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

FORM S-1
(Amendment No. 4)
REGISTRATION STATEMENT
Under
The Securities Act of 1933

Agile Therapeutics, Inc.
(Exact name of Registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

2834
(Primary Standard Industrial
Classification Code Number)

23-2936302
(I.R.S. Employer
Identification Number)

500 College Road East, Suite 310
Princeton, New Jersey 08540
(609) 683-1880
(Address, including zip code, and telephone number, including
area code, of Registrant's principal executive offices)

Alfred Altomari
Chief Executive Officer
Agile Therapeutics, Inc.
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Princeton, New Jersey 08540
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Approximate date of commencement of the proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(b) of the Securities Act.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus does not constitute an offer to sell securities and it is not soliciting offers to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

Agile Therapeutics, Inc.
\$15,000,000

Up to **Shares of Common Stock and**
Accompanying Series E-1 Warrants to Purchase up to **Shares of Common Stock**
and **Series E-2 Warrants to Purchase up to** **Shares of Common Stock**
or
Up to **Series F Pre-funded Warrants to Purchase up to** **Shares of Common Stock and**
Accompanying Series E-1
Warrants to Purchase up to **Shares of Common Stock and** **Series E-2**
Warrants to Purchase up to **Shares of Common Stock**

Placement Agent Warrants to Purchase up to **Shares of Common Stock**

Up to **Shares of Common Stock underlying the Series E-1 Warrants, Series E-2 Warrants, Series F Pre-funded**
Warrants, and Placement Agent Warrants

We are offering up to _____ shares of common stock, together with _____ Series E-1 warrants to purchase up to _____ shares of common stock (the “Series E-1 warrants”) and _____ Series E-2 warrants to purchase up to _____ shares of common stock (the “Series E-2 warrants”, and together with the Series E-1 warrants, the “Series E warrants”) at an assumed combined public offering price of \$ _____ per share and Series E warrants, which is equal to the last reported sale price per share of our common stock on the Nasdaq Capital Market on _____, 2024 (and the shares issuable from time to time upon exercise of the Series E warrants) pursuant to this prospectus. The shares of common stock and Series E warrants will be separately issued, but the shares of common stock and Series E warrants will be issued to purchasers in the ratio of one to one. Each Series E-1 warrant will have an exercise price of \$ _____ per share, will be exercisable upon beginning on the effective date of stockholder approval of the issuance of the shares upon exercise of the Series E warrants (the “Warrant Stockholder Approval”), provided however, if the Pricing Conditions (as defined below) are met, the Series E warrants will be exercisable upon issuance (the “Initial Exercise Date”) and will expire five years from the Initial Exercise Date. Each Series E-2 warrant will have an exercise price of \$ _____ per share, will be exercisable beginning on the Initial Exercise Date and will expire eighteen months from the Initial Exercise Date. As used herein “Pricing Conditions” means that the combined offering price per share and accompanying Series E warrants is such that the Warrant Stockholder Approval is not required under Nasdaq rules because either (i) the offering is an at-the-market offering under Nasdaq rules and such price equals or exceeds the sum of (a) the applicable “Minimum Price” per share under Nasdaq rule 5635(d) plus (b) \$0.125 per whole share of common stock underlying the Series E warrants or (ii) the offering is a discounted offering where the pricing and discount (including attributing a value of \$0.125 per whole share underlying the Series E warrants) meet the pricing requirements under the Nasdaq rules.

We are also offering up to pre-funded warrants (the “Series F pre-funded warrants” and collectively with the Series E warrants, the “warrants”) to those purchasers whose purchase of shares of common stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering in lieu of the shares of our common stock that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%). Each Series F pre-funded warrant will be exercisable for one share of common stock at an exercise price of \$0.001 per share. Each Series F pre-funded warrant is being issued together with the same Series E warrants described above being issued with each share of common stock. The assumed combined public offering price for each such Series F pre-funded warrant, together with the Series E warrants, is \$ _____, which is equal to the last reported sale price of our common stock on the Nasdaq Capital Market on _____, 2024 less the \$0.001 per share exercise price of each such Series F pre-funded warrant. Each Series F pre-funded warrant will be exercisable upon issuance and may be exercised at any time until all of the pre-funded warrants are exercised in full. The Series F pre-funded warrants and Series E warrants are immediately separable and will be issued separately in this offering. We are also registering the shares issuable from time to time upon exercise of the Series F pre-funded warrants and Series E warrants. For each Series F pre-funded warrant and the accompanying Series E warrants we sell, the number of shares of common stock and the accompanying Series E warrants we are offering will be decreased on a one-for-one basis.



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There is no established public trading market for the warrants, and we do not expect a market to develop. We do not intend to apply for listing of the warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the warrants will be limited.

This offering will terminate on _____, unless we decide to terminate the offering (which we may do at any time in our discretion) prior to that date. We will have one closing for all the securities purchased in this offering. The combined public offering price per share of common stock (or Series F pre-funded warrant) and Series E warrants will be fixed for the duration of this offering.

We have engaged _____, or the placement agent, to act as our exclusive placement agent in connection with this offering. The placement agent has agreed to use its reasonable best efforts to arrange for the sale of the securities offered by this prospectus. The placement agent is not purchasing or selling any of the securities we are offering and the placement agent is not required to arrange the purchase or sale of any specific number of securities or dollar amount. We have agreed to pay to the placement agent the placement agent fees set forth in the table below, which assumes that we sell all of the securities offered by this prospectus. There is no arrangement for funds to be received in escrow, trust or similar arrangement. There is no minimum offering requirement. We will bear all costs associated with the offering. See “Plan of Distribution” on page 127 of this prospectus for more information regarding these arrangements.

Our common stock is listed on the Nasdaq Capital Market under the symbol “AGRX.” On _____, 2024, the last reported sale price of our common stock on the Nasdaq Capital Market was \$ _____ per share. All share, Series E warrant, and Series F pre-funded warrant numbers are based on an assumed combined public offering price of \$ _____ per share or Series F pre-funded warrant, as applicable, and Series E warrants.

The combined public offering price per share and Series E warrants and the combined public offering price per Series F pre-funded warrant and Series E warrants will be determined between us and investors based on market conditions at the time of pricing, and may be at a discount to the current market price of our common stock. Therefore, the recent market price used throughout this prospectus may not be indicative of the actual public offering price.

Investing in the offered securities involves a high degree of risk. See “Risk Factors” beginning on page 9 of this prospectus for a discussion of information that you should consider before investing in our securities.

On March 27, 2023, we received a deficiency letter from the Listing Qualifications Department, or the Staff, of the Nasdaq Stock Market, or Nasdaq, notifying us that we are not in compliance with the minimum stockholders’ equity requirement for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(b)(1) requires companies listed on the Nasdaq Capital Market to maintain stockholders’ equity of at least \$2,500,000 (the “Stockholders’ Equity Requirement”). In accordance with Nasdaq rules, we were provided 45 calendar days from the receipt of the Nasdaq notification, or until May 11, 2023, to submit a plan to regain compliance (the “Compliance Plan”). We submitted that plan on May 11, 2023. On June 2, 2023, we received a letter (the “June Extension Notice”) from Nasdaq notifying us that we had been granted an additional 180-day period, or until September 25, 2023, to regain compliance with the Stockholders’ Equity Requirement. On September 27, 2023, we received a notice from the Staff advising us that the Staff had determined that we did not meet the terms of the extension and that unless we requested an appeal, the Staff would proceed with delisting. We submitted a hearing request to the Nasdaq Hearings Panel (the “Panel”) on October 4, 2023. The request stayed any delisting action by the Staff at least until the hearing process concludes and any extension granted by the Panel expires. The Panel hearing took place on November 30, 2023, where we presented a multi-step plan to regain compliance with the Stockholders’ Equity Requirement. Our common stock will continue to trade on the Nasdaq Capital Market under the symbol “AGRX” at least pending the ultimate conclusion of the hearing process.

On December 5, 2023, we received a letter (the “December Extension Notice”) from the Panel notifying us that it had been granted an additional period, or until February 16, 2024, to regain compliance with the Stockholders’ Equity Requirement. If our securities are delisted, it could be more difficult to buy or sell our securities and to obtain accurate quotations, and the price of our securities could suffer a material decline. Delisting could also impair the liquidity of our common stock and could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in potential loss of confidence by investors, employees, and fewer business development opportunities.

	Per Share and Series E Warrants	Per Series F Pre-Funded Warrant and Series E Warrants	Total
Public offering price	\$	\$	\$
Placement Agent’s fees ⁽¹⁾	\$	\$	\$
Proceeds, before expenses, to us ⁽²⁾	\$	\$	\$

- (1) We have agreed to pay the placement agent a total cash fee equal to 7.0% of the gross proceeds raised in this offering. We have also agreed to pay the placement agent a management fee equal to 1.0% of the gross proceeds raised in this offering and to reimburse the placement agent for its non-accountable expenses in the amount of \$10,000 and for its legal fees and expenses and other out-of-pocket expenses in an amount up to \$100,000, and for its clearing expenses in the amount of \$15,950. In addition, we have agreed to issue to the placement agent, or its designees, warrants to purchase a number of shares of our common stock equal to 5.0% of the aggregate number of shares of common stock and Series F pre-funded warrants being offered at an exercise price equal to 125% of the combined public offering price per share of common stock and Series E warrants. We refer you to “Plan of Distribution” on page 127 of this prospectus for additional information regarding placement agent compensation.
- (2) Because there is no minimum number of securities or amount of proceeds required as a condition to closing in this offering, the actual public offering amount, placement agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above. We refer you to “Plan of Distribution” on page 127 of this prospectus for additional information regarding placement agent compensation.

The placement agent expects to deliver the shares and warrants to purchasers in the offering on or about , 2024, subject to satisfaction of certain conditions.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Prospectus dated , 2024

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ABOUT THIS PROSPECTUS

The registration statement we filed with the Securities and Exchange Commission (the “SEC”) includes exhibits that provide more detail of the matters discussed in this prospectus. You should read this prospectus, the related exhibits filed with the SEC, before making your investment decision. You should rely only on the information provided in this prospectus or any amendment thereto. In addition, this prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed or will be filed as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the heading “Where You Can Find Additional Information.”

We have not, and the placement agent has not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus, or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. The information contained in this prospectus, herein or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

This prospectus is an offer to sell only the securities offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. We are not, and the placement agent is not, making an offer to sell these securities in any state or jurisdiction where the offer or sale is not permitted.

All other trademarks, trade names and service marks appearing in this are the property of their respective owners. Use or display by us of other parties’ trademarks, trade dress or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owner. Solely for convenience, trademarks, tradenames and service marks referred to in this prospectus 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 that the applicable owner will not assert its rights, to these trademarks and trade names.

FORWARD-LOOKING STATEMENTS

This prospectus contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. 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 prospectus 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®, including the level of reimbursement from third-party payors, the development of our other potential product candidates, the attractiveness of our business to potential investors or business partners, the strength and breadth of our intellectual property, our planned clinical studies, 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 study data, our results of operations, financial condition, liquidity, prospects, growth and strategies, including expense reduction strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, 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 prospectus. 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 prospectus, they may not be predictive of results or developments in future periods.

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

- our available cash and our ability to obtain additional funding to fund our business plan without delay and to continue as a going concern;
- our ability to come into compliance with the listing requirements of the Nasdaq Capital Market;
- our ability to successfully maintain and enhance the commercialization of and increase the uptake for Twirla, our only approved product;
- the rate and degree of market acceptance of Twirla by physicians, patients, clinics, institutions, third-party payors and others in the healthcare community;
- our ability to obtain adequate coverage and reimbursement for Twirla in the United States from private and public third-party payors;
- the size and growth of the markets for Twirla and our ability to serve those markets;
- shortages of key materials in the supply chain implicating the manufacture and distribution of Twirla;
- regulatory and legislative developments in the United States and foreign countries, which could include, among other things, a government shutdown or limiting access to prescription contraceptives;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;

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

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important cautionary statements in this prospectus, particularly in the “Risk Factors” section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. For a summary of such factors, please refer to the section entitled “Risk Factors” in this prospectus, as updated and supplemented by the discussion of risks and uncertainties under “Risk Factors” contained in any further supplements to this prospectus, as well as any amendments thereto, as filed with the SEC. The information contained in this document is believed to be current as of the date of this document. We do not intend to update any of the forward-looking statements after the date of this document to conform these statements to actual results or to changes in our expectations, except as required by law.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this prospectus might not occur. Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this prospectus. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise. All subsequent forward-looking statements attributable to us or to any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in shares of our common stock and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus, any applicable free writing prospectus. You should read all such documents carefully, especially the risk factors and our financial statements and the related notes included, before deciding to buy shares of our common stock. Unless the context requires otherwise, references in this prospectus to “Agile,” “we,” “us” and “our” refer to Agile Therapeutics, Inc.

Company Overview

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

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

We are focused on our advancement as a commercial company. During 2024, we plan to continue implementing our commercialization plan for Twirla, with the goal of establishing a growing position in the hormonal contraceptive market. We believe we can achieve this goal by focusing our growth strategy in the states with the highest Twirla reimbursement potential, which we estimate will allow us to reach approximately 45% of U.S. women between the ages of 18-24. We also believe we can increase uptake of Twirla in the United States by growing our telemedicine presence through our partnerships and our existing partnership with Nurx®, and driving growth in the non-retail channel through our collaboration with Afaxys, which provides us access to some of the largest Planned Parenthood organizations in the country. In addition to growing Twirla, we also plan to continue pursuing opportunities to broaden our portfolio to address areas of unmet medical need in women’s health.

Recent Developments

Perceptive Credit Agreement Amendment

On October 30, 2023, we entered into a seventh amendment (the “Seventh Amendment”) to that certain Credit Agreement and Guaranty, dated February 10, 2020, as amended (the “Perceptive Credit Agreement”), with Perceptive Credit Holdings III, LP (“Perceptive”). The Seventh Amendment: (1) amends our obligations to comply with certain financial covenants relating to minimum revenue requirements, (2) amends and waives our obligations to comply with certain financial covenants relating to minimum liquidity through December 31, 2023, and (3) requires us to make principal payments on its outstanding loan balance of \$150,000 per month beginning on December 1, 2023. The Company will make monthly payments of \$150,000 until February 10, 2024 (“Maturity Date”), at which time all remaining principal amount outstanding is due.

Warrant Amendments

On December 3, 2023, we entered into a Warrant Amendment and Additional Issuance Agreement (“Warrant Amendment and Additional Issuance Agreement”) relating to the amendment of warrants to purchase shares of our common stock that were issued in transactions on March 14, 2022, April 25, 2022, and May 25, 2023 (collectively, the “Warrants”). Collectively, the Warrants represent the right to purchase approximately 3.8 million shares of our common stock. Under the terms of the Warrant Amendment and Additional Issuance Agreement, the holder agreed to revise

provisions related to the use of a Black-Scholes model to value the Warrants in the event of a change of control transaction. The holder also agreed to revise provisions related to the cashless exercise of the Warrants. In exchange for the holder's agreement to amend the Warrants, we agreed to issue an additional new warrant (the "New Warrant") to purchase 1,005,560 shares of our common stock. The New Warrant has an exercise price of \$2.09 per share. The New Warrant is exercisable six months after issuance and will expire five years from the date that the New Warrant is initially exercisable. The exercise price of the New Warrant is subject to adjustment for stock splits, reverse splits, and similar capital transactions as described in the New Warrant.

We intend to use the revisions to the Warrants to support the reclassification of the Warrants from a liability and to account for the Warrants as a component of stockholders' equity on our balance sheet. We also intend to use the reclassification of the Warrants as part of our plan to regain compliance with the Nasdaq listing requirements relating to minimum shareholders' equity (as discussed below).

