Except as expressly set forth in this Agreement, the Loan Documents and all of the obligations of the Loan Parties thereunder and the rights and benefits of the Administrative Agent and the Lenders thereunder remain in full force and effect. This Agreement is not a novation nor is it to be construed as a release, waiver or modification of any of the terms, conditions, representations, warranties, covenants, rights or remedies set forth in the Loan Documents, except as specifically set forth herein. Without limiting

the foregoing, the Loan Parties agree to comply with all of the terms, conditions, and provisions of the Loan Documents except to the extent such compliance is irreconcilably inconsistent with the express provisions of this Agreement. This Agreement may not be amended, supplemented, or otherwise modified except by a written agreement entered into in accordance with Section 13.04 of the Credit Agreement. THIS AGREEMENT REPRESENTS THE FINAL AGREEMENT BETWEEN THE PARTIES AND MAY NOT BE CONTRADICTED BY EVIDENCE OF PRIOR, CONTEMPORANEOUS OR SUBSEQUENT ORAL AGREEMENTS OF THE PARTIES. THERE ARE NO UNWRITTEN ORAL AGREEMENTS BETWEEN THE PARTIES.

8. *Headings*. The headings in this Agreement are included for convenience of reference only and will not affect in any way the meaning or interpretation of this Agreement.

9. *Governing Law*. This Agreement, and all questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be governed by and construed and enforced in accordance with the internal laws of the State of New York.

10. *Incorporation of Sections 13.10 and 13.11 of the Credit Agreement*. The provisions set forth in Sections 13.10 (Jurisdiction, Service of Process and Venue) and 13.11 (Waiver of Jury Trial) of the Credit Agreement shall apply to this Agreement in all respects.

11. *Counterparts*. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, shall be deemed to be an original, and all of which, when taken together, shall constitute but one and the same Agreement. Delivery of an executed counterpart of this Agreement by facsimile, DocuSign or a scanned copy by electronic mail shall be equally as effective as delivery of an original executed counterpart of this Agreement.

12. *Severability*. If any term or other provision of this Agreement is invalid, illegal or incapable of being enforced by any rule of law, or public policy, all other conditions and provisions of this Agreement will nevertheless remain in full force and effect so long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner adverse to any party. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the parties hereto will negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in an acceptable manner to the end that the transactions contemplated hereby are fulfilled to the extent possible.

13. *Binding Effect*. This Agreement will be binding upon and inure to the benefit of and is enforceable by the respective successors and permitted assigns of the parties hereto.

[SIGNATURE PAGES TO FOLLOW]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed and delivered by their respective officers thereunto duly authorized as of the date first written above.

AGILE THERAPEUTICS, INC., as Borrower

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

[Signature Page to First Amendment to Credit Agreement and Guaranty]

PERCEPTIVE CREDIT HOLDINGS III, LP,
as Agent and Lender

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

ANNEX A

SCHEDULE 1
TO
CREDIT AGREEMENT

TRANCHE A TERM LOAN COMMITMENTS

LENDER	TRANCHE A TERM LOAN COMMITMENT
PERCEPTIVE CREDIT HOLDINGS III, LP	$5,000,000

TRANCHE B TERM LOAN COMMITMENTS

LENDER	TRANCHE B TERM LOAN COMMITMENT
PERCEPTIVE CREDIT HOLDINGS III, LP	$15,000,000

TRANCHE C TERM LOAN COMMITMENTS

LENDER	TRANCHE C TERM LOAN COMMITMENT
PERCEPTIVE CREDIT HOLDINGS III, LP	$15,000,000

TRANCHE D TERM LOAN COMMITMENTS

LENDER	TRANCHE C TERM LOAN COMMITMENT
PERCEPTIVE CREDIT HOLDINGS III, LP	$10,000,000

WARRANT SHARES

LENDER	NUMBER OF CLOSING DATE WARRANT SHARES	NUMBER OF FIRST AMENDMENT EFFECTIVE DATE WARRANT SHARES	TOTAL WARRANT SHARES
PERCEPTIVE CREDIT HOLDINGS III, LP	1,400,000	450,000	1,850,000

ANNEX B

Exhibit H
to Credit Agreement

FORM OF BORROWING NOTICE

Date: [_____]

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

Re: Borrowing under Credit Agreement

Ladies and Gentlemen:

The undersigned, AGILE THERAPEUTICS, INC., a Delaware corporation (the "***Borrower***"), refers to the Credit Agreement and Guaranty, dated as of February 10, 2020 (as from time to time amended, restated, supplemented or otherwise modified, the "***Credit Agreement***"), among Borrower, the Guarantors from time to time party thereto, the Lenders from time to time party thereto and PERCEPTIVE CREDIT HOLDINGS III, LP, as administrative agent for the Lenders (in such capacity, the "***Administrative Agent***"). The terms defined in the Credit Agreement are herein used as therein defined.

Borrower hereby gives you notice irrevocably, pursuant to Section **2.01[(b)] [(c)] [d]** of the Credit Agreement, of the borrowing of the Term Loans specified herein:

1. The proposed **Tranche [B] [C] [D] Term Loan Borrowing Date** is [_____].

2. The amount of the proposed Borrowing is **$[15,000,000] [10,000,000]**.

3. The payment instructions with respect to the funds to be made available to Borrower are as follows:

Bank name: [_____]
Bank Address: [_____]
Routing Number: [_____]
Account Number: [_____]
Swift Code: [_____]

Borrower hereby certifies that the following statements are true on the date hereof, and will be true on the date of the proposed borrowing of the Term Loans, before and after giving effect thereto and to the application of the proceeds therefrom:

(a) the representations and warranties of the Obligors contained in Article 7 of the Credit Agreement and each other Loan Document are true and correct in all material respects on and as of the **Tranche [B] [C] [D] Term Loan Borrowing Date**; *provided* that to the extent that such representations and warranties specifically refer to an earlier date, they are true and correct in all material respects as of such earlier date; *provided further* that any representation and warranty that is qualified as to "materiality", "Material Adverse Effect" or similar language is true and correct (after giving effect to any qualification therein) in all respects.;

(b) the conditions set forth in **Section [6.02] [6.03] [6.04]** of the Credit Agreement have been satisfied on or prior to the **Tranche [B] [C] [D] Term Loan Borrowing Date**; and

(c) no Default exists or will result from the proposed Borrowing or from the application of the proceeds therefrom.

[signature to follow]

IN WITNESS WHEREOF, Borrower has caused this Borrowing Notice to be duly executed and delivered as of the day and year first above written.

BORROWER:

AGILE THERAPEUTICS, INC.

By: _____
Name:
Title:

ANNEX C

Marked Credit Agreement

ANNEX D

Conformed Credit Agreement

(First Amendment)

Information in this exhibit identified by [***] is confidential and has been excluded pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed.

FIRST AMENDMENT TO PROJECT AGREEMENT (DETAILING – FIELD TEAM AND TELESOLUTIONS)

This First Amendment (the "Amendment") dated June 1, 2020 (the "Effective Date") is made by and between inVentiv Commercial Services, LLC, a Syneos Health® group company, with an office at 500 Atrium Drive, Somerset, N.J. 08873 ("Syneos Health") and Agile Therapeutics, Inc. with an office located at 100 Poor Farm Road, 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 and Telesolutions) made as of April 30, 2020 (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 Sales Team in Exhibit A, "Detailing Services," is hereby deleted in its entirety and replaced with the Amended and Restated Exhibit A attached hereto and made a part hereof.

3. Exhibit B, "Telesolutions Services," is hereby deleted in its entirety and any and all references to "Telesolutions Agents" or "Telesolutions Team" are likewise deleted in their entirety.

4. All references to "Wave Two" are hereby deleted in their entirety.

5. Exhibit A-1, "Field Operations Services," is hereby deleted in its entirety and replaced with the Amended and Restated Exhibit A-1 attached hereto and made a part hereof.

6. Exhibit F, "Compensation – Fixed Fees, Variable Fees and Pass-through Costs," is hereby deleted in its entirety and replaced with the Amended and Restated Exhibit F attached hereto and made a part hereof.

7. 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.

8. 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.	**INVENTIV COMMMERCIAL SERVICES, LLC**
By: */s/ Al Altomari*	By: */s/ Todd Tomasoski*
Name: Al Altomari	Name: Todd Tomasoski
Title: Chairman and CEO	Title: Vice President, Global Deal Management
Date: 11/24/2020	Date: 12/9/2020

AMENDED AND RESTATED
EXHIBIT A
THE DETAILING SERVICES

Syneos Health will provide Client with a field force that shall consist of up **[***]** full-time sales representatives (the "Representatives") and **[***]** regional sales representatives (the "RS Reps" and collectively with the Representatives, the "Syneos Health Sales Representatives" or "Sales Representatives"). The Sales Representatives shall detail the Client's Product by making calls pursuant to a Call Plan on Targets. The Sales Representatives will be managed by up to **[***]** regional sales managers (the "RSMs") who will also be Syneos Health employees. Syneos shall also provide **[***]** national sales director (the "NSD"). The Sales Representatives, RSMs and NSD may be referred to collectively herein as the "Project Team".