Risks Associated with this Offering

This offering is subject to numerous risks and uncertainties, including those highlighted in this section entitled "Risk Factors" immediately following this prospectus summary. These risks include, but are not limited to, the following:

- *we are not in compliance with the Nasdaq continued listing requirements. If we are unable to comply with the continued listing requirements of the Nasdaq Capital Market, our common stock could be delisted, which could affect our common stock's market price and liquidity and reduce our ability to raise capital;*
- *the price of our common stock may be volatile and fluctuate substantially, and you may not be able to resell your shares at or above the price you paid for them;*
- *we have identified a material weakness in our internal control over financial reporting. This material weakness could continue to adversely affect our results of operations and financial condition. In the future, we may identify additional material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting or adequate disclosure controls and procedures, which may result in material errors in our financial statements or cause us to fail to meet our period reporting obligations;*
- *there is no public market for the warrants being offered in this offering;*
- *holders of warrants purchased in this offering will have no rights as common stockholders until such holders exercise their warrants and acquire our common stock;*
- *the warrants being offered may not have value;*
- *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;*
- *management will have broad discretion as to the use of the proceeds from this offering, and we may not use the proceeds effectively; and*
- *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.*

Corporate Information

Information concerning our business is contained in the documents that we file with the SEC as a reporting company under the Exchange Act, which are accessible at www.sec.gov, and on our website at www.agiletherapeutics.com. The information contained on, or that can be accessed through, our website is not a part of this prospectus. Investors should not rely on any such information in deciding whether to purchase our common stock. We have included our website address in this prospectus solely as an inactive textual reference.

Our principal executive offices are located at 500 College Road East, Suite 310, Princeton, New Jersey 08540, and our telephone number is (609) 683-1880.

THE OFFERING

Securities we are offering	Up to shares of our common stock, Series E-1 warrants to purchase up to shares of common stock, and Series E-2 warrants to purchase up to shares of common stock or up to Series F pre-funded warrants to purchase shares of common stock, Series E-1 warrants to purchase up to shares of common stock, and Series E-2 warrants to purchase up to shares of common stock in each case, at a combined public offering price of \$ per share (or Series F pre-funded warrant in lieu thereof) and Series E warrants. The shares, or Series F pre-funded warrants, and Series E warrants will be separately transferable immediately upon issuance, but the shares, or Series F pre-funded warrants, and Series E warrants will be issued to purchasers in the ratio of one to one.
Description of Series E warrants	Each Series E-1 warrant will have an exercise price of \$ per share, will be exercisable beginning on the Initial Exercise Date and will expire five years from the Initial Exercise Date. Each Series E-2 warrant will have an exercise price of \$ per share, will be exercisable beginning on the Initial Exercise Date and will expire eighteen months from the Initial Exercise Date. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of these Series E warrants.
Description of Series F pre-funded warrants	<p>If the issuance of shares of our common stock to a purchaser in this offering would result in such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering, then such purchaser may purchase, if they so choose, in lieu of the shares of our common stock that would result in such excess ownership, a Series F pre-funded warrant to purchase shares of our common stock for a purchase price per share of common stock subject to such Series F pre-funded warrant equal to the per share public offering price for the common stock in this offering less \$0.0001. Each Series F pre-funded warrant will have an exercise price of \$0.0001 per share, will be exercisable upon issuance and may be exercised at any time until all of the pre-funded warrants are exercised in full. Purchasers of Series F pre-funded warrants will also receive Series E warrants as if such purchasers were buying shares of our common stock in this offering. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of these Series F pre-funded warrants.</p> <p>For each Series F pre-funded warrant and the accompanying Series E warrants we sell, the number of shares of common stock and the accompanying Series E warrants we are offering will be decreased on a one-for-one basis.</p>
Common stock outstanding before offering:	shares of common stock.
Common stock outstanding after this offering	shares of common stock, assuming no sale of Series F pre-funded warrants in this offering and no exercise of the Series E warrants being issued in this offering and assuming a combined public offering price of \$ per share and Series E warrants, which is equal to the last reported sale price per share of our common stock on the Nasdaq Capital Market on , 2024.
Use of proceeds	We intend to use the net proceeds from this offering for working capital, business development activities, repayment of certain indebtedness and general corporate purposes. See “Use of Proceeds” on page 31 of this prospectus.

Risk factors See “Risk Factors” beginning on page 9 of this prospectus, and the other information included elsewhere in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities.

Nasdaq Capital Market Symbol Our common stock is listed on the Nasdaq Capital Market under the symbol “AGRX.” There is no established trading market for the Series E warrants or the Series F pre-funded warrants, and we do not expect a trading market to develop. We do not intend to list the Series E warrants or the Series F pre-funded warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the Series E warrants or Series F pre-funded warrants will be extremely limited.

The number of shares of our common stock to be outstanding after this offering is based on 2,963,657 shares of our common stock outstanding as of December 31, 2023, and excludes:

- 43,043 shares of common stock issuable upon the exercise of outstanding options to purchase common stock as of December 31, 2023 at a weighted average exercise price of \$548.70 per share;
- 173,517 shares of common stock issuable upon the vesting of outstanding restricted stock units as of December 31, 2023;
- 6,200 shares of common stock reserved for future issuance under our 2023 Equity Incentive Plan as of December 31, 2023; and
- 5,589,637 shares of common stock issuable upon the exercise of outstanding warrants as of December 31, 2023 at a weighted average exercise price of \$8.55 per share.

Unless otherwise indicated, all information contained in this prospectus assumes:

- no exercise of the outstanding options or warrants described in the bullets above;
- no exercise of the Series E warrants or the placement agent warrants issued in this offering; and
- no sale of Series F pre-funded warrants in this offering.

All information included in this prospectus, where relevant, has been adjusted to reflect a 1-for-50 reverse stock split of our common stock effective on April 11, 2023.

RISK FACTORS

An investment in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should carefully consider the risks described below and those discussed elsewhere in this prospectus, and in any free writing prospectus that we have authorized for use in connection with this offering. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. Please also read carefully the section above entitled “Forward-Looking Statements.”

Risks Related to This Offering

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

We have incurred losses in each year since our inception in December 1997. Our net loss was \$10.0 million and \$21.5 million for the nine months ended September 30, 2023 and 2022, respectively, and \$25.4 million, \$71.1 million and \$51.9 million for the years ended December 31, 2022, 2021 and 2020, respectively. As of September 30, 2023, we had an accumulated deficit of approximately \$418.7 million. As of December 31, 2023, our unaudited cash and cash equivalents were approximately \$2.5 million, which will not be sufficient to fund our current and planned operations through December 31, 2024, 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 may 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 February 2024, including among other items, the commercialization of Twirla and advancing the development of our other potential product candidates. We may not be able to obtain sufficient additional funding to continue our operations at planned levels and be forced to reduce, or even terminate, our operations. To date, we have financed our operations primarily through sales of common stock, convertible preferred stock and convertible promissory notes and to a lesser extent, through term loans and government grants.

We expect that our expenses will increase as we continue to commercialize Twirla. As a result, we may continue to incur substantial losses for the foreseeable future if we are unable to generate positive cash flow from operations. 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.

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. Our inability to obtain additional funding when we need it could seriously harm our business.

This offering is being made on a best efforts basis and we may sell fewer than all of the securities offered hereby and may receive significantly less in net proceeds from this offering, which will provide us only limited working capital.

This offering is being made on a best efforts basis and we may sell fewer than all of the securities offered hereby and may receive significantly less in net proceeds from this offering. Assuming that we receive net proceeds of approximately \$ million from this offering (assuming an offering with gross proceeds of \$ million), we believe that

the net proceeds from this offering, together with our existing cash and cash equivalents, will meet our capital needs for the next months under our current business plan. Assuming that we receive net proceeds of approximately \$ million from this offering (assuming an offering with gross proceeds of \$ million), we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will satisfy our capital needs for the next months under our current business plan. Assuming that we receive net proceeds of approximately \$ million from this offering (assuming an offering with gross proceeds of \$ million), we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will satisfy our capital needs for the next months under our current business plan. Without giving effect to the receipt of any proceeds from this offering, we currently estimate that our existing cash and cash equivalents are sufficient to fund business operations into , .

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

On March 27, 2023, we received a deficiency letter from Nasdaq notifying us that we are not in compliance with the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(b)(1) (the "Rule") requires companies listed on the Nasdaq Capital Market to maintain stockholders' equity of at least \$2,500,000 (the "Stockholders' Equity Requirement"). Our Annual Report on Form 10-K for the fourth quarter and year ended December 31, 2022 reported stockholders' equity of \$(5,545,000), which is below the Stockholders' Equity Requirement for continued listing on the Nasdaq Capital Market. As of the date of this filing, the Company does not have a market value of listed securities of \$35 million, or net income from continued operations of \$500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years, the alternative quantitative standards for continued listing on the Nasdaq Capital Market. In accordance with Nasdaq rules, we were provided 45 calendar days from the receipt of the Nasdaq notification, or until May 11, 2023, to submit a plan to regain compliance (the "Compliance Plan"). We submitted that plan on May 11, 2023.

On June 2, 2023, we received a letter (the "June Extension Notice") from Nasdaq notifying us that we had been granted an additional 180-day period, or until September 25, 2023, to regain compliance with Nasdaq Listing Rule 5550(b)(1). On September 27, 2023, we received a notice from the Staff advising us that the Staff had determined that we did not meet the terms of the extension and that unless we requested an appeal, the Staff would proceed with delisting. We submitted a hearing request to the Nasdaq Hearings Panel (the "Panel") on October 4, 2023. The request stayed any delisting action by the Staff at least until the hearing process concludes and any extension granted by the Panel expires.

The hearing before the Panel took place on November 30, 2023. At the hearing, we presented a multi-step plan to regain compliance with the Stockholders' Equity Requirement, which included relying on the proceeds of this Offering to improve stockholder equity. Our common stock will continue to trade on the Nasdaq Capital Market under the symbol "AGRXX" at least pending the ultimate conclusion of the hearing process.

On December 5, 2023, we received a letter (the "December Extension Notice") from the Panel notifying us that it had been granted an additional period, or until February 16, 2024, to regain compliance with the Stockholders' Equity Requirement.

There is no guarantee that the Panel will grant this or any extension. In addition, even if an extension is granted, if we fail to complete this Offering, or any part of our compliance plan presented to the Panel, we may be unable to regain compliance with the Stockholders' Equity Requirement and may be delisted. There can be no assurance that following the closing of this Offering, that we will be able to regain compliance with the Stockholders' Equity Requirement or otherwise maintain compliance any of the other listing requirements, which could lead to the delisting of our securities.

If our securities are delisted, it could be more difficult to buy or sell our securities and to obtain accurate quotations, and the price of our securities could suffer a material decline. Delisting could also impair the liquidity of our common stock and could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in potential loss of confidence by investors, employees, and fewer business development opportunities.

If we do not raise sufficient funds in this offering, it will be difficult for us to come into compliance with the Stockholders' Equity Requirement by the deadline of February 16, 2024.

If we do not receive sufficient net proceeds in this offering, we may not come into compliance with the Stockholders' Equity Requirement discussed above. There are limited ways we can improve our financial condition by February 16, 2024 in order to demonstrate compliance with the Stockholders' Equity Requirement. We may attempt to raise further capital, on less favorable terms, which may result in further dilution to you and our current stockholders. We may be unsuccessful in raising further capital, or otherwise satisfying the Stockholders' Equity Requirement, and Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that we will be able to continue as a going concern or that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

The price of our common stock may be volatile and fluctuate substantially, and you may not be able to resell your shares at or above the price you paid for them.

The shares sold in this offering, if any, will be sold from time to time at various prices. The market price for shares of our common stock may be subject to wide fluctuations in response to many risk factors, including:

- Our failure to commercialize Twirla or develop and commercialize additional potential product candidates;
- Our ability to successfully enhance the commercialization and increase the uptake for Twirla, our only approved product;
- Unanticipated efficacy, safety or tolerability concerns related to the use of Twirla;
- Regulatory actions with respect to Twirla;
- The growth in demand for Twirla and our ability to manage the levels of Twirla inventory, which could result in our having to write off inventory and our inability to meet the minimum requirements under our supply agreement with Corium;
- 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;
- Coverage and reimbursement policies with respect to Twirla or our product candidates, if approved;
- Our ability to maintain compliance with the listing requirements of the Nasdaq Capital Market;
- 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 and retain 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.

In addition, the stock market has experienced significant volatility, particularly with respect to pharmaceutical and other life sciences company stocks. The volatility of such stocks often does not relate to individual company performance. As we operate in a single industry, we are especially vulnerable to these factors to the extent that they affect our industry or our product candidates or, to a lesser extent, our markets. In the past, securities class-action litigation has often been instituted against companies following periods of volatility in their stock price. We may face securities class-action litigation if we fail to commercialize Twirla or cannot obtain regulatory approvals for our product candidates. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources, which could materially harm our financial condition and results of operations.

There is no public market for the warrants being offered in this offering.

There is no established trading market for the warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the warrants on any securities exchange or nationally recognized trading system, including the Nasdaq Capital Market. Without an active market, the liquidity of the warrants will be limited.

Holders of warrants purchased in this offering will have no rights as common stockholders until such holders exercise their warrants and acquire our common stock, except as provided in the warrants.

Until holders of the warrants being offered in this offering acquire shares of our common stock upon exercise of such warrants, the holders will have no rights with respect to the shares of our common stock underlying such warrants. Upon exercise of the warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise.

The warrants being offered may not have value.

The warrants being offered by us in this offering have an exercise price of \$ _____ per share, subject to certain adjustments, and will expire _____ years from the date of issuance, after which date any unexercised warrants will have no further value. In the event that the market price of our common stock does not exceed the exercise price of the warrants during the period when they are exercisable, the warrants may not have any value.

The Series E warrants are not exercisable until stockholder approval, provided however, if the Pricing Conditions are met, the Series E warrants will be exercisable upon issuance.

The Series E warrants will have an exercise price of \$ per share and will be exercisable beginning on the effective date of the Warrant Stockholder Approval, provided however, if the Pricing Conditions are met, the Series E warrants will be exercisable upon issuance. The Series E-1 warrants will expire on the five-year anniversary of the Initial Exercise Date. The Series E-2 warrants will expire on the eighteen-month anniversary of the Initial Exercise Date.

While we intend to promptly seek Warrant Stockholder Approval, there is no guarantee that the Warrant Stockholder Approval will ever be obtained. If we are unable to obtain the Warrant Stockholder Approval, the Series E warrants may have no value.

Purchasers who purchase our securities in this offering pursuant to a securities purchase agreement may have rights not available to purchasers that purchase without the benefit of a securities purchase agreement.

In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers that enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. The ability to pursue a claim for breach of contract provides those investors with the means to enforce the covenants uniquely available to them under the securities purchase agreement including: (i) timely delivery of shares; (ii) agreement to not enter into variable rate financings for one year from closing, subject to an exception; (iii) agreement to not enter into any financings for days from closing, subject to certain exceptions; and (iv) indemnification for breach of contract.

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

In February 2020, we entered into the Perceptive Credit Agreement, the terms of which are described in more detail throughout this prospectus. The Perceptive Credit Agreement, as amended, subjects us to various customary affirmative and negative covenants. 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 assets. 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). The facility will mature on February 10, 2024 (“Maturity Date”), at which time all remaining principal outstanding is due. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness by the Maturity Date or at the time any such event of default occurs. We have received a waiver of certain financial covenants through December 31, 2023, see “Recent Developments” on page 4 of this prospectus.

In the event we do not pay off our indebtedness to Perceptive, we may need to negotiate for a waiver of our obligations to comply with certain financial covenants. If we cannot repay our indebtedness and do not receive a waiver, we may be required to delay, limit, reduce or terminate our pipeline development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Perceptive could also exercise its rights as collateral agent to take possession and dispose of the collateral securing the loan for its benefit, which collateral includes substantially all of our property. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

Management will have broad discretion as to the use of the proceeds from this offering, and we may not use the proceeds effectively.

Our management will have broad discretion with respect to the use of proceeds of this offering, including for any of the purposes described in the section of this prospectus entitled “Use of Proceeds.” You will be relying on the judgment

of our management regarding the application of the proceeds of this offering. The results and effectiveness of the use of proceeds are uncertain, and we could spend the proceeds in ways that you do not agree with or that do not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the price of our common stock to decline.

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

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

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

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

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

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

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

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

development efforts, and could be forced to limit funding of our efforts to commercialize Twirla. This could harm our business, operating results and financial condition and cause the price of our common stock to fall.

This is a best efforts offering, no minimum amount of securities is required to be sold, and we may not raise the amount of capital we believe is required for our business plans, including our near-term business plans.

The placement agent has agreed to use its reasonable best efforts to solicit offers to purchase the securities in this offering. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, placement agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth above. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to support our continued operations, including our near-term continued operations. Thus, we may not raise the amount of capital we believe is required for our operations in the short-term and may need to raise additional funds to complete such short-term operations. Such additional fundraises may not be available or available on terms acceptable to us.