For purposes of clarity, the Implementation Fees and Fixed Monthly Fees outlined in Section I(a) and (b) of Exhibit F includes the headcount for the Project Team as set forth in the table below.

Position	Headcount
Project Team	
Representatives	**[***]**
RS Reps	**[***]**
RSM	**[***]**
NSD	**[***]**

In the event that the Parties desire to increase the type and / or number of Project Team members providing Services under this Project Agreement they may do so by utilizing a Project Team Member Request Form (the "Request Form") in a format that is substantially similar to the one attached hereto as Attachment 1. The details set forth in the Request Form shall be mutually agreed upon by the Parties. For clarification, the Request Form may not be used in those situations where it is the intent of the Parties to amend terms and conditions of this Project Agreement other than those specific items set forth on the Request Form.

I. ADDITIONAL DEFINED TERMS

(a) "Call" means the activity undertaken by a Sales Representative to detail the Product, further described as a face-to-face presentation by a in Sales Representative to a Target and will include providing the Product Literature (as directed by Client).

(b) "Call Plan" means a plan jointly designed by Client and Syneos Health, which is intended to enhance the efficiency and effectiveness of the Project Team in making Calls. The Call Plan will be maintained by Syneos Health at its offices with a copy of such Call Plan maintained by Client at its offices, and may be amended or reconfigured from time to time solely at Client's written request (limited quarterly updates are included in the current fee) with Client paying Syneos Health a fee pursuant to the Standard Pricing Table outlined in Exhibit A-1, Section 3.1.1(d)(5), as agreed upon in writing, for the performance of such amendment or reconfiguration services. Client may add products to the call plan, which may be either products

owned by the Client or those for which the client has entered into a co-promotion agreement without having an impact on the monthly fees. If a Call Plan requires amending or reconfiguration a Change of Scope document would be executed by both Parties and the Standard Pricing Table see Exhibit A, Section 3.1.1(d)(5) would apply as applicable.

(c) "Deployment Date" means the date of the first Call by a Syneos Health Sales Representative, which is anticipated by the Parties to be on or about **[***]**. Notwithstanding the date set forth herein, the Deployment Date will be the actual date of the first Call by a Syneos Health Sales Representative.

(d) "Healthcare Professional" or "HCP" means a person, other than an individual patient, including, without limitation, any medical or health care professional or entity in a position to purchase, lease, recommend, use, influence or arrange for the purchase or lease of, or prescribe the Products with whom Syneos Health Sales Representatives come in contact with in connection with providing the Services hereunder.

(e) "Product" shall mean **Twirla®**.

(f) "Product Literature" shall mean promotional, informative and other written information concerning the Product. All Product Literature shall be prepared and provided by Client. The Syneos Health Sales Representatives shall utilize the Product Literature when making Calls.

(g) "Project Team member Hire Date" means the date the first Syneos Health Sales Representative is assigned to the Project Team.

(h) "Targets" mean the licensed practitioners who are identified by Client as potential prescription writers and/or customers for the Product as provided by Client to Syneos Health.

II. HIRE STATUS, FLEET, TRAINING AND MEETINGS

(a) Hire Status—Generally. Upon completion and approval by the parties of the field alignment and profile (including approval of the final number of Project Team members), Syneos Health will commence recruiting and hiring activities for the Project Team members. In the event that Syneos Health receives notification to commence recruiting and hiring activities with respect to a position or territory, and that position or territory is subsequently cancelled by Client at any time after **[***]** from the date of such notification, then Client shall pay a cancellation fee to Syneos Health in the amount of **[***]** for each such cancelled position or territory.

(b) Hire Status—Provisioning. Syneos Health shall provide following:

(i) Salary, benefits, and incentive compensation as agreed by Client to the Project Team members.

(ii) Fleet Vehicles and fleet management services for the Sales

Representatives include the following:

(1) Coordination of department of motor vehicle ("DMV") checks and confirmation of completion for all employees in Fleet Vehicles

(2) Management of vendor involvement for accidents, fuel cards, and insurance

(3) Coordination of delivery of bridge rentals or Fleet Vehicles dependent upon background and DMV check completion, timeline of deployment and vehicle availability

(4) Recommendations for snow belt vehicles as applicable for project

(5) Ordering new vehicles or transfer of existing surplus vehicles dependent upon team size, availability and Client budget

(6) Timely pick-up of fleet vehicles through third-party vendor for terminations and leaves of absence ("LOAs") as appropriate

(iii) The above stated fleet management services shall assume the following:

(1) Timely notification of territory and district locations for vehicle placement

(iv) Human resources management services for the Project Team to include, but not be limited to, the following:

(1) Creation, distribution, and tracking of offer letters and onboarding documents

(2) Distribution of emails from background and drug screening vendors to complete required data for background screening and drug screen

(3) Tracking of background and drug screening results (follow-up may be required)

(4) New hire orientation

(5) Works with project lead coordination on investigations of policy non-compliance, background and other performance issues

(6) Coordination with leave and benefits administration as required

(7) Delivery of termination notices, participation in notification calls regarding downsizing and conversions

(v) Human resources management services assume the following:

(1) Timely completion of background vendor required information through its link for new hires

(2) Information regarding vacation, incentive compensation, expectations are available for inclusion in the offer letters

(vi) Information technology hardware for the Sales Representatives to include iPads and laptop computers (including sales force automation software) and printers.

(vii) CRM and operational support for the Sales Representatives as further described in Exhibit A-1.

(c) Training - The training responsibilities of the Parties are as follows:

(i) Syneos Health shall be responsible for training members of the Project Team pursuant to Exhibit E.

(ii) Client shall be responsible for training members of the Project Team concerning all Product specific information including Product complaint handling procedures, applicable specific Client health care compliance policies and Client customer service policies and procedures, orientation to Client's business, compliance with Applicable Law, and adverse event reporting policies and procedures. The Parties agree to work together to mutually determine if, when, and at what cost additional training shall be provided to members of the Project Team.

(d) All expenses associated with Plan of Action (POA) meetings and national training meetings shall be pre-approved by Client and be paid for by Client as a pass-through expense or direct billed to Client.

(e) Syneos Health will be responsible for providing credit cards to any Syneos Health Project Team member as requested by Client who establishes credit-worthiness in accordance with standards established by Syneos Health's corporate credit card provider. Client and Syneos Health shall establish appropriate limitations on the amount of available credit. In the event a Syneos Health Sales Representative is unable to establish credit worthiness, Client shall determine if it nevertheless desires to have a credit card issued to such Syneos Health Sales Representative. All credit card expenses shall be submitted and processed through the Syneos Health expense reimbursement system. In the event of a default on a credit card invoice by any Syneos Health Sales Representative (i.e., the expenses/receipts are not input into the Concur system), Client shall nevertheless reimburse Syneos Health for all business related expenses properly incurred by such field personnel in accordance with the Project Agreement which are substantiated through credit card statement documentation, and not otherwise entered in the expense management system.

III. PERFORMANCE

If Client believes in good faith that the performance of any Syneos Health Project Team member is unsatisfactory or is not in compliance with the provisions of this Project Agreement,

Client shall notify Syneos Health and Syneos Health shall promptly address the performance or conduct of such person in accordance with its internal human resource policies. In the event that Client determines in good faith that a Syneos Health Project Team member has violated any applicable law, regulation or policy, Client shall notify Syneos Health in writing. Syneos Health shall promptly address the issue and take all reasonable and appropriate action (including but not limited to termination of such employee). No such action shall be contrary to Syneos Health's internal human resource policies and procedures, provided such human resource policies and procedures are in compliance with all Applicable Laws. If, despite any foregoing action by Syneos Health, Client is still reasonably unsatisfied with the performance of any Syneos Health Project Team member, Client may request the removal of such Syneos Health Project Team member by promptly notifying Syneos Health in writing, and Syneos Health shall remove the Syneos Health Project Team member from the provision of Services hereunder. Any action taken pursuant to this Section III will be in accordance with Syneos Health's internal human resource policies and procedure and the Applicable Laws governing employees. Syneos Health shall promptly notify Client if it becomes aware that any Project Team member has violated or is alleged to have violated any applicable law, regulation or policy.

IV CALLS AND TARGETS

The Syneos Health Project Team shall provide Product Literature and Product samples (as needed) when making Calls as directed and approved by Client. Client is solely responsible for the content, production and distribution (to the Syneos Health Sales Representatives) of the Product Literature. Each Syneos Health Sales Representative shall record information concerning each Call, including but not limited to Product sample distribution, and concerning the profile of each individual Target (or other physician called upon) on whom the Syneos Health Sales Representative calls. Client shall permit Syneos Health to access and use all Target, sales and Call-related data that supports or is associated with the Services that are performed in accordance with this Project Agreement (the "Data"). The Data shall be used by Syneos Health for the purpose of evaluating the performance of its Project Team members; and, provided that Syneos Health de-identifies all Client and Product specific components of the Data, for business development and analytics purposes.

V. THE PRODUCTS

The Product shall be promoted by Syneos Health under trademarks owned by or licensed to Client and are Products which Client has all lawful authority necessary to market and sell the Products in all geographic areas where the Products are to be promoted under this Project Agreement. This Project Agreement does not constitute a grant to Syneos Health of any property right or interest in the Products or the trademarks owned by or licensed to Client. Syneos Health recognizes the validity of and the title of Client to all its owned or licensed trademarks, trade names and trade dress in any country in connection with the Products, whether registered or not. Client represents to Syneos Health that neither those trademarks, trade names and trade address nor the promotion of the Products by Syneos Health infringes on any intellectual property right of any other person or entity.

VI. HIRING PROFILE

In selecting Project Team members, Syneos Health will use the preferred hiring profile approved by Client. Syneos Health will take reasonable steps to confirm the accuracy of information concerning background and experience received from applicants for positions of Project Team members. Syneos Health shall not knowingly employ or otherwise retain, or permit to be retained as a Project Team member, a practicing physician or a person affiliated on a professional level with or employed by any physician, physician practice or other healthcare professional or provider or a person who is in a position to unduly influence the purchase of the Products.

VII. BACKGROUND CHECKS

Syneos Health shall be responsible for performing drug testing and background checks of all Project Team members. Syneos Health represents and warrants that it will complete or cause to be completed a thorough background check of all Project Team members. This will include, Criminal Check, Social Security Check, Drug Screen, Motor Vehicle Record Check, Education Check, Past Employer Check. Syneos Health further represents and warrants that it will perform or cause to be performed background checks to confirm that no Sales Representative:

a. is an excluded person on the Office of Inspector General's List of Excluded Individuals/Entities and is not on the General Services Administration Excluded Parties List (as of the date the background check is performed);

b. is, so far as it is aware, an unfit or an improper individual for the performance of the Services;

c. is, so far as it is aware, engaged in any fraudulent or unlawful activity, or other inappropriate conduct as measured by the other requirements of this Project Agreement.

Syneos Health shall institute prompt corrective or disciplinary action against any Project Team member who fails to meet the requirements set forth in this Exhibit A. Syneos Health further agrees to cooperate and comply with all investigations by or on behalf of Client with respect to wrongdoing, or alleged or suspected wrongdoing, in respect of any obligations of Syneos Health or any Project Team members under this Project Agreement.

VIII. REPRESENTATIONS AND UNDERTAKINGS

(a) **[***]**

(b) Client represents that:

(i) it recognizes that for Syneos Health to comply with its obligations hereunder, it shall need the good faith cooperation of Client to provide Syneos Health with the

necessary materials and assistance required to enable Syneos Health to perform the Services;

(ii) the Services being provided by Syneos Health are in furtherance of Client's program of marketing and promoting the Products and as such, Client is responsible for ensuring, and further, Client represents and warrants, that the Client's program being implemented by Syneos Health pursuant to the terms hereof (but not the implementation thereof by Syneos Health), strictly adheres to all applicable state and federal statutes, laws, ordinances, and the rules and regulations of all governmental and regulatory authorities, including but not limited to, the Federal Food, Drug, and Cosmetic Act and the Prescription Drug Marketing Act;

(iii) it shall ensure that none of its employees add, delete or modify claims of efficacy or safety of the Products, nor makes any changes (including but not limited to, underlining or otherwise highlighting any language or adding any notes thereto) in the Product Literature, during the training on the Products or during any communications with Syneos Health employees;

(iv) it shall ensure that none of its employees working with the Project Team or in connection with the Services, directly or indirectly instruct any Syneos Health employee to pay, offer or authorize payment of anything of substantial value (either in the form of compensation, gift, contribution or otherwise) to any person or entity in a position to order, recommend or purchase the Products contrary to any law; and

(v) neither it nor any of its employees directly or indirectly instruct any Syneos Health employee to make any representations or warranties relating to the Products that conflict, or are inconsistent with, applicable laws or the Food and Drug Administration approved labeling for the Products.

(vi) Client shall:

A. provide Syneos Health Project Team members with all Product Literature and arrange for the provision of Product samples (as applicable).

B. inform Syneos Health promptly of any changes which Client believes are necessary or appropriate in the Product Literature or in information concerning the Products in order to be in compliance with all applicable federal and state law, regulations and administrative guidance.

C. Arrange for a timely and appropriate response to any inquiry concerning a Product communicated to Syneos Health from any licensed practitioner and communicated by Syneos Health to Client.

1.0 Executive Summary

This Exhibit A-1 describes the scope of work, deliverables, and assumptions for field operations initial implementation and ongoing annual support for the Project (as defined in Section 3.1.1(a)). Any changes to the assumptions, deliverables, or scope of work described in this Exhibit A-1, or any new work request(s), will follow Section 3.1.1(d), Change Control Process of this Exhibit A-1.

2.0 Scope of Services

The following service areas are part of field operations initial implementation and ongoing annual support:

- Operations Management
- Customer Relationship Management (CRM)
- Customer Master Source Data & Validation
- Travel and Expense Management
- Transparency Reporting
- Data Management
- Analytics and Reporting
- Targeting, Alignment and Call Plan Administration
- Incentive Compensation Management
- Field Support Services
- Technology Training Services
- LMS System Support
- Quality Management and Assurance
- Field Trigger Email with Veeva Engage

3.0 Scope of Work Definition

3.1 Operations Management

3.1.1 As part of operations management, Syneos Health will provide the following:

(a) Project Management. Syneos Health will provide a fully integrated project management approach for the implementation of the operations services (the "Project") including the following:

(1) Leadership of Project kick-off meeting to include review of scope, timelines, and assumptions for each functional area, Sales Team member introduction, and status reporting formats and meetings.

(2) Integration of all Project activity, timelines, and deliverables across all functional areas into a consolidated Project schedule.

(3) Leadership, facilitation, and documentation of all meetings, including meeting notes and action items.

(4) Management of the Project schedule including task management, escalation of issues, risk identification, and interdependencies through Project documentation including:

(i) Issue tracker;
(ii) Milestone tracker; and
(iii) Action item tracker.

(5) Project status meetings and Project status reporting, including weekly status reports and plan reviews with the Client.

(6) Project close-out and lessons learned session to include any information that can be applied to the ongoing operational support of the Client after the initial implementation is complete.

(7) Project management implementation deliverables including the following:

(i) Weekly implementation schedule identifying Project activities and target completion dates.
(ii) Weekly implementation log of risks, actions, issues, and key decisions ("RAID").

(b) Technical Operations Management. Technical operations Project implementation deliverables include the following:

(1) Ongoing communication plan;

(2) Technical operations deliverables document identifying standard deliverables and key business rules – delivered within six (6) weeks of the first day in the field;

(3) Monthly technical operations status report;

(4) Monthly operation leadership meeting and supporting documents; and

(5) Quarterly business review meeting and supporting documents.

(c) Field Administrative Management. Syneos Health will oversee all field administrative tasks, including the following activities:

(1) Field Administrative Management—Implementation.

(i) Project set up and roster management using Syneos Health's proprietary master roster system;

(ii) Onboarding of new hires, including all aspects of administrative systems and processes (e.g., travel, CRM system, business cards, welcome memo, conference call accounts, fleet coordination, credentialing, licensure);

(iii) Meeting planning logistics for national and POA meetings;

(iv) Venue sourcing, hotel sourcing/booking, meal and events arrangements, ground transportation set up, flight arrangements, travel letter development, and budget tracking for national and POA meetings;

(v) One (1) resource for on-site meeting support available, as needed;

(vi) Training development and coordination;

- Identify and coordinate Syneos Health/Client courses for LMS upload
- Coordinate presenters/training schedules & agendas
- LMS course completion monitoring
- Post launch mastery training plan development

(vii) Team Expense Travel and Budget Policy development.

(2) Field Administrative Management—Ongoing Support.

(i) Roster management and distribution;

(ii) Continuation of meeting planning logistics, as described above, either with Client vendor(s) or as a stand-alone offering;
(iii) Monitoring Project parameters and managing eligibility and payout of incentive compensation and awards within approved Project guidelines;
(iv) Coordinate, route, track, and report operational initiatives, questions, or directives across all of the internal administrative departments, as well as external vendors and Client home office;
(v) Review of monthly invoicing and budgets for adherence to Project P&L;
(vi) Coordination with sample management and fulfillment vendor (if applicable);
(vii) Coordination with Syneos Health compliance on HCP expense monitoring and reporting;
(viii) Onboarding of backfill new hires to include all aspects of administrative systems and processes;
(ix) Coordination of communication to the field;
(x) Ad hoc reporting (e.g., turnover/vacancy reports, budget tracker);
(xi) Monthly field employee roster audits; and
(xii) Payroll processing;
(xiii) Review and ensure all field expense reporting is completed, to include HCP reporting;
(xiv) Field communication to include the following for the team conference call:

- FAQ development with HR and business lead
- Communication script
- Project exit check list and acknowledgement

(xv) Monitor return of Syneos Health property;
(xvi) Monitor return of Client property (i.e., samples, marketing materials, etc.);
(xvii) Coordination with fleet department on return of vehicle (if applicable); and
(xviii) Deactivations of all Project specific accounts (i.e., conference call/WebEx, etc.).