The exercise of outstanding common stock purchase warrants and stock options will have a dilutive effect on the percentage ownership of our capital stock by existing stockholders.

As of December 31, 2023, we had outstanding warrants to acquire 5,589,637 shares of our common stock, and stock options to purchase 43,043 shares of our common stock. A number of such warrants have exercise prices that exceed the recent trading prices of our common stock, but such warrants contain a cashless exercise provision that permit exercise on a cashless basis at any time where there is no effective registration statement under the Securities Act of 1933, as amended, covering the issuance of the underlying shares. If a significant number of such warrants and stock options are exercised by the holders, the percentage of our common stock owned by our existing stockholders will be diluted.

If you purchase our securities in this offering you may experience future dilution as a result of future equity offerings or other equity issuances.

We will likely offer and issue additional shares of our common stock or other equity or convertible debt securities in order to raise additional capital. Future equity offerings or other equity issuances may be at a price per share that is equal to or greater than the price per share paid by investors in this offering. Future investors in such offerings may have rights superior to existing stockholders, and the price per share at which we sell additional shares of common stock or other equity or convertible debt securities in future transactions may be at a higher or lower price per share than the price per share in this offering.

You will likely experience immediate and substantial dilution in the net tangible book value per share of the common stock you purchase.

Since the public offering price for our common stock in this offering will likely be substantially higher than the net tangible book value per share of our common stock outstanding prior to this offering, you will likely suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering. The shares sold in this offering, if any, will be sold from time to time at various prices. After giving effect to the sale of our common stock in the maximum aggregate offering amount of \$ _____ at an assumed offering price of \$ _____ per share (the last reported sale price of our common stock on the Nasdaq Capital Market on _____, 2024), and after deducting estimated offering commissions and expenses payable by us, you would suffer immediate dilution of \$ _____ per share in the net tangible book value of the common stock. See the section entitled “Dilution” below for a more detailed discussion of the dilution you will incur if you purchase shares in this offering.

FINRA sales practice requirements may limit a stockholder’s ability to buy and sell our securities.

Effective June 30, 2020, the SEC implemented Regulation Best Interest requiring that “A broker, dealer, or a natural person who is an associated person of a broker or dealer, when making a recommendation of any securities transaction or investment strategy involving securities (including account recommendations) to a retail customer, shall act

in the best interest of the retail customer at the time the recommendation is made, without placing the financial or other interest of the broker, dealer, or natural person who is an associated person of a broker or dealer making the recommendation ahead of the interest of the retail customer.” This is a significantly higher standard for broker-dealers to recommend securities to retail customers than before under FINRA suitability rules. FINRA suitability rules do still apply to institutional investors and require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending securities to their customers, broker-dealers must make reasonable efforts to obtain information about the customer’s financial status, tax status, investment objectives and other information, and for retail customers determine the investment is in the customer’s “best interest” and meet other SEC requirements. Both SEC Regulation Best Interest and FINRA’s suitability requirements may make it more difficult for broker-dealers to recommend that their customers buy speculative, low-priced securities. They may affect investing in our common stock, which may have the effect of reducing the level of trading activity in our securities. As a result, fewer broker-dealers may be willing to make a market in our common stock, reducing a stockholder’s ability to resell shares of our common stock.

Risks Related to the Commercialization of Twirla

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

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

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

- The prescription contraceptive market could experience a decrease in growth or negative growth if fewer women choose to use hormonal contraception;
- Price pressures and decisions to deny reimbursement coverage from third party payors, including managed care organizations and government-sponsored health systems, could limit our revenue;
- The proportion of the hormonal contraceptive market comprised of generic products could continue to increase, making the commercialization of a branded contraceptive difficult and expensive and increasing costs associated with marketing and market access;
- The perceived safety of hormonal contraceptives could be negatively affected by media reports of adverse effects and advertisements for mass tort lawsuits due to adverse effects;
- Competition in the hormonal contraceptive market from existing branded or generic contraceptives, or as a result of the introduction of new contraceptives, including the potential of a new generic or branded competitive contraceptive patch;
- Healthcare reform activities, including, without limitation, the repeal, reform or replacement of the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010 or, collectively, the Affordable Care Act, or ACA, and its effects on pharmaceutical coverage, reimbursement and pricing, could limit our revenue.

Secondly, if Twirla does not gain an adequate level of acceptance among prescribers, patients and third party payors, we may not generate significant product revenues or become profitable. Market acceptance of Twirla by

prescribers, patients and third-party payors and our resulting ability to commercialize Twirla will depend on a number of factors, some of which are beyond our control, including:

- Availability of adequate coverage or reimbursement of Twirla by third parties, such as insurance companies and other payors, and by government healthcare programs, including Medicare, Medicaid and state health insurance exchanges;
- Efficacy, safety and other potential advantages of Twirla in relation to alternative treatments;
- Relative convenience, acceptability of use, and ease of administration of Twirla;
- Prevalence and severity of adverse events associated with Twirla;
- Willingness of prescribers to prescribe a contraceptive patch based on the labeling and prior safety experience with the generic contraceptive patch already on the market. *For more information regarding the prior safety and market experience with the prior patch see Business: Contraceptive Landscape and Market Opportunity, Contraceptive Patch Market Experience;*
- Openness among Planned Parenthood and other non-retail healthcare providers to make Twirla available to the patients they serve;
- Cost of Twirla in relation to alternative treatments, including generic products;
- Access to the prescriber universe, particularly obstetrics and gynecology physicians, and pharmacists (in states where they are permitted to prescribe) could be limited, decreasing our ability to promote Twirla efficiently;
- Our reliance on data from external, unverifiable sources of data and market research to estimate the size of the CHC market, the potential market opportunity for Twirla, and to identify healthcare providers most likely to prescribe Twirla;
- Extent and strength of our third-party manufacturer and supplier support and ability to meet our market demand;
- Extent and strength of our marketing and distribution support; and
- Dose, limitations, warnings, or contraindications contained in Twirla's FDA approved labeling, including safety warnings and precautions, contraindications and limitations on the use of Twirla for women based on BMI, and any potential revisions thereto.

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

If Twirla does not achieve an adequate level of acceptance by prescribers, third-party payors and patients, we may not generate sufficient revenue, we may not be able to achieve or sustain profitability, and the value of our common stock may be adversely impacted. Our efforts to educate prescribers, patients and third-party payors on the benefits of Twirla may require significant resources and may never be successful. Even if we are able to demonstrate and maintain a

competitive advantage over our competitors and become profitable, if the market for hormonal contraceptives fails to achieve expected future growth or decreases, we may not be able to generate sufficient revenue or sustain profitability. Our ability to generate sufficient revenue from Twirla will also be dependent on our ability to support the commercial demand for Twirla and we cannot assure that we and Corium will be able to manufacture sufficient quantities of Twirla in order to meet commercial demand.

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

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

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

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

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

- Our or our contractor's inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- The ability of sales personnel to obtain access to or persuade adequate numbers of prescribers to prescribe Twirla;
- The lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- The costs associated with training sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;
- Liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- Unforeseen costs and expenses associated with creating an independent sales and marketing organization or partnering with our contract sales organization, including difficulty managing the growth that both of these activities would require; and

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

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

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

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

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

- Modification to product labeling or promotional statements, such as additional boxed or other warnings contraindications, or limitations, or the issuance of “Dear Doctor Letters” or similar communications to healthcare professionals or the public regarding safety, efficacy, or other concerns;
- Imposition of additional post-marketing clinical trial requirements, distribution restrictions or other risk management measures, such as a risk evaluation and mitigation strategy, REMS, which could include elements to assure safe use;
- Suspension or withdrawal of regulatory approval;
- Suspensions or termination of ongoing clinical trials or refusal by regulators to approve pending marketing applications or supplements to approved applications;
- Suspension of, or imposition of restrictions on, our operations, including costly new manufacturing requirements with respect to Twirla;
- Costly and time-consuming corrective actions; and
- Voluntary or mandatory product recalls or withdrawals from the market and costly product liability claims.

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

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

The network through which we will sell Twirla and our potential product candidates, if and when approved, has undergone significant consolidation marked by mergers and acquisitions among wholesale distributors and the growth of large retail drugstore chains. As a result, a small number of large distributors control a significant share of the market. In

2021, three companies generated about 95% of all revenues from drug distribution in the United States, and, the top five chain pharmacy companies owned about 54% of all retail pharmacy outlets. Consolidation of drug wholesalers and retailers, as well as any increased pricing pressure that those entities face from their customers, including the U.S. government, may increase pricing pressure and place other competitive pressures on drug manufacturers, including us.

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

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

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

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

Other measures – such as provisions of the Medicare Modernization Act that would allow importation of drugs from Canada – have also been taken by Congress, the previous administration, and administrative agencies to increase drug competition and thus, decrease drug prices. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. New legislative and regulatory efforts could ultimately have an adverse impact on our business and results of operation.

Risks Related to Our Financial Position and Need for Capital

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

Our operations have consumed substantial amounts of cash since our inception. From our inception to December 31, 2022, we have cumulative net cash flows used by operating activities of \$375.7 million. We will need to obtain additional capital to fund our future operations, including the commercialization of Twirla. We will need to obtain additional financing to resume development of our pipeline. Moreover, our fixed expenses such as rent, interest expense and other contractual commitments are substantial and are expected to increase in the future.

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

- Our ability to successfully commercialize Twirla;

- Our ability to have commercial product successfully manufactured in compliance with FDA regulations;
- Amount of sales and other revenues from Twirla, including the selling prices and the availability of adequate third-party coverage and reimbursement;
- Our ability to control our operating expenses and inventory levels in relation to the revenue growth of Twirla;
- Our ability to meet our minimum purchase requirements under our supply agreement with Corium, our third party manufacturer;
- Sales and marketing costs associated with commercializing Twirla, including the cost and timing of expanding our marketing and sales capabilities and infrastructure;
- Time and cost necessary to obtain regulatory approvals for our other potential product candidates that may be required by regulatory authorities;
- Progress, timing, scope and costs of our clinical trials and studies, including the ability to timely meet our PMR milestones;
- Terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- Cash requirements of any future acquisitions or pipeline development;
- Time and cost necessary to respond to technological and market developments;
- Costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- Costs associated with any potential business or product acquisitions, strategic collaborations, licensing agreements or other arrangements that we may establish;
- Costs associated with the commercial manufacturing process for Twirla and/or the establishment of a backup supplier; and
- Costs associated with the hiring of new employees and maintaining our contract sales force.

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

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

consume capital more rapidly than we currently anticipate. If we choose to accelerate any elements of our commercial plan or we encounter any unforeseen events that affect our business plan, we may choose to raise additional funds to provide us with additional working capital. Our inability to obtain additional funding when we need it could seriously harm our business and we may be unable to continue our operations at planned levels and be forced to reduce, or even terminate, our operations.

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

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

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

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

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

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

Risks Relating to Maintaining Regulatory Compliance and Approval of Twirla

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

Twirla is subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, import, export, safety surveillance, advertising, marketing promotion, recordkeeping, reporting of adverse events and other post-market information, and further development, including ongoing requirements for costly post-marketing studies, including Phase 4 studies or post-market surveillance. For more information about the planned Phase 4 studies for Twirla, *Business: Twirla*. The results generated in these post-approval clinical trials and studies could

result in loss of marketing approval, changes in product labeling, or new or increased concerns about side effects or efficacy of a product. Failure to comply with post-market study requirements can also result in different enforcement actions.

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

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

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

We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act and similar state laws, which impact, among other things, our proposed sales, marketing and scientific/educational efforts. Federal criminal statutes also prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. We are also subject to complex laws and regulations regarding reporting and payment obligations due to our participation in government drug programs. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and drug pricing; and state laws, such as the California Consumer Privacy Act, governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal law, thus complicating compliance efforts.

The occurrence of any event or penalty described herein may inhibit our ability to commercialize Twirla and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure. Efforts to ensure that our business arrangements with third parties will

comply with applicable healthcare laws and regulations are costly. Compliance with these and other federal and state laws applicable to the sale, marketing, and distribution of commercial drug products will require that we expend time and financial resources to maintain compliance, and it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations.

Risks Related to Manufacturing and Our Reliance on Third Parties

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

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

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

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

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

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

will be limited while the new third-party manufacturer develops the necessary know-how to manufacture Twirla and while we obtain regulatory approval for the addition of a new manufacturer and processes.

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

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

We currently rely and plan to continue to rely on CROs and clinical trial sites for most aspects of our post-marketing study and any other clinical trials of our potential product candidates, such as trial conduct, data management, statistical analysis and electronic compilation of our FDA submission. We may enter into agreements with additional CROs and clinical trial sites to obtain additional resources and expertise in an attempt to accelerate our progress with regard to new or ongoing clinical and preclinical programs, which involves substantial cost and requires extensive management time and focus. Delays may occur, which may materially impact our ability to meet our desired post-marketing and clinical development timelines and ultimately have a material adverse impact on the commercialization of Twirla, our ability to maintain our marketing authorization for Twirla, our operating results, financial condition or future prospects. For example, we have engaged the services of a CRO to design, conduct, and complete the PMR database study, which will require substantial time and resources. If the CRO cannot obtain the necessary sample for the database and complete the study in a timely manner, we may be unable to meet study milestones and may fail to complete the study required by the FDA and subsequently may lose our marketing authorization for Twirla or be subject to other enforcement actions and be forced to suspend commercial activities regarding the product.

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

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

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

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

Risks Related to Intellectual Property Rights

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

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

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

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

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

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

Third parties may assert that we are employing their proprietary technology without authorization and may sue us for patent or other intellectual property infringement or misappropriation. Third parties could similarly claim that our employees, consultants, or contractors have misappropriated their intellectual property, including know-how or trade secrets of a third party, in violation of nondisclosure agreements or noncompete agreements in place with the third party. These lawsuits are costly and could adversely affect our results of operations and divert the attention of managerial and scientific personnel. If we are sued for patent infringement, we would need to demonstrate that our product, potential product candidates or methods either do not infringe the claims of the relevant patent or that the patent claims are invalid

or unenforceable, which is difficult and which we may not be able to do, and even if successful will result in substantial costs and time, which could have a material adverse effect on us. Successful third party claims could block our ability to commercialize Twirla or potential product candidates, if approved, and could result in liability and monetary damages, any of which could materially harm our business.

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

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

In infringement litigation, any award of monetary damages we receive may not be commercially valuable. There can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are resolved. Further, any claims we assert against a perceived infringer could provoke these parties to assert counterclaims against us alleging that we have infringed their patents. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

Risks Related to Our Business Operations and Industry

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

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

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

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

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

We have obtained limited product liability insurance coverage for Twirla and our clinical trials with a \$10.0 million annual aggregate coverage limit. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

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

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

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

We are exposed to the risk that employees, independent contractors, principal investigators, CROs, manufacturers, consultants, commercial partners and vendors may engage in fraudulent or other illegal activity, fraud or other misconduct. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the law and regulations of the FDA and non-U.S. regulators, including those laws that require the reporting of true, complete and accurate information to the FDA and non-U.S. regulators, (ii) healthcare fraud and abuse laws and regulations in the United States and abroad and (iii) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct in violation of these laws may also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct,

but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including enforcement actions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, contain rules that limit the ability of a company that undergoes an ownership change, which is generally any change in ownership of more than 50% of its stock over a three-year period, to utilize its net operating loss and tax credit carryforwards and certain built-in losses recognized in years after the ownership change. These rules generally operate by focusing on ownership changes involving stockholders owning, directly or indirectly, 5% or more of the stock of a company and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change occurs, the yearly taxable income limitation on the use of net operating loss and tax credit carryforwards and certain built-in losses is equal to the product of the applicable long-term tax-exempt rate and the value of the company's stock immediately before the ownership change. We may be unable to offset future taxable income, if any, with losses, or our tax liability with credits, before such losses and credits expire and therefore would incur larger federal income tax liability. Our net operating loss carryforwards arising in taxable years ending on or prior to December 31, 2017 will expire between 2019 and 2037 if we have not used them. Net operating loss carryforwards arising in taxable years ending after December 31, 2017 are no longer subject to expiration under the Code.

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

Risks Related to Ownership of Our Common Stock

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

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

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

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

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

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

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

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

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately \$ _____ million based on the sale of _____ shares of common stock, Series E-1 warrants to purchase _____ shares of common stock and Series E-2 warrants to purchase _____ shares of common stock at a combined public offering price of \$ _____ per share of common stock and Series E warrants, after deducting the placement agent fees and estimated offering expenses payable by us, and assuming no sale of Series F pre-funded warrants in this offering and no exercise of the Series E warrants being issued in this offering. However, because this is a best efforts offering and there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, the placement agent's fees and net proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth on the cover page of this prospectus. The table below depicts how we plan to utilize the proceeds in the event that 25%, 50%, 75%, and 100% of the securities in this offering are sold, after deducting estimated offering expenses payable by us.

<i>Use of Proceeds</i>	100%	75%	50%	25%
Working Capital/General Corporate Purposes	\$ _____	\$ _____	\$ _____	\$ _____
Total:	\$ _____	\$ _____	\$ _____	\$ _____

These estimates exclude the proceeds, if any, from the exercise of Series E warrants issued in this offering. If all of the Series E warrants issued in this offering were to be exercised in cash at an assumed exercise price of \$ _____ per share of common stock, we would receive additional proceeds of approximately \$ _____ million. We cannot predict when or if these Series E warrants will be exercised. It is possible that these Series E warrants may expire and may never be exercised. Additionally, the Series E warrants contain a cashless exercise provision that permit exercise of Series E warrants on a cashless basis at any time where there is no effective registration statement under the Securities Act of 1933, as amended, covering the issuance of the underlying shares.

We intend to use the net proceeds of this offering for working capital and other general corporate purposes, as well as to repay all or a portion of the Credit Agreement with Perceptive. The interest rate under the Perceptive Credit Agreement is an annual rate equal to the Secured Overnight Financing Rate, or SOFR, plus 10.25%, provided that SOFR shall not be less than 1.5%. Pursuant to the Perceptive Credit Agreement, beginning on August 31, 2022, we made monthly principal payments in an amount equal to \$75,000. Beginning on December 1, 2023 and pursuant to the Seventh Amendment, we began making monthly payments of \$150,000, which will continue until February 10, 2024, at which time all remaining principal amount outstanding is due, and the Credit Agreement will mature. We have used borrowings under the Perceptive Credit Agreement for working capital purposes. See "Risk Factors" beginning on page 9 of this prospectus for more information. Our operating activities may be restricted as a result of covenants related to the outstanding indebtedness under the Perceptive Credit 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. We may also use a portion of the net proceeds of this offering to invest in or acquire businesses or technologies that we believe are complementary to our own, although we have no current plans, commitments or agreements with respect to any acquisitions as of the date of this prospectus supplement. Pending these uses, we plan to invest these net proceeds in investment-grade, interest bearing securities.

These expected uses represent our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development as a commercial company, the implementation of our commercial plan for Twirla, the status of and results from future clinical trials, and any unforeseen cash needs. As a result, our management will have broad discretion in the application of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of the net proceeds from this offering. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the anticipated growth of our business.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of September 30, 2023:

- on an actual basis;
- On an as adjusted basis to give further effect to the sale of up to shares of common stock and accompanying Series E warrants in this offering at an assumed public offering price of \$ per share and accompanying Series E warrants, the last reported sale price of Common Stock on the Nasdaq Capital Market on , 2024, assuming no sale of any Series F pre-funded warrant and accompanying warrants, after deducting the estimated placement agent fees and estimate offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the warrants issued pursuant to this offering

You should read this table together with our financial statements and the related notes in this prospectus and the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in this prospectus.

	As of September 30, 2023	
	Actual	As Adjusted⁽¹⁾
	(in thousands, except share and per share data) (unaudited)	
Cash and cash equivalents	\$ 2,873	\$
Stockholders’ equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized, 4,850 shares issued and no shares outstanding actual and as adjusted.	—	—
Common stock, \$0.0001 par value; 300,000,000 shares authorized, 2,277,657 shares issued and outstanding, actual, shares issued and outstanding, as adjusted.	—	—
Additional paid-in capital	406,288	
Accumulated other comprehensive income	—	
Accumulated deficit	(418,699)	
Total stockholders’ equity (deficit)	\$ (12,411)	\$
Total capitalization	\$ (12,411)	\$

- ⁽¹⁾ The as adjusted balance sheet data reflects the sale of shares of common stock and Series E Warrants to purchase shares of common stock offered by us in this offering at the public offering price of \$ per share and accompanying Series E Warrants, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The discussion and table above assume no exercise of the warrants sold in this offering.

The foregoing table and calculations are based on 2,277,657 shares of our common stock outstanding as of September 30, 2023, and excludes:

- 43,510 shares of common stock issuable upon the exercise of outstanding options to purchase common stock as of September 30, 2023 at a weighted average exercise price of \$550.67 per share;
- 135,037 shares of common stock issuable upon the vesting of outstanding restricted stock units as of September 30, 2023;
- 6,074 shares of common stock reserved for future issuance under our 2023 Equity Incentive Plan as of September 30, 2023; and
- 686,000 shares of common stock issuable upon the exercise of outstanding pre-funded warrants as of September 30, 2023; and

- 4,484,077 shares of common stock issuable upon the exercise of outstanding warrants as of September 30, 2023 at a weighted average exercise price of \$10.10 per share.

Each \$0.25 increase or decrease in the assumed public offering price per share of common stock and accompanying Series E warrants of \$, the last reported sale price of our common stock on the Nasdaq Capital Market on , 2024, would increase or decrease the net proceeds to us from this offering by \$ million, assuming that the number of shares of common stock and accompanying Series E warrants offered by us, as set forth on the cover page of this prospectus, remains the same, assuming no sale of any Series F pre-funded warrants and accompanying Series E warrants, after deducting the estimated placement agent fees and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the warrants issued pursuant to this offering. We may also increase or decrease the number of shares of common stock and accompanying Series E warrants offered in this offering. Each increase or decrease of 1,000,000 shares of common stock and accompanying Series E warrants offered by us would increase or decrease the net proceeds to us by approximately \$ million, assuming the assumed public offering price per share of common stock and accompanying Series E warrants of \$ remains the same, assuming no sale of any Series F pre-funded warrants and accompanying Series E warrants, after deducting the estimated placement agent fees and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the warrants issued pursuant to this offering. The as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering as determined between us and the placement agent at pricing.

DILUTION

If you invest in our common stock and warrants in this offering, your ownership interest will be diluted to the extent of the difference between the effective public offering price per share of common stock included in the share of common stock and accompanying Series E warrants or issuable upon the exercise of the Series F pre-funded warrants and the as adjusted net tangible book value per share of common stock after this offering. As of September 30, 2023, our historical net tangible book value was \$(12.4) million, or \$(5.45) per share, based on 2,277,657 shares of common stock outstanding as of September 30, 2023. Our historical net tangible book value per share represents the amount of our total tangible assets reduced by the amount of our total liabilities, divided by the total number of shares of common stock outstanding as of September 30, 2023.

After giving further effect to our sale in this offering of _____ shares of common stock and accompanying Series E warrants at an assumed public offering price per share of common stock and accompanying Series E warrants of \$ _____, the last reported sale price of common stock on the Nasdaq Capital Market on _____, 2024, assuming no sale of any Series F pre-funded warrants in this offering, and after deducting the estimated placement agent fees and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the warrants issued in this offering, our as adjusted net tangible book value as of September 30, 2023 would have been \$ _____ million, or \$ _____ per share. This represents an immediate increase of net tangible book value of \$ _____ per share to our existing stockholders and an immediate dilution of net tangible book value of \$ _____ per share to investors purchasing shares of common stock and accompanying Series E warrants in this offering. The following table illustrates this per share dilution:

Assumed public offering price per share of common stock and accompanying Series E warrants	\$
Historical net tangible book value (deficit) per share as of September 30, 2023	\$ (5.45)
Increase in net tangible book value per share attributable to investors purchasing in this offering	\$
As adjusted net tangible book value per share as of September 30, 2023 after this offering	\$
Dilution per share to investors purchasing in this offering	\$

Each \$0.25 increase or decrease in the assumed public offering price per share of common stock and accompanying Series E warrants of \$ _____, the last reported sale price of our common stock on the Nasdaq Capital Market on _____, 2024, would increase or decrease the net proceeds to us from this offering by \$ _____ million, assuming that the number of shares of common stock and accompanying Series E warrants offered by us, as set forth on the cover page of this prospectus, remains the same, assuming no sale of any Series F pre-funded warrants and accompanying Series E warrants, after deducting the estimated placement agent fees and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the warrants issued pursuant to this offering. We may also increase or decrease the number of shares of common stock and accompanying Series E warrants offered in this offering. Each increase or decrease of 1,000,000 share of common stock and accompanying Series E warrants offered by us would increase or decrease the net proceeds to us by approximately \$ _____ million, assuming the assumed public offering price per share of common stock and accompanying Series E warrants of \$ _____ remains the same, assuming no sale of any Series F pre-funded warrants and accompanying Series E warrants, after deducting the estimated placement agent fees and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the warrants issued pursuant to this offering. The as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering as determined between us and the placement agent at pricing.

The discussion and table above assume no exercise of the warrants sold in this offering.

The foregoing table and calculations are based on 2,277,657 shares of our common stock outstanding as of September 30, 2023, and exclude:

- 43,510 shares of common stock issuable upon the exercise of outstanding options to purchase common stock as of September 30, 2023 at a weighted average exercise price of \$550.67 per share;
- 135,037 shares of common stock issuable upon the vesting of outstanding restricted stock units as of September 30, 2023;

- 6,074 shares of common stock reserved for future issuance under our 2023 Equity Incentive Plan as of September 30, 2023; and
- 686,000 shares of common stock issuable upon the exercise of outstanding pre-funded warrants as of September 30, 2023; and
- 4,484,077 shares of common stock issuable upon the exercise of outstanding warrants as of September 30, 2023 at a weighted average exercise price of \$10.10 per share.

DIVIDEND POLICY

We have never declared or paid a cash dividend on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. In addition, our Credit Agreement and Guaranty, as amended, among us, the guarantors 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 determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

BUSINESS

Overview

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

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

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

Our Strategy

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

Our current priorities are as follows:

- Continue to manage our available cash and obtain financing to fund our business plan without delay;
- Continue to implement our commercialization plans for Twirla to increase uptake of Twirla in the United States, through targeted digital direct to consumer advertising, growing our telemedicine presence through new partnerships and our existing partnership with Nurx, and driving growth in the non-retail channel through our collaboration with Afaxys, which provides us access to some of the largest Planned Parenthood organizations in the country;
- Continue to expand access to Twirla through multiple business channels including retail and specialty pharmacies, telemedicine, government contracting, and non-retail channels, including public health centers through our relationship with Afaxys;
- Expand coverage and reimbursement for Twirla in the United States from private and public third-party payors;

- Maintain and manage the supply chain for Twirla to support increased commercialization of Twirla across the United States and working through existing and future inventory prior to product becoming short-dated;
- Reduce our operating loss and continue to progress towards generating positive cash flows;
- Evaluate the advancement of our existing pipeline and its possible expansion through business development activities; and
- Continue to implement our obligations related to our post-marketing requirement study of Twirla.

Twirla

Twirla is our first and only approved product. Twirla received FDA approval on February 14, 2020, as a method of contraception for use in women of reproductive potential with a body mass index (“BMI”) < 30 kg/m² 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/m² before prescribing. Twirla is contraindicated in women with a BMI ≥ 30 kg/m² because, compared to women with a lower BMI, women in this group had reduced effectiveness and may have a higher risk for VTEs. Twirla’s label also includes the class-wide boxed warning, contraindications, and warnings and precautions applicable to all combined hormonal contraceptives, or CHCs.

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

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

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

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

Systems—Product Development and Quality Considerations. The PMC study was completed in the fourth quarter of 2021, and the study report was submitted to the FDA in June 2022. The FDA notified us in August 2023 that the PMC requirement was fulfilled. We continue to discuss the results of the PMC study with the FDA.

Contraceptive Landscape and Market Opportunity

U.S. Hormonal Contraceptive Market Background

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

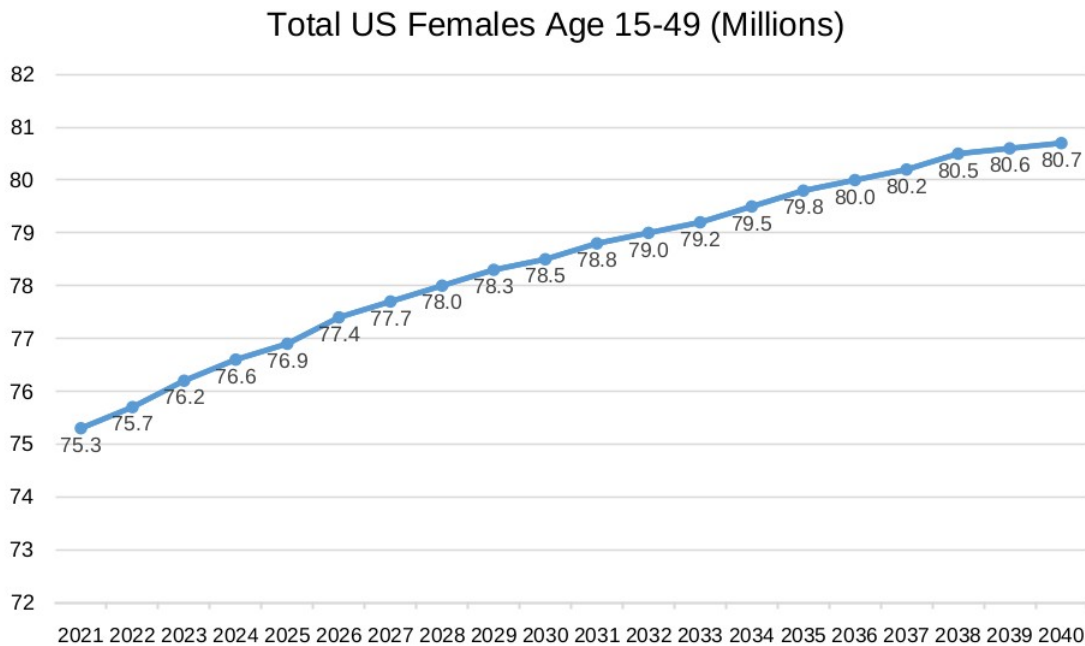
- oral contraceptive;
- vaginal ring;
- transdermal patch;
- hormonal IUD;
- subcutaneous implant; and
- injectable.

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

The U.S. hormonal contraceptive market is a mature market, with many branded and generic products available. For the past 5 years, sales revenue in the CHC market has been essentially flat, at approximately \$6 billion per year using gross sales. Total prescription volume, or TRx, declined from 2018 to 2022 by 27%, from 76 million to 56 million; however the number of cycles dispensed (1 cycle = 1 month supply) declined by only 11% over the same time period, as the average TRx size (cycles/TRx) grew from 1.5 to 1.9 over the same time period. Therefore, the value of a TRx has grown significantly over the past 5 years, particularly for branded products, where the average revenue per TRx increased from \$183.67 in 2018 to \$269.29 in 2022.

Despite the availability of generic contraceptives for over 30 years, branded products have maintained a significant, though declining, share of CHC sales, with 16% of sales in 2022. In the five years ended December 2022, the average annual price increase among the same branded products was 6.9%. The average price per cycle, referred to as the wholesale acquisition cost, or WAC, for a single 28-day cycle of these branded products was \$155.58 in 2018 and rose to \$170.28 by December 2022. The branded CHC transdermal patch (Ortho Evra) was discontinued in October 2014 and the branded generic CHC transdermal patches (Xulane and Zafemy) are both currently priced at \$122.15 per cycle. Our current WAC price for Twirla is \$204.57. The other non-oral form of CHC, the monthly vaginal ring, is currently priced at \$162.63 per cycle for the branded version, Nuvaring, and \$138.24, \$140.52, and \$103.82 for generic versions. We cannot predict how the manufacturers of branded or generic products will manage prices going forward.