(d) Change Control Process. During the Term of this Project Agreement, the Parties may mutually agree to alter the Field Operations Services outlined in this Exhibit A-1. Such changes will be addressed as follows:

(1) Assess the impact of scope changes on Project schedules, resources and pricing;

(2) Provide a formal vehicle for approval to proceed with any changes to the Project Agreement;

(3) Provide a Project audit record of all material changes to the original Project Agreement; and

(4) If requirements arise that are outside the scope of this Exhibit A-1, a Change of Scope document (or an amendment to the Project Agreement, as applicable) will be submitted for Client approval following the below process:

(i) Client requests additional requirements for new functionality or deliverables outside the scope of work provided herein.
(ii) Syneos Health reviews change, meets with Client and internal team members to understand and scope Client expectations regarding business need, timelines, and other deliverable expectations.
(iii) Syneos Health provides Change of Scope (or Amendment or new Project Agreement, as applicable) document, which outlines work effort, timeline and pricing impacts of the change. Pricing will be determined based on standard rates provided below.
(iv) Client accepts proposal and signs Change of Scope (or Amendment or new Project Agreement, as applicable) document which authorizes work to begin on the change request.

(5) Standard Pricing Table.

Role	Price/HR
Software Development	**[***]**
CRM Configuration	**[***]**
Data Management	**[***]**
Alignment/Call Planning	**[***]**
Incentive Comp Modeling/Design	**[***]**
Analytics & Reporting	**[***]**
Project Management/Business Analysis/Solution Design	**[***]**

Role	Price/HR
Testing	**[***]**
IC Administration	**[***]**
Training (Content/Delivery)	**[***]**
Hardware/Help Desk	**[***]**

3.2 Customer Relationship Management ("CRM")

3.2.1 CRM; Client Configuration and Available Functionality. Syneos Health will provide a CRM application. Additionally, within its CRM application, Syneos Health will set-up a single, Client-specific, dedicated CRM environment configured specifically to the Client's business rules (the "Client Configuration"). The core functionalities within the Client Configuration are as follows, and will be configured by Syneos Health upon selection by Client:

(a) Customer profile management across account types (individuals and organizations);

(b) Call recording, reporting, and loading of Call plans;

(c) Closed-Loop Marketing ("CLM"), loading and presentation of digital media as part of integrated call record;

(d) Sample management and recording of samples and physician signature capture as part of integrated call record, including Prescription Drug Marketing Act (PDMA), CFR Part 11 Validation, if requested by Client;

(e) Medical Inquiry Request Form ("MIRF") including physician signature capture;

(f) Field Coaching Report (FCR) configuration;

(g) Pre-established reports and dashboards to enable field and field management performance (online only); and

(h) iPad/online platform options including online/home office PC, field tablet PC, and iPad to support mobility needs and improved customer interaction.

3.2.2 CRM; Client Configuration Development and Implementation. CRM implementation will be led using an agile development approach including the following deliverables:

Project Deliverable	Definition
Initial Requirements	Demonstration of the Client Configuration; and discussion of Client needs and business environment to support the general usage and end-user experience; will include accounts, functions, Call types, products, customer profile maintenance, etc.
Alpha Review	First iteration of the Client configuration based on requirements gathered in the Initial Requirements session. Detailed demonstration of the Client Configuration for more in-depth review of Client requirements.
Configuration Requirements Document ("CRD")	After the Alpha Review, Syneos Health will provide the Client with a draft CRD document which summarizes all end-user system requirements taken from both the Initial Requirements and Alpha Review sessions. The CRD will form a basis for the final Client Configuration specifications, risk assessment, testing, training, and validation (if applicable).
Beta Review	The final phase of the Client requirements will be a Beta Review, which will allow for any changes to the Client Configuration system requirements for final testing and production readiness.
CRD Sign-Off	Any changes or additions to the Client Configuration requirements during the Beta Review will be incorporated into the final CRD and submitted to the Client after the Beta Review session for final approval and signature.

3.2.3 Client Configuration Assumptions. The scope of the Client Configuration CRM delivery and associated timelines for the Project assumes the following:

(a) Necessary Client members are available for the Initial Requirements, Alpha Review, and Beta Review meetings (each typically 3 hours), based on the weeks assumed in the agreed upon Project plan (Alpha Review/Beta Review may be done via WebEx);

(b) Sign-off of documentation within 5 days of delivery by necessary Client members;

(c) No customization of code outside of CRM provided configuration capabilities;

(d) Use of standard MIRF functionality and data extracts to medical information;

(e) Client Configuration/CRM does not include Adverse Events/Pharmacovigilance ("AE") reporting or recording. An alert is setup in the CRM system to remind field users of the appropriate number/process to communicate to HCPs;

(f) Linking to company or external web-based systems within CRM tab structure;

(g) Access to Syneos Health Veeva Vault for Client approved content including: CLM presentations and approved email templates. Alternatively, Syneos Health Veeva Vault may be setup to attach directly to Client internal Veeva Vault system in cases where Client is using Veeva Vault for internal Medical, Legal, Review ("MLR"). Syneos Health Veeva Vault is not used for internal Client MLR usage, only for field delivery of approved content;

(h) Sample management functionality, if required, and data feeds for sample shipments, SLN validation, and sample product information as determined by Client requirements;

(i) Inclusion of sales data within standard Veeva reporting functionality (online only);

(j) Field Coaching Report originates from manager, not representative, including data entry only. Form will not be pre-populated with any data from any source;

(k) Call history within the Sales Force Automation ("SFA") system not to exceed 15 months (5 Quarters) without purchasing additional data storage from Salesforce.com;

(l) External access for Client home office administrators can be granted with change control processes in place to ensure integrity of Syneos Health production environment, with additional license costs as dictated by home office license pricing in contract; and

(m) Ongoing support for CRM system including tier 2/technical support for escalated calls from field support desk, and home office support needs;

3.3 Customer Master Source Data and Validation

3.3.1 Veeva Network and Veeva OpenData Validation.

(a) Syneos Health shall provide a near real-time customer validation process leveraging the integration of Veeva Network and Veeva OpenData. This combination gives direct access to Veeva OpenData for adding and changing of HCP and HCO data, which allows for field users to search, add, and immediately pull-down HCPs/HCOs industry standard identifiers and compliance information, such as SLN and DEA, upon adding the new prescriber, as opposed to waiting the standard 2-3 weeks for weekly data exports and validation.

(b) Client and Syneos Health's targeting and alignment team will also have access to Veeva OpenData for sales or marketing research, such as to identify initial target universe, ongoing target adjustments, new product or market evaluations, etc.

(c) The Veeva Network service includes the following:

(1) Configuration and support for utilizing Veeva OpenData and the Veeva Network to allow for this Customer Master Data solution to control the universe in the CRM system and to provide for data stewardship services via Veeva OpenData provided controls.

(2) Data change requests can be submitted by field users to the Veeva OpenData data stewards, which increases efficiency and decreases timelines associated with routine action request processing for universe changes discovered by the field.

(3) The Veeva Network account search will allow for the field to search the Veeva OpenData Customer Master Data for any HCP or HCO that meets the search criteria, and provides the ability to add that HCP or HCO to their Veeva CRM territory. The information included is pre-validated by Veeva OpenData so an eligible HCP can be sampled immediately. Additionally, all valid address information known for that account will be brought down with the HCP or HCO selected.

(d) The Veeva OpenData service includes access to the following data set:

(1) Licensed field and home office users have access to entire customer universe (HCPs, HCOs, addresses, affiliations) in the Veeva OpenData customer universe.

(2) Usage of compliance data scrub – for industry standard identifiers SLN, NPI, DEA #s for initial and ongoing data validation.

(3) Usage of data hygiene scrub – for HCP demographic data such as address, specialty etc. for initial data validation.

(4) Access to email address data is not included in standard offering but may be available on a per record basis for marketing initiatives as needed and is recommended for usage if Client is implementing enhanced approved email functionality (not included in base CRM license).

3.4 Travel and Expense Management

3.4.1 Travel & Expense Set-Up and Ongoing Services. Syneos Health shall leverage its then current travel and expense ("T&E") management system application (and solution provider) (collectively, the "T&E Management Solution"), currently Concur, for capture and reimbursement of all expenses incurred by Syneos Health employees recruited for the Client's Project, and for HCP data capture necessary for transparency reporting. The T&E Management Solution assumes the following:

(a) Required Client members are identified and available for requirements gathering;

(b) Client's requirements align with the standard baseline Concur configuration, (i.e. able to utilize existing expense types, approval workflow, etc., without customization);

(c) Completion of Configuration Request document for Project set-up based on Client spend limits and business rules;

(d) Acceptance of Syneos Health universe for HCP selection utilizing Medpro Concur Connect;

(e) Ongoing support for Concur T&E management system including tier 2/technical support for escalated calls from field support desk;

(f) Changes to or additional audit rules may be requested post-deployment;

(g) On-going roster management as teams expand or re-align (including territory and manager changes);

(h) Information on areas such as Amex cards, mileage rates, report approvers, etc. are communicated and decided on at onset of implementation based on Client business rules;

(i) T&E management system setup and support is only provided for Syneos Health employees. If any Client employees are supported, Client will be responsible for the deployment of the T&E management system and capture of any HCP meal spend, etc. for the Client employees;

(j) Coordination of Learning Management System ("LMS") Project set-up and communication of system access and viewing of Concur module to new hires/end users;

(k) Inclusion of Expense Management in Technology Training sessions; and

(l) Tracking of completed Concur module review in LMS per user.