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



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

Contraceptive Pills

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

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

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

Contraceptive Patch Market Experience

The Ortho Evra® contraceptive patch, or Evra, was introduced in early 2002 and was the first FDA-approved contraceptive patch. The initial approved labeling for Evra indicated that it delivered a daily EE dose of 20 micrograms. Evra had rapid uptake in the hormonal contraceptive market and achieved a 10% share of the CHC market by September

2003. Following FDA approval of Evra, users of Evra began to report thrombotic and thromboembolic events to the FDA. Johnson & Johnson, the manufacturer of Evra, revised the Evra labeling in November 2005 to include information that EE exposure with Evra is 60% higher than that of an oral contraceptive containing EE of 35 micrograms, based on area under the curve, a commonly-used metric for measuring EE exposure in contraceptives. This information was ultimately included in an addition to the boxed warning that was unique to the Evra label. In 2020, the Xulane label was revised to reflect a contraindication in women with a BMI ≥ 30 kg/m² because of the reduced efficacy and increased potential risk for VTEs in this population. In making this revision, the information about increased estrogen exposure was removed from the boxed warning but remains in the warnings and precautions and pharmacokinetics sections of the label. The Evra market share declined rapidly following the 2005 labeling changes, from a peak share of 11% in 2005, to 4% by the end of 2006, to 1.4% by the end of 2013, where it stabilized, with a 1.5% share of the market based on combined prescriptions for Evra and its generic equivalent (Xulane[®]) in 2014. In more recent years, the Xulane share of the CHC market TRx has grown, from a 2.2% share in 2018 to a 2.8% share in 2022. Zafemy, a second generic of Ortho Evra launched in 2021, had a market share of 0.8% in December 2022.

The FDA has maintained, in spite of the wording in the labeling for Evra, which has been discontinued, and its approved branded generic, that none of the epidemiologic studies provides a definitive answer regarding the relative risk of VTE with Evra compared to combined oral contraceptive use or whether the increased risk that some studies demonstrated is directly attributable to Evra. In spite of the labeling changes, and Johnson & Johnson ceasing promotion of Evra in 2007, the generic equivalent of Evra (Xulane) generated estimated gross sales of \$277 million in 2022. On February 26, 2021, Amneal Pharmaceuticals, Inc. announced that it had received approval by the FDA for Zafemy, a generic version of Ortho Evra. Zafemy generated estimated gross sales of \$88.8 million in 2022.

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

Twirla Potential Market Share

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

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

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

Twirla Commercialization Strategy

Our top priority is the successful commercialization of Twirla. Promptly after approval by the FDA in February 2020, we began implementation of our plan to market Twirla. Our plan is focused on promoting Twirla in the states with the highest Twirla reimbursement potential, which we estimate will allow us to reach approximately 45% of U.S. women

between the ages of 18-24. During 2023 we concentrated our marketing efforts on increasing both patient awareness and access through digital advertising to consumers in our target market and strategic partnering, while at the same time reducing marketing activities during strategic timeframes to conserve cash. We also focused on increasing patient access to Twirla across different channels, including specialty pharmacy as well as through continuing our eVoucher programs at the pharmacy level, growing our relationship with Afaxys GPO, and growing our relationship with Nurx, a leader in female-focused telehealth. In 2024, we intend to continue implementation of our commercial strategy for Twirla with an emphasis on leveraging our strategic partners and expanding market access through multiple business channels, including third-party payor contracts, retail and specialty pharmacies, additional telemedicine presence, and government contracts. We also plan to continue to engage with third-party payors and insurers to seek expanded access and re-imburement coverage of Twirla.

Twirla Promotion Strategy

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

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

Twirla Coverage and Reimbursement Strategy

After approval of Twirla by the FDA, we began meeting with formulary decision makers as appropriate to secure positions for Twirla that minimize access barriers for prescribers and patients, and since then we estimate that we have been able to achieve access for approximately fifty-five to sixty percent (55-60%) of the estimated covered lives by commercial third-party payors. Third-party payors are increasingly challenging the prices charged for pharmaceutical products. The United States government and other third-party payors are increasingly limiting both coverage and level of reimbursement for new drugs, in addition to questioning their safety and efficacy. In this challenging environment, we plan to continue our efforts to expand formulary access to Twirla through contracting strategies and engaging with formulary boards on the clinical profile of Twirla. We believe that it is important in this category for women to have equal access to all methods, dosing regimens and hormonal options so that they and their provider can select the choice that is the most appropriate to meet their lifestyle and family planning goals.

Our Pipeline: Twirla Line Extensions and Potential Product Candidates

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

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

Our primary potential product candidate is a progestin-only (P-only) contraceptive patch, or P-Patch, and is intended for use by women of reproductive potential to prevent pregnancy. The intended population for the P-Patch would be women who are unable or unwilling to take estrogen, including those who are breastfeeding or who are at greater risk of VTE, such as women who smoke, are over 35 years of age, or who have a BMI greater than 30 kg/m² (criteria for obesity).

Currently, the P-only market consists of pills and several non-oral options, including intrauterine systems (IUS)/intrauterine devices (IUDs), implants, and injections. We believe there is a need for a P-only option in a convenient, non-daily, user-controlled method, especially as the population of women with obesity increases in the United States. We have completed formulation selection and conducted early pre-clinical work on our P-only patch. Additional formulation development work and dose selection is required, along with additional studies to optimize the formulation and determine the optimal dose to advance to Phase 3. We continue to explore our plan to develop this program and are considering all of our potential pathways, including a co-development and co-funding partnership to advance this program into the clinic.

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

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

We do not expect to be required to conduct preclinical toxicology studies for any of these potential product candidates. Based upon a number of factors, including, but not limited to, our available capital resources and feedback from the FDA, we continue to review the clinical path and the budgetary requirements for each of our potential product candidates.

Competition

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

We face competition from a variety of non-permanent birth control products across method categories. There are non-hormonal barrier methods, such as the contraceptive sponge, diaphragm, cervical cap or shield and condoms. Then, there are hormonal methods, which is the category for Twirla and our potential product candidates. Within the hormonal category, there are various methods of contraception, such as oral contraceptives, injections, implants, hormonal IUDs,

vaginal rings, and transdermal contraceptive products. Each of the methods carries different efficacy and side effect profiles, which are important to providers and patients when making a contraceptive decision.

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



BIRTH CONTROL GUIDE

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

FDA-Approved Methods	Number of pregnancies expected (per 100 Women)*	Use	Some Risks or Side Effects*
Sterilization Surgery for Women	Less than 1	One-time procedure. Permanent.	Pain Bleeding Infection or other complications after surgery
Sterilization Implant for Women	Less than 1	One-time procedure. Permanent.	Pain/cramping Pelvic or back discomfort Vaginal bleeding
Sterilization Surgery for Men	Less than 1	One-time procedure. Permanent.	Pain Bleeding Infection
IUD: Copper	Less than 1	Inserted by a healthcare provider. Lasts up to 10 years.	Cramps Heavier, longer periods Spotting between periods
IUD with Progestin	Less than 1	Inserted by a healthcare provider. Lasts up to 3-5 years, depending on the type.	Irregular bleeding No periods (amenorrhea) Abdominal/pelvic pain
Implantable Rod	Less than 1	Inserted by a healthcare provider. Lasts up to 3 years.	Menstrual Changes Weight gain Acne Mood swings or depressed mood Headache
Shot/ Injection	5	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 Nausea Mood changes Breast tenderness
Diaphragm with Spermicide	12	Must use every time you have sex.	Iritation Allergic reactions Urinary tract infection
Sponge with Spermicide	12-24	Must use every time you have sex.	Iritation
Cervical Cap with Spermicide	17-23	Must use every time you have sex.	Iritation Allergic reactions Abnormal Pap test
Male Condom	18	Must use every time you have sex. Provides protection against some STIs.	Iritation Allergic reactions
Female Condom	21	Must use every time you have sex. Provides protection against some STIs.	Discomfort or pain during insertion or sex. Burning sensation, rash or itching
Spermicide Alone	28	Must use every time you have sex.	Iritation 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)	7 out of every 8 women who would have gotten pregnant will not become pregnant after taking this EC.	Swallow the pills as soon as possible within 3 days after having unprotected sex.	Menstrual changes Headache Dizziness Breast pain Lower stomach (abdominal) pain Nausea Vomiting Tiredness
Levonorgestrel .75 mg (2 pills)	6 or 7 out of every 10 women who would have gotten pregnant will not become pregnant after taking this EC.	Swallow the pills within 5 days after having unprotected sex.	Headache Abdominal pain Tiredness Nausea Menstrual pain Dizziness

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

Our potential competitors include large, well-established pharmaceutical companies, and specialty pharmaceutical sales and marketing companies. The branded products with established market presence include Nuvaring[®], marketed by Merck, and Annovera[®], marketed in the U.S. by Mayne Pharmaceuticals, the Loestrin[®] franchise, marketed by Allergan (formerly known as Actavis), consisting of three oral contraceptives, Minastrin[®] 24, LoLoestrin[®] and Taytulla[®], and Beyaz[®], Yaz[®], Yasmin[®] and Natazia[®] marketed by Bayer. Xulane[®], a branded generic to Ortho Evra, generated an estimated \$277 million in gross sales for Viatris in 2022. On February 26, 2021, Amneal Pharmaceuticals, Inc. announced that it had received approval by the FDA for Zafemy[™], a second generic version of Ortho Evra. Zafemy had estimated gross sales of \$88.8 million in 2022. Additionally, several generics manufacturers currently market and continue to introduce new generic contraceptives, including Sandoz, Glenmark, Lupin, Amneal, Mylan, Aurobindo, and Xiromed. Based on the market experience of other non-oral CHC dosage forms, including Evra and Nuvaring, we believe there is a continuing demand for an innovative transdermal contraceptive patch that can provide convenience in a low-dose transdermal format.

There are several other contraceptive products that are more recently approved and a limited number in development, which we are aware of that may compete with Twirla and our other potential product candidates. Phexxi[®], a prescription non-hormonal vaginal gel approved for use as an on-demand contraceptive, was developed by Evofem and launched in August of 2020. Nextstellis[®], a combined oral contraceptive containing drospirenone and a new form of estrogen, estetrol (E4), was developed by Mithra Pharmaceuticals and is licensed to Mayne Pharmaceuticals for marketing in the U.S. and Australia. Mayne fielded a new women's health team in the U.S. and launched Nextstellis in June of 2021. The Population Council has a transdermal gel contraceptive and a vaginal ring contraceptive, both containing segesterone acetate (the same progestin contained in Annovera) and ethinyl estradiol in Phase 2 development. Bayer has an IUD containing both LNG and an NSAID (a non-steroidal anti-inflammatory), to reduce pain upon insertion in Phase 2. Bayer also signed a license agreement in January of 2020 with Dare Bioscience for U.S. commercial rights to Ovaprene, a hormone-free monthly contraceptive vaginal ring, which is in Phase 2 development. Allergan has a P-only patch for which they received a CRL from the FDA in 2013.

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

Manufacturing

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

Strategic Agreements

Agreement with Corium

In April 2020, we entered into a Manufacturing and Commercialization agreement with Corium, which we refer to as the Corium Agreement, and which replaced our previous development agreement. Corium continues to operate under the Corium Agreement after the Corium Reorganization. Pursuant to the Corium Agreement, Corium will manufacture and supply all of our product requirements for Twirla at certain specified rates. Under the terms of the Corium Agreement, Corium is to be the exclusive supplier of Twirla for ten years. The Corium Agreement included a quarterly minimum purchase commitment and a fixed price per unit for two years from December 2020, the date of the first commercial batch purchase order invoice, depending on annual purchase volume. During 2021, we did not meet all of our minimum quantity

purchases from Corium, and as a result, paid penalties as required by our agreement with Corium. On July 25, 2022, we, along with Corium, amended the Corium Agreement to restructure the minimums applicable to the purchase of manufactured Twirla and to extend the term of the Corium Agreement until December 31, 2033. Pursuant to the amended Corium Agreement, the parties agreed to transfer ownership of certain manufacturing equipment used in the manufacture of Twirla from us to Corium under a Bill of Sale dated July 25, 2022.

The Corium Agreement terminates automatically on December 31, 2033, but may be terminated for any reason upon the written mutual agreement of both parties; provided, however, that the parties must confer in good faith regarding possible mutual termination. In the event of such termination, we may still effect purchase orders after the notice of termination is given and until the time any such termination becomes effective. As of December 31, 2022, the minimum amount committed totals \$233.8 million.

Agreement with Syneos Selling Solutions

In April 2020, we entered into a project agreement with inVentiv Commercial Services, LLC, or inVentiv, a Syneos Health Group Company, which we refer to as the Syneos Agreement, under our Master Services Agreement with inVentiv. Pursuant to the Syneos Agreement, inVentiv, through its affiliate Syneos Selling Solutions, will provide a field force of sales representatives to provide certain detailing services, sales operation services, compliance services and training services with respect to Twirla to us in exchange for an up-front implementation fee and a fixed monthly fee.

Effective February 1, 2022, we entered into an amendment to the Syneos Agreement that extended the term until August 23, 2024. At that time, the Syneos Agreement will terminate automatically unless extended upon the mutual written agreement of the parties. We may terminate the Syneos Agreement for any reason upon timely written notice without incurring a termination fee. As of December 31, 2022, the minimum amount committed totals \$3.5 million.

Pricing and Reimbursement

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

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

Similarly, in order for a covered outpatient drug to receive federal reimbursement under the Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts on the covered outpatient drug to entities that are enrolled and participating in the 340B drug pricing program, which is a federal program that requires manufacturers to provide discounts to certain statutorily-defined safety-net providers. The 340B discount for each product is calculated based on certain Medicaid Drug Rebate Program metrics that manufacturers are required to report to CMS.

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

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

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

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

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

The 2022 FAQ noted that plans and issuers subject to these requirements are reminded of their responsibility to fully comply with the requirements under PHS Act section 2713 and the HRSA Guidelines, as interpreted in The Departments' implementing regulations and guidance, including the requirement that, if an individual and their attending provider determine that a particular service or FDA-approved, cleared or granted contraceptive product is medically

appropriate for the individual (whether or not the item or service is identified in the current FDA Birth Control Guide), the plan or issuer must cover that service or product without cost sharing.

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

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

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

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

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

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

FDA Regulation

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

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

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

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

Preclinical Studies and IND Submission

Preclinical studies include laboratory evaluations of drug substance chemistry, pharmacology, toxicity and drug product formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data, proposed clinical protocols, and any available clinical data or literature, among other things, to the FDA as part of an IND, unless the sponsor is relying on prior FDA findings of safety or efficacy of the drug product, in which case, some of the above information may be omitted. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

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

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

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

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

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

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or

terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to subjects. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of trial subjects, potential trial subjects, and the continuing validity and scientific merit of the clinical trial. We may also suspend or terminate a clinical trial based on evolving business objectives or competitive climate.

U.S. Marketing Approval

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

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

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

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

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

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

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection or remote regulatory assessment reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a Complete Response Letter, or a CRL. A CRL indicates that the review cycle of the application is complete, and the application is not ready for approval. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the drug product and may require

additional clinical or preclinical testing, or other information in order for the FDA to reconsider the application. If an application receives a CRL, the applicant may resubmit the application, addressing all of the FDA-cited deficiencies, withdraw the application, or request the opportunity for a hearing. Resubmitted applications may also be subject to FDA inspection or remote regulatory assessment of clinical and manufacturing sites, as well as review by FDA advisory committees. Following its review of a resubmitted NDA, the FDA may issue an approval letter or another CRL.

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

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

Hatch-Waxman Act

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

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

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

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

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

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

Recently, Congress, the executive branch, and FDA have taken certain measures to increase drug competition and thus, decrease drug prices. By example, measures have been proposed and implemented to facilitate drug importation and Florida recently had its plan to import drugs from Canada approved by FDA. Moreover, the 2020 Further Consolidated Appropriations Act also required sponsors of NDA approved products to provide sufficient quantities of drug product on commercially reasonable market-based terms to entities developing generic and similar drug products. Failure to do so can

subject the approved product sponsor to civil actions, penalties, and responsibility for attorneys' fees and costs of the civil action. This bill also included provisions on shared and individual REMS for generic drug products.

Combination Drug/Device Regulation

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

U.S. Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to manufacturing recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion, reporting of adverse experiences with the product and drug shortages, and compliance with any post-approval requirements imposed as a condition of approval, such as Phase 4 clinical trials, REMS and surveillance to assess safety and efficacy after commercialization. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There are also continuing, annual prescription drug program user fee requirements for any approved products. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and list drugs manufactured at their facilities with the FDA.

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

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- Restrictions on the marketing, distribution or manufacturing of the product, complete withdrawal of the product from the market or requests for product recalls;
- Fines, or Untitled, Cyber or Warning Letters or holds on or termination of post-approval clinical trials;
- Refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- Product seizure or detention, or refusal to permit the import or export of products;

- Injunctions or the imposition of civil or criminal penalties including disgorgement, restitution, fines and imprisonment;
- Consent decrees, corporate integrity agreements or exclusion from federal healthcare programs;
- Debarment;
- Mandated modification of promotional materials and labeling and the issuance of corrective information; or
- The FDA or other regulatory authorities may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications, pharmaceutical companies and third parties engaged on their behalf to promote their drug products are prohibited from marketing or promoting their drug products for uses outside the approved label, a practice known as off-label promotion. Companies that market drug products must also provide adequate balancing information on a product's risk in its advertising and promotional pieces. Communications about drug products is an evolving space. In 2023, FDA issued a final rule and a guidance on risk and efficacy disclosures in direct-to-consumer advertising, and a guidance on communication of off-label scientific information about approved products. The FDA and other agencies enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including criminal fines and civil penalties under the FDCA and False Claims Act, exclusion from participation in federal healthcare programs, mandatory compliance programs under corporate integrity agreements, debarment and refusal of government contracts.

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

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

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

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

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

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any healthcare item or service, for which payment may be made in whole or in part under federally financed healthcare programs such as Medicare and Medicaid. The term “remuneration” has been interpreted broadly to include anything of value. Additionally, the intent standard under the Anti-Kickback Statute and criminal healthcare fraud statutes was amended by the Affordable Care Act, or ACA, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce or reward referrals or federal healthcare program business, including purchases of products paid by federal healthcare programs, the statute has been violated. In addition, the ACA established that a claim for reimbursement involving items or services resulting from a violation of the federal Anti-Kickback Statute is grounds for the government or a whistleblower to assert that a claim for reimbursement submitted to a federal healthcare program for payment of items or services resulting from such a violation constitutes a per se false or fraudulent claim for purposes of the federal civil False Claims Act. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers, among others, on the other. The Beneficiary Inducement Civil Monetary Penalties Law imposes similar restrictions on interactions between pharmaceutical manufacturers and federal healthcare program beneficiaries. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. Practices that involve remuneration that may be alleged to be intended to induce or reward prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. On December 2, 2020, the U.S. Department of Health and Human Services (HHS) Office of Inspector General, or OIG, published further modifications to the federal Anti-Kickback Statute regulatory safe harbors. OIG promulgated two additional safe harbor regulations relative to pharmaceutical manufacturers under the final rule, the first of which excluded from the definition of “remuneration” limited categories of manufacturer rebates or other price reductions to a plan sponsor under Medicare Part D or a Medicaid Managed Care Organization plan reflected in point-of-sale reductions in price. The second safe harbor regulation excludes from the definition of “remuneration” PBM service fees paid by a manufacturer to a PBM. In addition, OIG revised the discount safe harbor regulation to exclude from the definition of “discount” a reduction in price by a manufacturer to plan sponsors under Medicare Part D, either directly to the plan sponsor or indirectly through a pharmacy benefit manager. The effective date of the two new safe harbors and the revision to the discount safe harbor was delayed by court order until January 1, 2023. Recent legislation further delayed implementation of the new safe harbors and the revision to the discount safe harbor until January 1, 2032. The final rule also added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others.

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

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government; knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government; or avoiding, decreasing, or concealing an obligation to pay money to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. Claims under the federal civil

False Claims Act may be initiated by whistleblowers, who receive substantial financial incentives to come forward, through qui tam actions. If the government decides to intervene in a qui tam action and prevails in the lawsuit, the whistleblower will share in the proceeds from any damages, penalties or settlement funds. If the government declines to intervene, the whistleblower may pursue the case alone. The civil False Claims Act provides for treble damages and a civil penalty for each false claim, such as an invoice or pharmacy claim for reimbursement, which can aggregate into tens and even hundreds of millions of dollars. For these reasons, False Claims Act lawsuits against pharmaceutical manufacturers have increased significantly in volume and breadth in recent years, leading to several substantial civil and criminal settlements, including for as much as \$3.0 billion regarding certain sales practices and promoting off label uses. Intent to deceive and actual knowledge of falsity is not necessary to establish civil liability, which may be predicated on reckless disregard for or deliberate ignorance of the truth or falsity of the information provided. The federal government continues to use the False Claims Act, and the accompanying threat of significant liability, in investigations against pharmaceutical and health care companies. The False Claims Act has been used to assert liability on the basis of kickbacks and other improper relationships with referral sources, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper promotional activities, including off-label promotion of uses not expressly approved by the FDA in a drug's label, cGMP violations, and allegations as to misrepresentations with respect to products, contract requirements, and services rendered. In addition, private payors have been filing follow-on lawsuits alleging fraudulent misrepresentation and other claims, although establishing liability and damages in these cases is more difficult than under the False Claims Act. The federal criminal False Claims Act imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false fictitious or fraudulent. Conviction or civil judgment for violation of the False Claims Act can also result in debarment from federal government procurement and non-procurement programs and exclusion from participation in federal healthcare programs. The majority of states also have statutes or regulations similar to the federal False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs. Additionally, the civil monetary penalties statute, among other things, imposes fines against any person who is determined to have presented, or caused to be presented, claims to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent.

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

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

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

In addition, we may be subject to healthcare data privacy and security regulations promulgated by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic And Clinical Health Act, ("HITECH Act"), and their respective implementing regulations, impose certain requirements on covered entities relating to the privacy, security, and transmission of certain individually identifiable

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

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

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

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

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

If personal or other sensitive information about patients or employees is disclosed in an unauthorized manner, or if we or our service providers are subject to real or perceived cyberattacks, ransomware, data breaches, or other security incidents or compromises, or disruption of information technology systems or software, our customers may curtail use of

our platform, we may be exposed to liability, our reputation may suffer and our operations may be materially harmed and disrupted.

We, and third parties acting on our behalf, receive, collect, access, generate, store, disclose, share, make accessible, protect, secure, transmit, transfer, dispose of, use, store and otherwise process (collectively, “Process” or “Processing”) personal, confidential and proprietary information. The information technology networks and systems owned, operated, controlled or used by us or our service providers to Process information, including personal and other sensitive information, and to perform other business operations may be vulnerable to damage, disruptions or shutdowns, software or hardware vulnerabilities, data breaches, ransomware attacks, security incidents, supply-side attacks, failures during the process of upgrading or replacing software, databases or components, power outages, natural disasters, hardware failures, attacks by computer hackers, telecommunication failures, user errors, user malfeasance, computer viruses, unauthorized access, phishing or social engineering attacks, ransomware attacks, denial-of-service attacks and other real or perceived cyberattacks or catastrophic events. Any of these incidents could lead to interruptions or shutdowns of our platform, loss or corruption of data, or unauthorized access to or disclosure of personal information or other sensitive information. Cyberattacks could also result in the theft of, or unauthorized access to or use or disclosure of, our intellectual property. We utilize security tools and controls and we rely on our service providers to use sufficient security measures, including encryption and authentication technology, in an effort to protect personal and other sensitive information. However, advances in computer capabilities, increasingly sophisticated tools and methods used by hackers and cyber terrorists, new discoveries in the field of cryptography or other developments may result in our failure or inability, or the failure or inability of our vendors, to adequately protect personal information and there can be no assurance that we or our vendors will not suffer a data compromise, that hackers or other unauthorized parties will not gain access to personal information or other data, or that any such data compromise or unauthorized access will be discovered in a timely fashion.

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

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

Security incidents and vulnerabilities may cause some of our customers to cease doing business with us and our failure, or perceived failure, to meet expectations or legal obligations with regard to the security, integrity, availability and confidentiality of our systems and the Processing of data could damage our reputation and affect our ability to retain customers, attract new customers and grow our business. Applicable data protection laws, privacy policies and data protection obligations (including contractual obligations) may require us to notify relevant stakeholders of a security incident, including affected individuals, customers, regulators and credit reporting agencies, and may also require us to provide other remedies, such as credit monitoring. Such notifications and other remedies are costly, and the notifications or the failure to comply with such requirements, could lead to material adverse impacts, including without limitation, negative publicity, a loss of customer confidence in our services or security measures or breach of contract claims.

Furthermore, actual or perceived security breaches or attacks on our systems or those of our service providers may cause us to incur increasing operational costs, including costs to deploy additional personnel and protection technologies, train employees, and engage third-party experts and consultants.

There can be no assurance that the limitations of liability or other risk-mitigation provisions in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable data protection laws, privacy policies or data protection obligations (including contractual obligations) related to information security or security incidents. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from, or to adequately mitigate, liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or material adverse impacts arising out of our privacy and security practices, Processing of data or security incidents we may experience, or that such coverage will continue to be available on commercially reasonable terms or at all.

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

Coverage and Reimbursement Generally

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

Third-party payors are increasingly imposing additional requirements and restrictions on coverage and limiting access to and reimbursement levels for medical products, including pharmaceuticals. For example, federal and state governments reimburse covered prescription drugs at varying rates generally below average wholesale price. These restrictions and limitations influence the purchase of healthcare services and products. Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication. Certain third-party payors routinely impose additional requirements before approving reimbursement of a prescription, including prior authorization and the requirement to try another therapy first. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order

to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our potential product candidates may not be considered medically necessary or cost-effective. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development for a product candidate. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our potential product candidates, exclusion of our potential product candidates from coverage or the requirement for payment of increased manufacturer rebates on units dispensed. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce our revenues from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our potential product candidates in whole or in part.

Healthcare Reform

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

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

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

In addition, in August 2011, President Obama signed into law the Budget Control Act of 2011, as amended, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. In concert with subsequent legislation, this has resulted in aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2031 (with the exception of a temporary suspension from

May 1, 2020 through March 31, 2022, due to the COVID-19 pandemic) unless additional congressional action is taken. While we do not currently have any products available through Medicare, these and other healthcare reform initiatives may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our financial operations. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could further limit the prices we are able to charge, or the amounts of reimbursement available, for our potential product candidates if they are approved.

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

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

The Foreign Corrupt Practices Act

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

Foreign Regulation

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

Research and Development

Conducting research and development is central to our business model. We have invested and expect to continue to invest significant time and capital in our research and development operations. Our research and development expenses were \$3.3 million, \$6.2 million, and \$13.5 million for the years ended December 31, 2022, 2021, and 2020, respectively.

In 2023, we expect to continue to incur research and development expenses as we conduct our post marketing obligations to the FDA.

Intellectual Property

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

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

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

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

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

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

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

In our Twirla product candidate line the active adhesive system consists of the active ingredients in a polyacrylate adhesive polymer matrix comprising the permeation enhancers dimethylsulfoxide, ethyl lactate, capric acid and lauryl lactate. The active blend is coated onto a release liner, and a backing layer is added on top of the active blend. The

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

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

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

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

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

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

Regulatory Exclusivity

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

Employees

As of December 31, 2023, we had 19 full time employees, including three in research and development and sixteen in selling, general and administrative roles. 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. On August 16, 2023, Scott M. Coiante became our Senior Vice President, Chief Financial Officer ("CFO"). In connection with his appointment as CFO, Mr. Coiante entered into an employment agreement that outlined

his initial annual base salary and his eligibility to participate in the Company's benefit and compensation plans, including the Company's annual bonus plan and the 2023 Equity Incentive Compensation Plan.

Available Information

Our corporate website address is www.agiletherapeutics.com. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus 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.

Properties

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

Legal Proceedings

None.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following information should be read in conjunction with the audited and unaudited financial information and the notes thereto included in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section above, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Dollars in the text and in tabular format are presented in thousands, except per share data, or as otherwise indicated.

Financial Overview

Since our inception in 1997 through 2022, we generated minimal revenue and have never been profitable. Through September 30, 2023, we had an accumulated deficit of \$418.7 million. Our net loss was \$0.8 million and \$5.9 million for the three months ended September 30, 2023 and 2022, respectively and \$10.0 million and \$21.5 million for the nine months ended September 30, 2023 and 2022, respectively. We expect to continue to incur operating losses for the foreseeable future as we commercialize Twirla. We have financed our operations primarily through the public offerings of equity securities, convertible preferred stock, term loans and sale of our New Jersey net operating losses. As of September 30, 2023, we had approximately \$2.9 million in cash and cash equivalents.

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

As we develop as a commercial company, we anticipate that our operating expenses will be primarily focused on commercialization activities for Twirla. We also expect a portion of our operating expenses in the future will be related to research and development as we design and conduct our long-term, prospective observational safety study for Twirla, which is a post marketing requirement from the FDA, and evaluate the development of our pipeline. As of September 30, 2023, we have significantly reduced our operating expenses through several measures, including optimizing our sales force, reorganizing our internal operations, reducing our advertising spend, and reorganizing our executive leadership team and general personnel. We are committed to continuing to explore ways to reduce expenses in a manner that allows us to simultaneously focus efforts and available resources on the commercialization, uptake and growth of Twirla. Our ability to reduce our operating loss and begin to generate positive cash flow from operations depends on the continued success in commercializing Twirla and maintaining discipline over our operating expenses. We continue to explore business development opportunities to commercialize a second product, and to do so in a way that we believe would contribute to our ability to reduce our operating losses and reduce our time to achieving positive cash flow from operations.

Going Concern

As of December 31, 2023, our unaudited cash and cash equivalents were approximately \$2.5 million, which will not be sufficient to fund our current and planned operations through December 31, 2024. We closely monitor our cash and cash equivalents and expect that our current cash will support operations through February 2024.

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

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

The unaudited financial statements as of September 30, 2023 have been prepared under the assumption that we will continue as a going concern for the 12 months following the date on which this prospectus 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 continue the commercial growth of Twirla. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

Financial Operations Overview

Revenue

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

For the years ended December 31, 2022 and 2021, net sales totaled \$10.9 million and \$4.1 million, respectively, representing the sale of 114,546 units and 35,172 units, respectively. The increase in net sales was driven by increased sales in both the retail and non-retail channels.

For the three months ended September 30, 2023 and 2022, net sales totaled \$6.7 million and \$3.0 million, respectively, representing the sale of 74,424 units and 33,072 units, respectively. For the nine months ended September 30, 2023 and 2022, net sales totaled \$16.0 million and \$6.9 million, respectively, representing the sale of 179,640 units and 71,442 units, respectively.

Cost of Product Revenues

Cost of product revenues include direct and indirect costs related to the manufacturing of Twirla sold, including packaging services, freight, obsolescence, and allocation of overhead costs that are primarily fixed such as depreciation, salaries and benefits, and insurance. We expect these relatively fixed costs to become less significant as a percentage of sales with anticipated volume increases.

For the years ended December 31, 2022 and 2021, cost of product revenues totaled \$6.8 million and \$10.7 million, respectively.

For the three months ended September 30, 2023 and 2022, cost of product revenues totaled \$2.5 million and \$1.4 million, respectively. For the nine months ended September 30, 2023 and 2022, cost of product revenues totaled \$6.8 million and \$5.2 million, respectively.

Research and Development Expenses

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

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

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

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

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

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

For the three months ended September 30, 2023 and 2022, our research and development expenses were approximately \$0.7 million and \$0.8 million, respectively. For the nine months ended September 30, 2023 and 2022, our research and development expenses were approximately \$2.2 million and \$2.9 million, respectively. The following table summarizes our research and development expenses by functional area.

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	(In thousands)		(In thousands)	
	2023	2022	2023	2022
Clinical development	\$ 29	\$ 115	\$ 108	\$ 917
Regulatory	176	107	408	366
Personnel related	406	476	1,394	1,334
Stock-based compensation	94	90	261	284
Total research and development expenses	<u>\$ 705</u>	<u>\$ 788</u>	<u>\$ 2,171</u>	<u>\$ 2,901</u>

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 U.S. Food and Drug Administration (“FDA”) or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, or experience issues with our manufacturing capabilities, we could be required to expend significant additional financial resources and time with respect to the development of that product candidate. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, coupled with an assessment of each product candidate’s commercial potential. Substantially all of our resources are currently dedicated to continuing to commercialize Twirla.

Selling and Marketing Expenses

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

For the years ended December 31, 2022, 2021 and 2020, our selling and marketing expenses totaled approximately \$30.4 million, \$43.4 million and \$23.3 million, respectively. Our commercial launch of Twirla in the United States utilized a contract sales force.