3.4.2 Travel & Expense Deliverables. The T&E management system application work stream will be managed by the Operations Manager, the Concur system subject matter expert, and the compliance lead, and will include the following deliverables:

Project Deliverable	Definition
T&E Guidelines	General Syneos Health guidelines provided to assist the Client in developing their T&E program; this can be reviewed and modified by Client as required.
Compliance Business Rules Document	Detailed document describing all compliance business rules associated with the Client Project. A draft will be provided with Syneos Health's base business rules and guidance with review and modifications as needed, and approval by Syneos Health and Client.
ERD (Expense Requirements Document)	Detailed document describing standard Concur functionality and Client-specific business rules based on requirements gathering and configuration request. Following internal review, final document will be reviewed and approved by Syneos Health and Client.
Training Documentation	Training documentation provided to field users and management with guidance on T&E management system application and compliance business rules and usage.

3.5 Transparency Reporting

3.5.1 Background. H.R. 3590, Section 6002: "Transparency Reports and Reporting of Physician Ownership or Investment Interests," also referred to as the "National Physician Payment Transparency Program" a/k/a the "OPEN PAYMENTS" or "Sunshine Act" and H.R. 3590, Section 6004: "Prescription Drug Sample Transparency," requires certain data collection and reporting regarding payments or transfers of value and drug sample distribution to physicians.

3.5.2 Data Management. Syneos Health will provide the following data management services to Client:

(a) Regular reports of HCP-related meal expenses in Syneos Health's standard format;

(b) Regular reports Syneos Health's standard format of items of value non-sample items left with HCPs;

(c) Syneos Health will run full-cycle system testing and support UAT testing; and

(d) All reports will be clearly defined in terms of layout, content and delivery in the Data Requirements Document.

Syneos Health will work with Client in the data requirements process to confirm the file format, data elements, file delivery process and frequency to meet Client specifications for transparency reporting and Client System Integration. Syneos Health's Monitoring and Auditing processes for transparency reporting is detailed in Exhibit C, below.

3.6 Data Management

3.6.1 Generally.

(a) Syneos Health will provide data loads and data integration services for standard data imports and exports. Data management services includes data flowing to and from the Veeva CRM application, including Client data sources, third parties (i.e. sales data), or service partners. The data management team will work with the Veeva CRM, and analytics and reporting tools, to ensure that all Client business rules and data requirements are understood and planned for in the overall implementation plan.

(b) A full description of all data files and formats for data interfaces will be provided in the Data Requirements Document ("DRD"), which will be included as part of the Project Plan with necessary approvals from the Client and Project leads. The DRD will also include a Production Schedule, for ongoing data management services.

3.6.2 Data Loads, Imports and Extracts—Standard. The Project assumes use of standard data loads and file formats for all initial and ongoing data support as provided below:

(a) Standard initial data loads shall use agreed upon Syneos Health/Client formats including:

(1) Territory hierarchy;

(2) Customer universe, alignments, and Targets/Call plans;

(3) Product information; and

(4) Call history (if required).

(b) Standard reoccurring data imports shall be conducted at set frequencies and in agreed upon formats within five (5) business days of receipt as needed for the following:

(1) Prescriber/account sales data (weekly & monthly);

(2) Prescriber payer data (weekly & monthly);

(3) Call Plan/Targets (quarterly); and

(4) Customer universe updates—validation responses (weekly).

(c) Standard reoccurring data extracts shall be provided at set frequencies to either home office or third-party vendors as needed for processing to include:

(1) Call/activity data (weekly or monthly – Syneos Health to provide within 5 business days from the end of the cycle);

(2) Medical inquiries (daily);

(3) Sample activity (weekly or monthly – Syneos Health to provide within 5 business days from the end of the cycle);

(4) Extracts supporting Transparency Reporting in Section 3.5 (monthly or quarterly);

(i) DME Spend data from Concur;

(ii) Items of value, open payments reports;

(iii) Hand-carry sample reports for ACA 6004 (Knipper clients only); and

(5) Customer Universe Validation Requests (weekly – Syneos Health to provide within 5 business days from the end of the cycle).

(d) Standard data maintenance services will be provided for the ongoing support of the systems and data at fixed frequencies as defined below to include:

(1) State license validation process to reduce field impact in sampling (weekly);

(2) PDRP flagging on accounts (monthly);

(3) Routine merging of accounts (quarterly);

(4) Setup of integration between Veeva CRM and data warehouse, which allows roster, Territory hierarchy and Product management to be seamless (daily);

(5) Processing of action requests (Client data changes) (quarterly);

(6) Time off Territory and holiday updates (monthly);

(7) Ongoing maintenance of sales and payer data (weekly or monthly based on sales data provider availability);

(8) Training database setup and management (quarterly);

(9) Tier 2/technical support for data issues routed from the Field Support Desk (daily);

(10) Customer sales data extracts for IC (as defined in Section 3.10) processing (monthly); and

(11) Customer sales data and Call/activity extracts for A&R processing (monthly).

3.6.3 Assumptions. The scope of the data management delivery and associated timelines for the Project assumes the following:

Project Deliverable	**Definition**
Initial Requirements	Discussion of client needs regarding data loads, extracts, and imports and finalization of Project plan and scope based on SOW assumptions and change management process
Third Party Agreements (TPA)	Syneos Health will secure, in coordination with Client, any rights and licenses that Syneos Health needs from external vendors such as sales data companies which require TPA for data services to be provided
DRD (Data Requirements Document)	Syneos Health will provide the Client with a DRD document which summarizes all data loads, imports, and extracts, as well as any business rules, frequencies, and formats associated with the data services to be provided as part of implementation and ongoing data management services, the DRD draft will be reviewed, modified as needed, and signed by the Client to confirm Project deliverables
Test Files	The Client or third parties will provide needed test files in specified formats and agreed dates in the Project plan based on the implementation schedule
Final Production Files	The Client or third parties will provide final production files in specified formats and agreed dates in the Project plan based on the implementation schedule

3.6.4 Non-Standard; Changes. Any additional data feeds not included in the standards as defined above, or changes to data exchanges or maintenance subsequent to the approved DRD will follow the change control process and rate schedule set forth in Sections 3.1 and 3.1.1(d) respectively.

3.7 Analytics and Reporting

3.7.1 Veeva CRM Dashboard Reporting.

(a) Reporting Generally; User Types. The Project assumes general field activity reporting will be provided in the Veeva CRM Dashboard Reporting environment utilizing Syneos Health's pre-configured reporting tools to optimize field performance and implementation setup time. Syneos Health reporting will be provided for the following user types aggregated based on the user type's span of control:

(1) Representative (Territory level);

(2) Field Management (regional level); and

(3) Home Office (national level).

3.7.2 Veeva Report Configuration and Templates.

(a) Syneos Health will configure the reporting tools to include Client specific fields and terminology, where applicable, within Veeva and SalesForce.com guidelines. Veeva requirements, development, and deployment will follow the requirements and format as provided in the Veeva CRD as stated in Section 3.2, and may include the following: field activity, including the following: Call activity, Call plan adherence, sample activity, CLM utilization, synchronization monitoring, manager exceptions, and/or administration.

(b) Report Templates. The Veeva template field reporting package is designed to drive sales behavior in the following ways:

(1) Evaluation of prescriber sales for pre-Call planning from account summary report;

(2) Measure that the most valuable drivers of sales were detailed and sampled in accordance with the recommended Call plan - account/physician –

(i) Average Calls per day –reviews Call activity against Target or segmentation;

(ii) Reach and frequency can be found on analytics tab;

(iii) Call plan information can be found on the Call plan tab; and

(iv) Call Plan Analysis Report can be found on the analytics tab.

(3) Measure the impact of detailing and sampling on sales –

(i) Effort vs. results report can be found on the analytics tab.

(4) Examine the landscape for the product to identify top sales accounts and potential –

(i) Territory sales analysis—reviews trends in Client Product and competitive landscape; can be found on analytics tab;

(ii) Territory payer analysis –examines payer information; can be found on analytics tab; and

(iii) Territory comparison report—compares sales performance at the Territory level for all territories within span of control; can be found on analytics tab.

(5) Report Template Table.