For the three months ended September 30, 2023 and 2022, our selling and marketing expenses totaled approximately \$4.8 million and \$5.6 million, respectively. For the nine months ended September 30, 2023 and 2022, our selling and marketing expenses totaled approximately \$14.0 million and \$23.5 million, respectively. Since the commercial launch of Twirla in the United States, we have utilized a contract sales force. We anticipate that our selling and marketing expenses will continue to be significant as our commercialization efforts continue.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance and administrative functions including payroll taxes and health insurance, stock-based compensation and travel

expenses. Other general and administrative expenses include facility-related costs, insurance and professional fees for legal, patent review, consulting, and accounting services. General and administrative expenses are expensed as incurred.

For the years ended December 31, 2022, 2021 and 2020, our general and administrative expenses totaled approximately \$11.9 million, \$14.7 million and \$12.7 million, respectively.

For the three months ended September 30, 2023 and 2022, our general and administrative expenses totaled approximately \$2.7 million and \$2.8 million, respectively. For the nine months ended September 30, 2023 and 2022, our general and administrative expenses totaled approximately \$8.8 million and \$9.8 million, respectively. We anticipate that our general and administrative expenses will stabilize in the future.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations is 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 prospectus. We believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

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

In accordance with ASC 606, we recognize revenue when our performance obligation is satisfied by transferring control of the product to a customer. Per our contracts with customers, control of the product is transferred upon the conveyance of title, which occurs when the product is sold to and received by a customer. Trade accounts receivable due to us from contracts with our customers are stated separately in the balance sheet, net of various allowances as described in the Trade Accounts Receivable policy in note 3 to the financial statements as of December 31, 2022, "Summary of Significant Accounting Policies."

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

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

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

Cost of Product Revenues

Costs of product revenues consist of direct and indirect costs related to the manufacturing of Twirla sold, including third-party manufacturing costs, packaging services, freight, obsolescence, and allocation of overhead costs.

Accrued Research and Development Expenses

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

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

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

Warrants

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

All Perceptive Warrants are accounted for in equity, whereas all warrants associated with our various financings are accounted for as liabilities. In accordance with ASC Topic 815-40, *Derivatives and Hedging, Contracts in Entity's Own Equity*, these liabilities are measured at fair value upon issuance, with subsequent changes in fair value reported in the Statement of Operations each reporting period. Initial fair value measurements are recorded as liabilities with any

excess value over net cash proceeds representing a current period loss, in the event fair value is less than the net cash proceeds, the remaining value is recorded in additional paid-in capital.

In February 2020 we entered into a senior secured term loan facility with Perceptive Credit Holdings III, L.P. (“Perceptive”), pursuant to which we issued warrants to purchase 35,000 shares of our common stock to Perceptive. In connection with an amendment to that facility in February 2021, we issued additional warrants to purchase 11,250 shares of our common stock (together with the February 2020 warrants, the “Perceptive Warrants”). The Perceptive Warrants qualify for equity classification and have been allocated based upon the relative fair value of the base instrument and the warrant. The Perceptive Warrants are subject to repricing in the event of an offering of securities at a price lower than the existing strike price before December 31, 2022. In connection with the Waiver and Sixth Amendment to the Perceptive Credit Agreement (the “Sixth Amendment”), we amended and restated the Perceptive Warrants to reset the strike price of the Perceptive Warrants. See note 10 to the financial statements as of December 31, 2022 for additional information.

In connection with an underwritten public offering completed in October 2021, we issued warrants to purchase 333,333 shares of our common stock. This offering triggered an adjustment to the exercise price of the Perceptive Warrants, which resulted in a reduction of the strike price for these warrants. This reduction resulted in an immaterial increase to additional paid-in-capital. See note 10 to the financial statements as of December 31, 2022 for additional information.

In connection with a registered direct offering completed in March 2022 we issued warrants to purchase 1,242,813 shares of our common stock. This offering also triggered an adjustment to the exercise price of the Perceptive Warrants, which resulted in a reduction of the strike price for these warrants. This reduction resulted in an immaterial increase to additional paid-in-capital. See note 10 to the financial statements as of December 31, 2022 for additional information.

In connection with a letter agreement and waiver entered into with an investor on April 2022, we issued warrants to purchase 212,188 shares of common stock. See note 10 to the financial statements as of December 31, 2022 for additional information.

In connection with a public offering completed in July 2022 we issued warrants to purchase 54,666,665 shares of our common stock. This offering also triggered an adjustment to the exercise price of the Perceptive Warrants, which resulted in a reduction of the strike price for these warrants.

Stock-Based Compensation

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

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

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

Results of Operations

Comparison of Years Ended December 31, 2022 and 2021

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

Revenues. Revenues, net increased by \$6.8 million, or 165%, from \$4.1 million for the year ended December 31, 2021, to \$10.9 million for the year ended December 31, 2022. Unit sales increased by approximately 79,000 units, or 226%, from 35,172 units for the year ended December 31, 2021, to 114,546 units for the year ended December 31, 2022. The decrease percentage in growth between dollars and units pertains to increased price discounts offered to the non-retail sales channel. Revenue, net consists of sales of Twirla, which was approved by the FDA in February 2020 and launched in the US in December 2020, and reflects the shipment of Twirla to specialty distributors, net of estimates for applicable variable consideration, which consist primarily of wholesale distribution fees, prompt pay and other discounts, rebates, chargebacks, product returns and co-pay assistance programs.

Cost of product revenues. Costs of product revenues decreased by \$3.9 million, or 36% from \$10.7 million for the year ended December 31, 2021, to \$6.8 million for the year ended December 31, 2022. Costs of product revenues consist of direct and indirect costs related to the manufacturing of Twirla sold, including third-party manufacturing costs, packaging services, freight, obsolescence and allocation of overhead costs that are primarily fixed such as depreciation, salaries and benefits, and insurance. Cost of product revenues for the year ended December 31, 2021 included approximately \$5.3 million of obsolescence reserves for inventory not expected to be sold prior to its shelf-life date.

Research and development expenses. Research and development expenses decreased by \$3.0 million, or 48%, from \$6.2 million for the year ended December 31, 2021 to \$3.3 million for the year ended December 31, 2022. This decrease in research and development expenses was primarily due to a decrease in clinical development expenses of \$2.4 million for the year ended December 31, 2022 as compared to the year ended December 31, 2021. This decrease reflects a reduction in spending related to our pipeline evaluation and development.

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

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

Loss on disposition of assets. In accordance with ASC 610-20, we recognized an \$11.1 million one-time, non-cash charge, which represents the loss on the transfer of fixed assets to Corium in connection with the amended Corium agreement (see note 13 to the financial statements as of December 31, 2022).

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

Interest expense. Interest expense is attributable to our term loan with Perceptive and includes the amortization of the discount associated with allocating value to the common stock warrants issued to Perceptive and the amortization of the deferred financing costs associated with the term loan. Interest expense decreased by \$0.8 million, from \$3.9 million for the year ended December 31, 2021 to \$3.1 million for the year ended December 31, 2022, due to principal payments made throughout 2022.

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

Net Operating Losses and Tax Carryforwards

As of December 31, 2022, we had approximately \$390.6 million of federal and \$79.90 million of state net operating loss carryforwards. We also potentially have federal and state research and development tax credits which would offset future taxable income. We have not completed a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since our inception, due to the significant costs and complexities associated with such studies. Accordingly, our ability to utilize the aforementioned carryforwards may be limited. Additionally, for federal net operating losses generated prior to 2018, U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes. As of December 31, 2022, all of our net operating losses were fully offset by a valuation allowance.

Comparison of the Three Months Ended September 30, 2023 and 2022

	Three Months Ended September 30, (In thousands)		Change
	2023	2022	
Revenues, net	\$ 6,662	\$ 3,002	\$ 3,660
Cost of product revenues	2,477	1,425	1,052
Gross profit	4,185	1,577	2,608
Operating expenses:			
Research and development	\$ 705	\$ 788	\$ (83)
Selling and marketing	4,800	5,560	(760)
General and administrative	2,680	2,815	(135)
Loss on disposition of assets	—	11,122	(11,122)
Total operating expenses	8,185	20,285	(12,100)
Loss from operations	\$ (4,000)	\$ (18,708)	14,708
Other income (expense)			
Interest income	13	46	(33)
Interest expense	(341)	(1,004)	663
Unrealized gain on warrant liability	3,529	13,736	(10,207)
Total other income, net	3,201	12,778	(9,577)
Loss before benefit from income taxes	(799)	(5,930)	5,131
Benefit from income taxes	—	—	—
Net loss	\$ (799)	\$ (5,930)	\$ 5,131

Revenues. Revenue, net increased by \$3.7 million, or 122% from \$3.0 million for the three months ended September 30, 2022 to \$6.7 million for the three months ended September 30, 2023. Unit sales increased by 41,352 units, or 125%, from 33,072 units for the three months ended September 30, 2022, to 74,424 units for the three months ended September 30, 2023. The decrease in the percentage of growth between dollars and units pertains to increased price discounts offered to the non-retail sales channel. Revenue, net consists of sales of Twirla and reflects the shipment of Twirla to specialty distributors, net of estimates for applicable variable consideration, which consist primarily of wholesale distribution fees, prompt pay and other discounts, rebates, chargebacks, product returns, and co-pay assistance programs.

Cost of product revenues. Cost of product revenues increased by \$1.1 million, or 74% for the three months ended September 30, 2022 to \$2.5 million for the three months ended September 30, 2023 and consists of direct and indirect costs related to the manufacturing of Twirla sold, including third-party manufacturing costs, packaging services, freight, and allocations of overhead costs that are primarily fixed, such as salaries, benefits, and insurance.

Research and development expenses. Research and development expenses decreased by \$0.1 million, or 11%, from \$0.8 million for the three months ended September 30, 2022 to \$0.7 million for the three months ended September 30, 2023. This decrease in research and development expenses was primarily due to a decrease in clinical development expenses for the three months ended September 30, 2023 as compared to the three months ended September 30, 2022. This decrease primarily reflects a decrease in personnel costs and decreased consulting expenses.

Selling and marketing expenses. Selling and marketing expenses decreased by \$0.8 million, or 14%, from \$5.6 million for the three months ended September 30, 2022 to \$4.8 million for the three months ended September 30, 2023. This decrease in selling and marketing expenses is due to reduced spending on marketing initiatives and the continued optimization of our contract sales force.

General and administrative expenses. General and administrative expense decreased by \$0.1 million, or 5%, from \$2.8 million for the three months ended September 30, 2022 to \$2.7 million for the three months ended September 30, 2023.

Loss on disposition of assets. In accordance with ASC 610-20, we recognized an \$11.1 million, one-time, non-cash charge during the three months ended September 30, 2022, which represented the loss on the transfer of fixed assets

to Corium in connection with the amended Corium Agreement. There was no comparable expense during the three months ended September 30, 2023.

Interest income. Interest income comprises interest earned on cash and cash equivalents.

Interest expense. Interest expense is attributable to our term loan with Perceptive and includes the amortization of the discount associated with allocating value to the common stock warrants issued to Perceptive and the amortization of the deferred financing costs associated with the term loan. Interest expense decreased by \$0.7 million for the three months ended September 30, 2023 compared to the three months ended September 30, 2022 due to the reduction in the principal amount outstanding on the loan.

Unrealized gain on warrant liability. Unrealized gain on warrant liability reflects the non-cash changes in the estimated fair value of the warrant liability.

Comparison of the Nine Months Ended September 30, 2023 and 2022

	Nine Months Ended September 30, (In thousands)		Change
	2023	2022	
Revenues, net	\$ 15,979	\$ 6,888	\$ 9,091
Cost of product revenues	6,787	5,183	1,604
Gross profit	9,192	1,705	7,487
Operating expenses:			
Research and development	\$ 2,171	\$ 2,901	\$ (730)
Selling and marketing	14,040	23,523	(9,483)
General and administrative	8,813	9,837	(1,024)
Loss on disposition of assets	—	11,122	(11,122)
Total operating expenses	25,024	47,383	(22,359)
Loss from operations	\$ (15,832)	\$ (45,678)	29,846
Other income (expense)			
Interest income	61	50	11
Interest expense	(1,114)	(2,699)	1,585
Unrealized gain on warrant liability	6,890	22,171	(15,281)
Total other income (expense), net	5,837	19,522	(13,685)
Loss before benefit from income taxes	(9,995)	(26,156)	16,161
Benefit from income taxes	—	4,675	(4,675)
Net loss	\$ (9,995)	\$ (21,481)	\$ 11,486

Revenues. Revenue, net increased by \$9.1 million or 132% from \$6.9 million for the nine months ended September 30, 2022 to \$16.0 million for the nine months ended September 30, 2023. Unit sales increased by 108,198 units, or 151%, from 71,442 units for the nine months ended September 30, 2022, to 179,640 units for the nine months ended September 30, 2023. The decrease in the percentage of growth between dollars and units pertains to increased price discounts offered to the non-retail sales channel. Revenue, net consists of sales of Twirla and reflects the shipment of Twirla to specialty distributors, net of estimates for applicable variable consideration, which consist primarily of wholesale distribution fees, prompt pay and other discounts, rebates, chargebacks, product returns, and co-pay assistance programs.

Cost of product revenues. Cost of product revenues increased by \$1.6 million or 31% from \$5.2 million for the nine months ended September 30, 2022 to \$6.8 million for the nine months ended September 30, 2023, and consists of direct and indirect costs related to the manufacturing of Twirla sold, including third-party manufacturing costs, packaging services, freight, and allocations of overhead costs that are primarily fixed such as salaries, benefits, and insurance.

Research and development expenses. Research and development expenses decreased by \$0.7 million or 25% from \$2.9 million for the nine months ended September 30, 2022 to \$2.2 million for the nine months ended September 30, 2023. This decrease in research and development expenses was primarily due to a decrease in clinical development

expenses of \$0.8 million for the nine months ended September 30, 2023 as compared to the nine months ended September 30, 2022. This decrease reflects a reduction in spending related to our pipeline evaluation and development.

Selling and marketing expenses. Selling and marketing expenses decreased by \$9.5 million, or 40%, from \$23.5 million for the nine months ended September 30, 2022 to \$14.0 million for the nine months ended September 30, 2023. This decrease in selling and marketing expenses is due to reduced spending on marketing initiatives and the optimization of our contract sales force.

General and administrative expenses. General and administrative expenses decreased by \$1.0 million, or 10%, from \$9.8 million for the nine months ended September 30, 2022 to \$8.8 million for the nine months ended September 30, 2023. This decrease in general and administrative expense was primarily due to lower personnel-related costs due to lower headcount.

Loss on disposition of assets. In accordance with ASC 610-20, we recognized an \$11.1 million, one-time, non-cash charge during the nine months ended September 30, 2022, which represented the loss on the transfer of fixed assets to Corium in connection with the amended Corium Agreement. There was no comparable expense during the nine months ended September 30, 2023.

Interest income. Interest income comprises interest earned on cash and cash equivalents.

Interest expense. Interest expense is attributable to our term loan with Perceptive and includes the amortization of the discount associated with allocating value to the common stock warrants issued to Perceptive and the amortization of the deferred financing costs associated with the term loan. Interest expense decreased by \$1.6 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 due to the reduction in the principal amount outstanding on the loan.

Unrealized gain on warrant liability. Unrealized gain on warrant liability reflects the non-cash changes in the estimated fair value of the warrant liability.

Benefit from income taxes. Benefit from income taxes represents \$4.7 million received under the State of New Jersey's Technology Business Tax Certificate Transfer Program sponsored by The New Jersey Economic Development Authority during the nine months ended September 30, 2022.

Liquidity and Capital Resources

At December 31, 2022, we had cash and cash equivalents totaling \$5.2 million. We invest our cash equivalents and marketable securities in short-term highly liquid, interest-bearing investment-grade and government securities in order to preserve principal.