Template Reports	Base Assumptions	Standard Frequency
Account Summary	Prescriber based product level prescription data	At same frequency as sales data (aka prescription data) delivery to Client
Activity/ Administrative	1. Reviews key territory and/or district performance indicators with drill down details for: a. Interactions b. Detailing c. Sampling 2. Review key territory and/or district administrative metrics with drill down details 3. Any information collected within a check box or drop down list into the Veeva systems can be aggregated into a dashboard element. 4. Text box information can be rolled into a report but not the dashboard. 5. Dashboards can have up to 20 measurement elements	Real time as of last synchronization and refresh

Template Reports	Base Assumptions	Standard Frequency
	6. All Dashboard elements are pictorials which aggregate data from an underlying report 7. All pictorials are flexible but limited to two dimensions 8. Color selection is not an option 9. Filters can be applied to comparable data 10. Reports can be filtered by user level (Field, Management, Home Office) 11. Other Reportable Activity: a. System Utilization b. Pending Interaction (Exception/incomplete information) c. Time off Territory d. Synchronization Reports e. Interaction by Date and Time f. Field Action Requests 12. Account Demographics a. Target/Non-Target b. Account Type (practitioner, pharmacy, staff, etc.) c. Specialty d. Segmentation e. Custom Profile Attributes 13. Closed Loop Marketing (CLM) a. Slide Utilization as % of Calls b. View Duration c. Ranking of Slides by View count and Average Duration d. Viewer Reaction (Positive, Neutral, Negative)	
Reach and Frequency	Adapted to specific activity measurements and goals within set up matrix (calls, targets only, reach, frequency, sample distribution)	Real Time as of last synchronization and refresh

Template Reports	Base Assumptions	Standard Frequency
Average Calls Per Day	Average Calls Per Day versus goal	Real Time as of last synchronization and refresh
Territory Sales Analysis	1. Adapted to specific product/market definition 2. Monthly prescriber-based product level prescription data; Up to 3 promoted products	At same frequency as sales data (aka prescription data) delivery to Client
Territory Comparison (Mgmt. supplement)	1. Adapted to specific product/market definition 2. Monthly prescriber-based product level prescription data; Up to 3 promoted products 3. Comparison of sales data amongst the assigned span of control	At same frequency as sales data (aka prescription data) delivery to Client
Territory Payer Analysis	1. Monthly payer-based product level prescription data 2. Analysis of the prescriber payer 3. Top payers 4. Comparison of payer market products	At same frequency as sales data (aka prescription data) delivery to Client
Effort vs. Results aka Impact Report	1. Adapted to specific product/market definition 2. Up to 3 promoted products 3. Monthly prescriber-based product level prescription data	At same frequency as sales data (aka prescription data) delivery to Client

3.7.3 Custom Analysis & Insights.

Additional work-effort will require work estimates and Change of Scope as detailed in Section 3.1.1(d), to be coordinated by the PM.

3.8 Targeting, Alignment and Call Plan Administration

3.8.1 Generally. Syneos Health will provide targeting and sales force alignment services for optimization of key targets. The goal of these services is to:

(a) Optimize geographic coverage on the most valuable Targets while balancing Territory workload;

(b) Target list generation based on business-specific workload parameters including the incorporation of any segmentation, detailing and frequency provided; and

(c) Identification of uncovered white space geography.

3.8.2 Deliverables.

(a) Metropolitan Statistical Area (MSA) overview;

(b) Alignment summary including coverage of top targets;

(c) Uncovered geography summary;

(d) Mapping at territory, district and national levels;

(e) Zip-Terr;

(f) Span of control; and

(g) Target list.

3.8.3 Assumptions.

(a) The scope assumes the following:

(1) Alignment will be created utilizing Syneos Health's preferred alignment software;

(2) Territory workload parameters and Project assumptions are agreed upon before work starts;

(3) All third-party agreements are signed off on before work starts;

(4) If third-party data purchased by Syneos Health will be passed through to Client;

(5) Client will supply physician level universe which will include best address. Any workload specific data points will be mutually agreed upon by the Parties (i.e., Rx, Deciles, etc.);

(6) One (1) per-deployment interactive alignment session for the field managers for minor geographic tweaks; and

(7) Quarterly Target or Call plan updates will be managed through the Veeva Action Request process, with timing provided for call plan updates that represent **[***]** changes in territories, geographies or segmentation. This will be done for alignment and Target updates each quarter, with District Manager/Sales Management reviews, per the agreed upon process between Client and Syneos Health. Additional work-effort will require work estimates and Change of Scope as detailed in Section 3.1.1(d), to be coordinated by the PM.

(b) Items not included in the assumptions:

(1) Major realignments or re-targeting exceeding **[***]** changes in territories, geography, or segmentation such as new Target strategy, expansions, or down-sizing; and

(2) Additional mapping and data analysis.

3.9 Incentive Compensation Management

3.9.1 Generally. Syneos Health incentive compensation management will design and /or implement an annual incentive compensation ("IC") plan and administer quarterly payouts. Syneos Health IC personnel will facilitate an IC assessment meeting to ascertain scope of work, IC plan parameters, data availability, budget, IC plan goals and incentive compensation culture. Sessions will be led by Syneos Health IC employees experienced in the discipline of IC plan design and field performance measurements. The assessment sessions are strategically structured to aid in the IC plan design, consisting of metrics aligned to business strategy. After the IC plan design has been approved by the parties, the Syneos Health incentive compensation department will implement, manage and administer IC plan.

3.9.2 Standard IC Services are inclusive of the following:

(a) Post the launch year, which will include at least one full year from the date of launch, a single annual IC plan for each Client team (i.e. Sales and Sales Managers) for the covered field employees, with no more than two (2) Plan Updates (as defined herein) per year. A "Plan Update" is defined as a change, which does not alter the IC plan structure thus resulting in an amendment to the IC plan. Changes to IC plan structure, which require a new set of modeling, design work, and/or plan communication documentation are considered a "New Plan," and may be subject to a separate Statement of Work ("SOW").

(b) The components of an IC plan will include the following:

(1) Plan concept presentation deck;

(2) Formal plan document with electronic signature;

(i) Inclusive of:

- Plan design measurements
- Business rules
- Data crediting
- Calculations
- Participation rules
- Terms and Conditions

(ii) IC Plan document will be reviewed by the following:

- Syneos Health Sales Leadership
- Syneos Health Human Resources
- Syneos Health Corporate Compensation
- Syneos Health Authorized Legal

(3) Monthly spreadsheet ("IC Grid") of calculated results (dependent on data availability and IC plan design);

(4) Monthly field scorecards (dependent on data availability and IC plan design);

(5) Quarterly payout administration in accordance with the Syneos Health payroll calendar;

(6) A single contest/special performance for field force per year to include:

(i) Contest Concept Presentation Deck;

(ii) Formal Plan Document with electronic signature;

(iii) Single payout administration in accordance with the Syneos Health payroll calendar; and

(iv) Single contest grid and/or scorecard of contest results.

(7) A single annual President's Club contest/trip to include:

(i) Results published in conjunction with the monthly IC reporting process.

(8) Additional services and changes will be subject to the Change Control Process and subject to an amendment.

3.9.3 IC Plan Deliverables and Timelines.

(a) Design Phase.

Category	Description	Duration/Timeline
IC Plan Meeting(s)	Initial Meeting to discuss: ● Corporate Philosophy ● Sales Goals/Objectives ● Sales/Marketing Strategy ● Business Rules ● Data Inputs ● Eligibility Requirements	1 day – initial meeting; subsequent follow-up meetings may be held to discuss pending topics or matters requiring further discussion from initial meeting. Maximum timeline 3 weeks
IC Modeling	Based on inputs derived from initial IC meeting(s), Syneos Health will create/provide IC deck illustrating: ● Recommended IC plan(s) ● Payout Scenarios/Distribution	● 1 week to provide recommendation ● 1 week for feedback/follow-up ● Additional time may be needed if data is required for modeling
Field Communication	IC Plan communication includes: ● PowerPoint deck (Management Team & Sales force) ● Word/PDF document (for IC plan participants/acknowledgement)	3 weeks (maximum) once IC plan has been finalized.

(b) Implementation Phase.

Category	Description	Duration/Timeline
IC Plan Programming	● Data Process Setup ● SQL Programming ● User Interface Setup ● Report/Scorecard Programming ● KPI/MBO Programming (if applicable)	Maximum of 3 weeks after receipt of initial sales data file in final format

Category	Description	Duration/Timeline
	● Acknowledgement Portal Setup ● Administration Portal Setup ● Programming QC & Testing ● Validation & QC of IC plan programming (independent of Programming QC) ● Minor changes (cosmetic, etc.)	

(c) Maintenance/Management Phase.

Category	Description	Duration/Timeline
Plan Administration	IC plan processing ● Report Generation o Payout Grid/Summary o Scorecard o Management Summary ● IC plan QC ● Report Distribution ● Roster Management ● Eligibility; LOA; PIP; New Hire ● IC Portal Maintenance ● Acknowledgment ● Administration	4 weeks after receipt of monthly sales data file

As IC is a passthrough expense to Client, Syneos Health encourages Client input on IC plan design. In instances where Client has given input into the IC plan design or when Syneos Health implements an IC plan design created by Client, Client acknowledges and agrees that it shall use best efforts to timely approve such IC plan design. The foregoing notwithstanding, in the event field force goals, dependent data, Client requested input, and/or plan documentation are not approved by Client and/or acknowledged by the field force within forty-five (45) calendar days into the then current IC plan period, Syneos Health reserves the right to implement either the IC plan which was utilized in the prior IC period or an Syneos Health standard best practice IC plan, and Client

acknowledges that by engaging Syneos Health to perform incentive compensation management, Client is expressly consenting to the foregoing.

3.10 Field Support Services

3.10.1 Help Desk. The Syneos Health field support service desk supports Syneos Health systems and operational processes for field user readiness and performance.

(a) Field support service desk hours are Monday through Friday, 8am-10pm, Eastern Standard Time

(b) Standard Syneos Health metrics and KPIs for call and ticket resolution

(c) Field Support can be reached via telephone or via email

(d) Knowledge base will be supplied for field support service desk based on Client business rules and system configuration

(e) Standard monthly reporting will be provided along with post-rollout daily monitoring reporting for 2 weeks following each field deployment

3.10.2 Asset Management.

(a) Syneos Health will provide asset management services ranging from hardware procurement, to configuration and deployment, and includes tracking IT assets throughout the life of the Project. Syneos Health maintains a suite of standard Windows images and custom images available as needed. Client hardware is asset tagged, scanned and secured in a locked area with restricted access for designated IT personnel.

(b) Standard hardware platform includes:

(1) Field laptop with carrying case

(2) Apple iPad with cover

(3) Printer

(c) Users are given Syneos Health-hosted email boxes with the option to configure with Client-like domains/addresses to give the look and feel of a Client employee.

(d) All Client launches include a **[***]** spare pool of hardware to be used as replacements in the event of breakage or theft/loss. Repairs/replacements are shipped out to the end-users within 48 hours of receipt of broken hardware.

(e) Passcode-protected iPads are deployed using our mobile device management software with remote-wipe capabilities for added security. App packaging and deployment capabilities are available. For clients opting for iPads with data plans, we can activate with one of the major carriers prior to shipment and then maintain that data plan throughout the life of the contract.

3.11 Technology Training Services

3.11.1 Generally. Syneos Health will provide technology training services for the Sales Team. The technology training services format follows Syneos Health's core training content and facilitation approach. Training delivery assumes the following structure:

(a) Pre-learning home study training (e-modules)

(b) Face-to-face training (up to 1 day)

(c) Post-training mastery (up to 2 hours WebEx)

3.11.2 Content. The training content will include key Syneos Health supported field hardware and applications including the following topics: iPad basics, Concur T&E, HCP Spend Capture, Veeva CRM, Veeva Analytics & Dashboards, and Customer Maintenance. New hire training will be delivered using the same content developed for implementation and offered at the frequency of **one class per quarter**, with the preferred Client format of either WebEx or face-to-face delivery. Additional training is offered as needed following the Change of Scope process in Section 3.1.1(d) of this Exhibit A-1.

3.12 Learning Management System (LMS)

Syneos Health will supply Client with our standard LMS system for the delivery and tracking of all online training. Standard LMS reporting will be provided to internal Syneos Health leadership and Client for communication of training completion and verification of required compliance training. The LMS can contain a combination of Syneos Health and Client-created content to enable its use across all product, selling skills, soft skills, and compliance training and service as a central repository for all training records.

Standard LMS Service Levels are indicated in the below table:

Standard SLA Agreement - Content Load*	
Task/Request	**Timeline**
Simple PDF Load	1-2 days
Simple SCORM Load	2-4 days
Simple Assessment	2-3 days
Registrations/Assignments for existing activities and users	24 hours
Add Additional users (upon notice)	End of next business day
Transcripts	24 hours
Complex Assessment	3-5 days
Complex Course with Assessment	5-7 days
High Stakes/Large Assessment	5-7 days

3.13 Quality Management and Assurance

3.13.1 Quality Management System (QMS). All Client implementations are managed via an approved set of Standard Operating Procedures (SOPs) which are part of Syneos Health's Quality Management System (QMS) under the Head of Quality Assurance. Key processes such as project governance, document control, CRM implementation and training are required for assigned operations personnel. Other SOPs such as Change Control, security and access control, asset provisioning, and CRM end-user training are additional required training for implementation teams, which are also delivered and tracked within Syneos Health's Learning Management System (LMS).

3.13.2 System Validation (Sampling Only). When required by sampling, formal Computer System Validation (CSV) is conducted by professional validation resources following Syneos Health's System Validation SOP. The work is driven by the approved Configuration Requirements Document (CRD), and includes a Validation Plan, Operational Qualification, Performance Qualification, Test Evidence (typically screen shots), Deviation Reports, Traceability Matrix and a Validation Summary Report.

3.14 Field Trigger Email with Veeva Engage

3.14.1 Field Trigger Email with Veeva Engage. Syneos Health will provide field-trigger email follow-up to HCPs to reinforce key messages in the Call and distribute the Prescribing Information. Syneos Health leverages Veeva's approved email capabilities to ensure compliance and a controlled environment to protect the integrity of the HCP communication. Approved content for email templates may be stored in the Syneos Health Veeva Vault or the Client's internal Veeva Vault (if applicable) and linked with the CRM Client Configuration. The solution will also include Veeva Engage to deliver built in virtual voice and video capabilities in a single solution for the field teams.

4.0 Operations Services Termination and Data/System Conversion

Syneos Health will retain all documented business requirements, system configurations, and data collected during the term of the Project Agreement. If the Client wishes to convert the field team pursuant to the Project Agreement, Client may have the option to continue on with Syneos Health-provided operations services to limit the disruption of field operations and leverage custom built systems, business rules and data integration. In such a case, a separate agreement will be established to confirm the scope and fees for any stand-alone operations services required. Alternatively, the parties may agree to convert the pre-built CRM configuration utilized for Client, for a fee mutually agreed to by the parties, to cover the migration of data, requirements documentation, and transfer of CRM configuration ownership, training on Client configuration settings and administration, as well as the Project management of the operations conversion, all to ensure a successful migration. Additionally, if the Client does not want to migrate the Syneos Health CRM configuration, the option may be made for Syneos Health to transfer Client data, business rules documentation, current data production schedules, and custom reporting formats for a fee mutually agreed to by the parties. If Syneos Health provides any migration or materials, Client is solely responsible for the system knowledge and performance post-conversion. Syneos Health may provide additional services based on the standard rates provided in the Change Control 3.1.1(d) of this Exhibit A-1.

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AMENDMENT AND RESTATED
EXHIBIT F
COMPENSATION - FIXED FEES, VARIABLE FEES AND PASS-THROUGH COSTS

I. FIXED FEES

The Fixed Fees provided in this Exhibit F are based on per position headcount as follows:

Position	Headcount
Project Team	
Sales Representatives	**[***]**
RS Reps	**[***]**
RSM	**[***]**
NSD	**[***]**

The Fixed Fees will be proportionally modified based on the final headcount.

(a) Implementation Fee

(i) Client has paid, or shall pay, **[***]** pursuant to the Initial Service Agreement (the "ISA") by and between Client and Syneos Health dated as of March 30, 2020, which will be applied as a credit against the Implementation Fee invoice.

(ii) Client shall pay Syneos Health an Implementation Fee of **[***]** associated with performance of the Services for the Project Team.

(b) Fixed Monthly Fees

(i) Commencing on the Project Team Hire Date, Client shall pay Syneos Health a Fixed Monthly Fee as follows:

PERIOD	PROJECT TEAM FIXED MONTHLY FEE
Year One	**[***]**
Year Two	**[***]**

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 agrees 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.

(c) Scale Up/Down

(i) Client may increase the number of Representatives, RS Reps, or RSMs above the number outlined in Exhibit A (a "Scale Up") upon written notification to Syneos Health. In the event of a Scale Up, Client shall pay to Syneos Health an additional Implementation Fee and Fixed Monthly Fee as follows:

Position	Implementation Fee
Per Representative	**[***]**
Per RS Rep	**[***]**
Per RSM	**[***]**

Position	Fixed Monthly Fee (Year One)	Fixed Monthly Fee (Year Two)
Per Representative	**[***]**	**[***]**
Per RS Rep	**[***]**	**[***]**
Per RSM	**[***]**	**[***]**

(ii) Client may decrease the number of Representatives, SR. Reps, Telesolutions Agents or DMs below the number outlined in Exhibit A (a "Scale Down") upon [***] prior written notice to Syneos Health; provided, however, that the Client may not perform a Scale Down prior to the **[***]** anniversary of the Deployment Date. In the event of a Scale Down, Syneos Health shall reduce the Fixed Monthly Fee as follows:

Position	Fixed Monthly Fee (Year Two)
Per Representative	**[***]**
Per RS Rep	**[***]**
Per RSM	**[***]**

(iii) The Parties shall meet to agree upon Project Team composition in the event of a Scale Up/Scale Down.

(d) Salary Reconciliation

The parties agree that the Fixed Monthly Fees set forth in Section I(b), above, are based on the annual salary per the below table (the "Annual Salary").

Position	Salary (Year One)	Salary (Year Two)
Per Representative	**[***]**	**[***]**
Per RS Rep	**[***]**	**[***]**
Per RSM	**[***]**	**[***]**

Syneos Health and Client will reconcile actual salaries and payroll taxes at **[***]** (pricing assumption), excluding incentive compensation, measured by actual days worked, for each Syneos Health Sales Representative and RSM in such calendar month against an amount equal to the appropriate percentage of the Annual Salary. The parties agree that the Annual Salary does not include incentive compensation for the Syneos Health Sales Representatives or RSM (plus the applicable employer portion of taxes). If any review shows that Syneos Health's actual annual salary per Syneos Health Sales Representative or RSM is below the Annual Salary, then Syneos Health shall issue a credit for the entire amount of such difference to Client. If any review shows that Syneos Health's actual salary per Syneos Health Sales Representative or RSM is above the Annual Salary, then Syneos Health shall bill the difference to Client.

(e) Vacancy Credit

Syneos Health agrees to fill vacant territories as requested by Client. Syneos Health will continue to invoice Client the amounts set forth above as Fixed Monthly Fee during any such vacancy period. Syneos Health will provide a monthly credit to Client, prorated for the number of business days per month that a territory is vacant, for each vacant territory, including leaves of absence lasting longer than **[***]**, until such territory is filled, as set forth in the following table:

Monthly Vacancy Credit*	Year One	Year Two
Per Representative	**[***]**	**[***]**
Per RS Rep	**[***]**	**[***]**
Per RSM	**[***]**	**[***]**

* Within the month a territory becomes vacant.

Monthly Vacancy Credit*	Year One	Year Two
Per Representative	**[***]**	**[***]**
Per SR. Rep	**[***]**	**[***]**
Per RSM	**[***]**	**[***]**

* Subsequent months of vacancy.

(f) Backfill Recruiting

Client agrees to pay Syneos Health a fee, per the table below, for recruiting and onboarding costs associated with any backfill for a vacant territory, provided that Client shall only pay such fee in the event that such territory becomes vacant **[***]** after the applicable hire date.

Position	Backfill Recruiting Fee
Per Sales Representative	**[***]**
Per RS Rep	**[***]**
Per RSM	**[***]**

II. VARIABLE FEES

(i) Client shall pay Syneos Health the following monthly fees per Client employee receiving operations support (Veeva and LMS Licenses) commencing on the date a Client employee is provided such support.

Position	Monthly Fee (Year One)	Monthly Fee (Year Two)
Veeva License Only Per Client User	**[***]**	**[***]**
LMS License Only Per Client User	**[***]**	**[***]**

(ii) Client shall pay Syneos Health an annual fee of **[***]** for each Client employee to have access to a list of Client programs on the LMS System (same environment as the Syneos Health Project Team – i.e., no customization per view set-up) commencing on the date a Client employee is provided such support.

(iii) Syneos Health shall invoice Client the following Variable Fees associated with the Project Team as incurred.

Additional Services	Variable Fee
Phone Append Access (up to 13,000 Records)	**[***]**
Phone Append Access, per Record (After 13,000 Records)	**[***]**
Phone Append Transfer (up to 650 Records)	**[***]**
Phone Append Transfer, per Record (After 650 Records)	**[***]**
Outbound Fax, per page	**[***]**
E-mail, each	**[***]**

III. PASS-THROUGH COSTS

In addition to the Fixed Fees, certain expenses will be charged to Client on a pass-through basis. These expenses will be billed to Client at actual cost. Pass-through costs include:

- Incentive compensation payments for the Syneos Health Sales Representatives, RSMs and NSD(plus applicable employer portion of taxes at **[***]**)
- Travel expenses (e.g. transportation, lodging, meals etc.)
- Costs for all meetings, including but not limited to POA Meetings
- Marketing expenses and costs (e.g. Lunch & Learns, etc.)
- Sales TRx data and any third party data acquisition expenses
- Syneos Health Sales Representative product storage units
- Data plan overages
- Interview expenses (including turnover recruiting)
- Business cards
- Managers' severance
- Licensing and credentialing expenses
- Shipping, freight, and postage of samples (if incurred)
- Other expenses which have been approved by Client
- Costs associated with Project Team Protective Equipment (PPE)

IV. INCENTIVE FEES

(a) Included in the Fixed Monthly Fees (set forth in Section I(b)(i), above) is Syneos Health's management fee, a portion of which (the "Incentive Fee") is subject to Syneos Health's achievement of certain performance objectives (the "Performance Objectives") which will be mutually agreed upon by the Parties.

(b) The monthly Incentive Fee for the annual period from the Deployment Date through the end of Year One is equal to **[***]** and the monthly Incentive Fee during Year Two is equal to **[***]**.

(c) In the event of a Scale Up or Scale Down, the monthly Incentive Fee shall be adjusted by **[***]** per Syneos Health Sales Representative from the Deployment Date through the end of Year One, and **[***]** per Syneos Health Sales Representative during Year Two.

(d) In the event of termination of this Project Agreement by the Client, effective as of the date of notification of such termination from the Client, the Performance Objectives shall no longer be applicable and the outstanding incentive fees will be earned at **[***]**; unless Project Agreement is terminated due to material breach by Syneos Health in accordance with Section 12(ii) of the MSA.

V. SERVICE CREDITS

Syneos Health shall issue to Client annual service credits of **[***]** per Syneos Health Sales Representative (estimated to be **[***]** in Year One and **[***]** in Year Two). Credits shall be earned at a rate of **[***]** per month per Syneos Health Sales Representative territory, for which a fee has been paid, commencing on the Deployment Date. Client may use all expected credits at any time during the Term and shall repay Syneos Health at the end of the Term for any credits used, but never accrued. The service credits shall be used to purchase additional services from Syneos Health's Affiliates. The term Affiliate means, with respect to any entity, any other entity directly or indirectly, through one or more intermediaries, controlling, controlled by or under common control with such entity. As used in this definition, the term "control" (including "controlled by" or "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of an entity, whether through ownership of voting securities, as trustee, by contract or otherwise. For purposes of clarity, Client shall not be permitted to apply the credits against any of the fees or costs associated with Services provided under this Work Order or any others services provided by Syneos Health, it being understood that the credits are applicable only for services provided by a Syneos Health Affiliate. The credits shall be valid until expiration or termination of this Work Order. Syneos Health shall not provide any form of refund, rebate or any other form of monetary incentive to Client in lieu of the credits.

VI. INVOICES; BILLING TERMS

The Implementation Fees outlined in Section I(a), above, shall be invoiced to Client upon execution of the Project Agreement. **[***]** of Sales Team Fixed Monthly Fee and **[***]** of Agents Fixed Monthly Fee (the "Advanced Fees") shall be paid by Client to Syneos Health which will be invoiced to the Client **[***]** prior to the sales representative hire date. The Advanced Fees shall be held as a deposit and credited to Client upon expiration or termination of the Project Agreement. Thereafter, commencing on the Project Team Hire Date, Client will be billed monthly in advance the amounts stated above as the Fixed Monthly Fees. Pass-through Costs will be billed to Client at actual cost as incurred by Syneos Health.

Invoices are due in accordance with Section 5 of the MSA. All invoices shall include the following:

- A/P Email
- A/P Telephone
- A/P Mailing Address
- A/P E-invoice System
- Other Contacts to be Included on Submission of Invoice
- Accountant

Payment to Syneos Health may be made by the following method:

- ACH Payment (Preferred Method)
  [***]
  ACH # **[***]**
  Account # **[***]**

Advice transmittals should be directed to **[***]**.

In the event Client will be issuing purchase orders for payment of Syneos Health invoices, Client shall issue such purchase orders within **[***]** following the execution of this Project Agreement. A purchase order shall include the following:

- PO Number
- PO Contact Name
- PO Contact E-mail
- PO Contact Telephone

Purchase Orders should be directed to **[***]**.

The Parties understand and agree that all terms and conditions set forth in a purchase order are null and void, it being understood and agreed that this Project Agreement provides the terms and conditions governing the relationship between the Parties.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

(1) Registration Statement (Form S-8 No. 333-199441), pertaining to the 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 (filed on August 2, 2019), and

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

of our report dated March 1, 2021, 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, 2020.

/s/ Ernst & Young LLP
Iselin, New Jersey
March 1, 2021

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 1, 2021

/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, Dennis P. Reilly, 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 1, 2021

/s/ DENNIS P. REILLY
Dennis P. Reilly
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

STATEMENT OF CHIEF EXECUTIVE OFFICER OF
AGILE THERAPEUTICS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Agile Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2020 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 1, 2021

/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, 2020 as filed with the Securities and Exchange Commission (the "Report"), I, Dennis P. Reilly, 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 1, 2021

/s/ DENNIS P. REILLY
Dennis P. Reilly
Chief Financial Officer
(Principal Financial Officer)