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

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

At September 30, 2023, we had cash and cash equivalents totaling \$2.9 million. We invest our cash equivalents 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:

	Nine Months Ended September 30,	
	(In thousands)	
	2023	2022
Net cash used in operating activities	\$ (9,748)	\$ (34,388)
Net cash used in investing activities	—	(133)
Net cash provided by financing activities	7,375	21,523
Net decrease in cash and cash equivalents	\$ (2,373)	\$ (12,998)

Operating Activities

Net cash used in operating activities was \$35.9 million for the year ended December 31, 2022 and consisted primarily of a net loss of \$25.4 million, a \$25.5 million non-cash gain on the warrant liability and a net increase in working capital items of \$2.1 million. These uses of cash were partially offset by non-cash stock-based compensation expense of \$2.5 million, an \$11.1 million non-cash loss on the disposition of assets, depreciation expense of \$1.3 million and \$2.2 million of other non-cash charges, primarily interest expense. Net cash used in operating activities was \$65.2 million for the year ended December 31, 2021 and consisted primarily of a net loss of \$71.1 million, a \$3.8 million non-cash gain on the warrant liability and a net increase in working capital items of \$2.9 million, largely an increase in inventory of \$6.3 million and an increase in prepaid expenses of \$1.0 million, offset by an increase in accounts payable and accrued expenses of \$5.2 million. These uses of cash were partially offset by non-cash stock-based compensation expense of \$3.3 million, a non-cash inventory reserve of \$5.3 million, depreciation expense of \$2.1 million and \$1.8 million of other non-cash charges, primarily interest expense. Net cash used in operating activities was \$47.3 million for the year ended December 31, 2021 and consisted primarily of a net loss of \$51.9 million, offset by non-cash stock-based compensation expense of \$2.8 million, and \$1.6 million of other non-cash charges, primarily interest expense. Our net change in operating assets and liabilities was negligible.

Net cash used in operating activities was \$9.8 million for the nine months ended September 30, 2023 and consisted primarily of a net loss of \$9.3 million offset by a \$6.9 million unrealized gain on warrants, non-cash stock-based compensation expense of \$1.4 million, \$1.1 million of other non-cash charges, primarily interest expense, and \$3.9 million of positive working capital changes, primarily an increase in accounts payable and accrued expenses and a decrease in deposits. Net cash used in operating activities was \$34.4 million for the nine months ended September 30, 2022 and consisted primarily of a net loss of \$43.6 million and negative working capital changes of \$7.0 million, offset by non-cash stock-based compensation expense of \$2.0 million, depreciation expense of \$1.3 million, a \$11.1 million non-cash loss on the disposition of fixed assets, and \$1.8 million of other charges, primarily interest expense.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2022 was \$0.1 million and represents purchases of property and equipment. Net cash provided by investing activities for the year ended December 31, 2021 was \$39.5 million and primarily represents net sales and maturities of marketable securities. Net cash used in investing activities for the years ended December 31, 2020 was \$40.7 million. Cash used in investing activities for the year ended December 31, 2020 primarily represents net purchases of marketable securities of \$40.3 million with the balance being the acquisition of equipment to be used in the commercialization of Twirla.

Net cash used in investing activities for the nine months ended September 30, 2023 was zero. Net cash used in investing activities for the nine months ended September 30, 2022 was \$0.1 million and consisted of acquisitions of equipment.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2022 was \$22.2 million, which primarily represents net proceeds of \$21.9 million received from the issuance of 26,666,666 shares of our common stock through a public offering, net proceeds of \$4.1 million from the sale of 4,850 shares of preferred stock in a registered direct offering, and net proceeds of \$13.5 million from the sale of 12,655,773 shares of common stock through at-the-market, or ATM sales programs. These proceeds were partially offset by \$17.4 million of long-term debt payments. Net cash

provided by financing activities for the year ended December 31, 2021 was \$30.4 million, which primarily represents net proceeds of \$21.1 million received from the issuance of 666,666 shares of our common stock through a public offering and net proceeds of \$9.3 million from the sale of 172,8749 shares of common stock through at-the-market, or ATM sales programs. Net cash provided by financing activities for the year ended December 31, 2020 was \$68.0 million, which primarily represents net proceeds of \$48.4 million received from the issuance of 431,250 shares of our common stock through a public offering, proceeds of \$20.0 million from the Perceptive term loan, and stock option exercise proceeds of \$0.6 million. These proceeds were partially offset by debt financing costs of \$1.0 million.

Net cash provided by financing activities for the nine months ended September 30, 2023 was \$7.4 million, which consists of net proceeds of \$6.5 million from a public offering of common stock and prefunded warrants, \$1.7 million from the sale of 207,882 shares of our common stock through an at-the-market, or ATM, sales program partially offset by \$0.7 million of principal payments on our debt. Net cash provided by financing activities for the nine months ended September 30, 2022 was \$21.5 million, which consisted of net proceeds of \$4.1 million from the sale of preferred stock in a registered offering, \$22.0 million from the sale of 533,333 shares of common stock in a public offering and proceeds of \$12.6 million from the sale of 174,263 shares of our common stock through an at-the-market, or ATM sales program, partially offset by a principal payment of short-term debt of \$17.0 million.

Funding Requirements and Other Liquidity Matters

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

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

On March 13, 2022, we entered into a Securities Purchase Agreement (the “Purchase Agreement”) with a single healthcare-focused institutional investor (the “Purchaser”), pursuant to which we issued, in a registered direct offering (the “2022 Preferred Stock Offering”), 2,425 shares of Series A convertible preferred stock (the “Series A Preferred Stock”) and 2,425 shares of Series B convertible preferred stock (the “Series B Preferred Stock”) and Series A warrants (the “Series A Warrants”) to purchase up to an aggregate of 12,125 shares of the common stock of the Company (the “Common Stock”) and Series B warrants (the “Series B Warrants”) to purchase up to an aggregate of 12,125 shares of Common Stock. Each share of Series A Preferred Stock and Series B Preferred Stock has a stated value of \$1,000 per share and a conversion price of \$400.00 per share. The shares of preferred stock issued in the offering are convertible into an aggregate of 12,125 shares of Common Stock. The Series A Warrants have an exercise price of \$520.00 per share, will become exercisable six months following the date of issuance, and will expire 5 years following the initial exercise date. The Series B Warrants have an exercise price of \$520.00 per share, will become exercisable six months following the date of issuance, and will expire one and one-half years following the initial exercise date. The Purchase Agreement contains customary representations and warranties and agreements of the Company and the Purchaser and customary indemnification rights and obligations of the parties. The 2022 Preferred Stock Offering closed on March 14, 2022 and total net proceeds were approximately \$4.3 million.

On April 25, 2022, we entered into a Letter Agreement with the Purchaser, pursuant to which the Purchasers consented to us entering into and effecting an ATM offering facility. Pursuant to the Letter Agreement, we issued to the Purchaser the New Warrant, on the same terms and conditions as the Series A Warrants, provided that such New Warrant shall be exercisable into 4,243 warrant shares, subject to adjustment thereunder. The Series A Warrants have an exercise price of \$520.00 per share, will become exercisable six months after the date of the Letter Agreement, and will expire 5 years following the initial exercise date.

On April 27, 2022, we entered into the April 2022 ATM Agreement under which we are authorized to sell up to an aggregate of \$12.8 million in gross proceeds through the sale of shares of common stock from time to time in the April 2022 ATM. We agreed to pay a commission of up to 3% of the gross proceeds of any common stock sold under this agreement. Through September 30, 2022, we issued and sold a total of 173,750 shares of common stock under the April 2022 ATM Agreement, representing the entire capacity of the April 2022 ATM, resulting in net proceeds of approximately \$12.2 million. On August 22, 2022, we increased the April 2022 ATM (“August 2022 ATM”). As increased, we were eligible to offer and sell, from time to time through the Sales Agent, shares of our common stock having an aggregate offering price of up to \$75.0 million. During the year ended December 31, 2022, we issued and sold 78,852 shares of common stock under the August 2022 ATM resulting in net proceeds to us of approximately \$0.9 million. During the nine months ended September 30, 2023, we issued and sold 207,883 shares resulting in net proceeds of approximately \$1.7 million. On April 12, 2023, we filed a prospectus supplement to our registration statement on Form S-3 for the August 2022 ATM verifying that we were then eligible to sell up to \$4.5 million worth of shares through our ATM.

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

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

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

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

We may also need to raise additional funds if we need to change components of our commercial plan or if 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, forego future development and other opportunities or even terminate our operations, which may involve

seeking bankruptcy protection. Because of the numerous risks and uncertainties associated with such developments, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the commercialization of Twirla. Our future capital requirements will depend on many factors, including:

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

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

Contractual Obligations and Commitments

In April 2020, we entered into a Manufacturing and Commercialization Agreement (the “Corium Agreement”) with Corium Innovations, Inc., (“Corium”) which replaced our previous development agreement. Pursuant to the Corium Agreement, Corium will manufacture and supply all of our product requirements for Twirla at certain specified rates. Under the terms of the Corium Agreement, Corium is to be the exclusive supplier of Twirla for ten years. The Corium Agreement included a quarterly minimum purchase commitment and a fixed price per unit for two years from December 2020, the date of the first commercial batch purchase order invoice, depending on annual purchase volume. During 2021, we did not meet all of our minimum quantity purchases from Corium, and as a result, paid penalties as required by our agreement with Corium. On July 25, 2022 we, along with Corium, amended the Corium Agreement to restructure the minimums applicable to the purchase of manufactured Twirla and to extend the term of the Corium Agreement until December 31, 2033. The Corium Agreement terminates automatically on December 31, 2033, but may be terminated for any reason upon the written mutual agreement of both parties; provided, however, that the parties must confer in good faith regarding possible mutual termination. In the event of such termination, we may still submit purchase orders after the notice of termination is given and until the time any such termination becomes effective. As of September 30, 2023, the minimum amount committed totals \$230.1 million.

In April 2020, we entered into a project agreement with inVentiv Commercial Services, LLC, or inVentiv, a Syneos Health Group Company, which we refer to as the Syneos Agreement, under our Master Services Agreement with inVentiv. Pursuant to the Syneos Agreement, inVentiv, through its affiliate Syneos Selling Solutions, will provide a field force of sales representatives to provide certain detailing services, sales operation services, compliance services, and training services with respect to Twirla to us in exchange for an up-front implementation fee and a fixed monthly fee. Effective February 1, 2022, we entered into an amendment to the Syneos Agreement that extended the term until August 23, 2024. At that time, the Syneos Agreement will terminate automatically unless extended upon the mutual written agreement of the parties. We may terminate the Syneos Agreement for any reason upon timely written notice without incurring a termination fee. On September 28, 2023, we entered into the Seventh Amendment to the Syneos Agreement, pursuant to which we will pay Syneos a fixed weekly fee for the performance of Services (as defined in the Syneos Agreement) through August 23, 2024. As of September 30, 2023, the minimum amount committed totals \$2.4 million.

Our operating lease commitment relates to our lease of office space in Princeton, New Jersey. The lease for this space commenced in December 2021, and the minimum payments over the remaining 18-month term totals \$0.6 million as of September 30, 2023.

Recent Accounting Pronouncements

See Note 3 to the financial statements as of December 31, 2022 that discusses new accounting pronouncements.

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 and cash equivalents of \$2.9 million and \$5.2 million at September 30, 2023 and December 31, 2022, respectively, consisting primarily of funds in cash and money market accounts. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our investment portfolio, we do not believe an immediate 10.0% increase in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

Our results of operations and cash flows are subject to fluctuations due to changes in interest rates. We do not believe that we are materially exposed to changes in interest rates. We do not currently use interest rate derivative instruments to manage exposure to interest rate changes. Based on average debt outstanding of \$9.8 million for the year ended December 31, 2022, a 1% increase or decrease in interest rates would have increased or decreased interest expense by \$0.1 million for the year ended December 31, 2022. We estimated that a 1% unfavorable change in interest rates would not have a material effect on interest expense for the nine months ended September 30, 2023.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and pricing of contracts and agreements. We do not believe that inflation had a material effect on our business, financial condition, or results of operations during the year ended December 31, 2022 or the nine months ended September 30, 2023.

CORPORATE GOVERNANCE

Corporate Governance Materials and Practices

Our board of directors (the “Board”) structure reflects our Corporate Governance Principles and commitment to good governance. The Board believes the governance structure we have created among the Board, its committees, the Lead Independent Director, the Board chairperson and Chief Executive Officer, and management is supporting the growth of the Company.

Our written corporate governance materials, including our Bylaws, Corporate Governance Guidelines, Code of Business Conduct and Ethics, Audit Committee Charter, Compensation Committee Charter, Nominating and Corporate Governance Committee Charter, and Science and Technology Committee Charter are posted on our website at www.agiletherapeutics.com under the heading “Investor Relations—Corporate Governance.” Our corporate governance practices include the following:

- Our Board has a Lead Independent Director, and all of our non-employee directors and committee members are independent.
- Our Board oversees succession planning for executive officers, including the Chief Executive Officer.
- Directors have access to all levels of management and are provided with opportunities to meet with members of management on a regular basis.
- Directors may retain their own independent advisors at our expense.
- Our Board and each committee thereof conduct self-evaluations at least once per year to assess their performance and ways in which performance could be improved.
- Our Board addresses the importance of incorporating new viewpoints through the director evaluation and nomination process. Our director composition reflects a mix of tenure on our Board (ranging from 1 year to 17 years), which we believe provides an effective balance of historical perspective and an understanding of the evolution of the Company with fresh perspectives and insights.

Board Diversity Matrix

The tables below provide certain highlights of the composition of our Board as of December 31, 2023. Each of the categories listed in the tables below has the meaning as it is used in Nasdaq Rule 5605(f).

Board Diversity Matrix				
Total Number of Directors	6			
	Female	Male	Non-Binary	Did Not Disclose Gender
Part I: Gender Identity				
Directors	3	3	0	0
Part II: Demographic Background				
African American or Black	0	0	0	0
Alaskan Native or Native American	0	0	0	0
Asian	0	0	0	0
Hispanic or Latinx	0	0	0	0
Native Hawaiian or Pacific Islander	0	0	0	0
White	3	2	0	0
Two or More Races or Ethnicities	0	0	0	0
LGBTQ+	0			
Did Not Disclose Demographic Background	1			

Environmental, Social and Governance Considerations

We are a women’s healthcare company dedicated to fulfilling the unmet needs of today’s women, and we take our responsibility to patients, employees, the medical community, and the communities in which we live and work very seriously. We are an emerging company that is focused on growing as a commercial organization. We recognize that as we grow, we have an opportunity to positively influence a variety of environmental, social and governance (“ESG”) considerations and partner with companies that reflect our values as a company and our commitment to our larger community. Our Board helps to shape and monitor management’s approach to ESG. We plan to seek ways to incorporate these ESG considerations into our business plans with a strategic focus on the following areas:

Diversity, Equity and Inclusion: We are focused on promoting diversity in our workforce and to taking steps to support equity and inclusion for all. We believe that these values provide us with a competitive advantage that can drive creative and innovative thinking and ultimately enhance our business. We have a diverse Board and leadership team supporting our commercial operations. Overall, of the last seven (7) openings on our Board and management team, six (6) have been filled with women candidates. We continue to strive to enhance our Board and workforce diversity by ensuring we have a gender-balanced and diverse slate of qualified candidates for all open positions, advancing the development of diverse talent, and pursuing diverse succession plans both in our employee workforce and our Board.

Patient Support: Advancing women’s health is at the core of our mission. Our current product and product candidates are designed to offer women more freedom and flexibility through additional contraceptive options. The key phase 3 clinical trial we conducted to support the approval of Twirla, our transdermal contraceptive product, included a broad and diverse population of women representative of the U.S. female population seeking hormonal contraception. The trial included women across a broad range of demographic characteristics such as age, race, ethnicity and weight and was one of the first trials to generate data on the relationship between body mass index, or BMI, and the safety and efficacy of a hormonal contraceptive. Our goal is to make our products as accessible as possible in all communities, and we are working with numerous stakeholders to enable this access as appropriate. We seek to support this objective with a comprehensive series of programs that include educational, product replacement and co-pay support (implemented in a compliant way). We also have engaged more broadly with women’s health advocacy groups and other advisory groups to understand the needs of the patients we seek to help.

Employee Wellness: We believe that our employees are a key to our success. We are dedicated to investing in our employees and workplace culture. As part of this effort, we have put in place several financial wellness programs to help empower our workforce including offering a 401(k) match program, short-term and long-term disability insurance, and educational programs to help employees understand how to manage their finances. We also offer several programs to promote the physical and mental wellbeing of our employees, including an employee assistance program, disease management and prevention programs and financial incentives to encourage physical and emotional health.

Environmental Impact: We are cognizant of our responsibility to our broader environment and our need to grow in a sustainable way. Prior to the pandemic and working remotely, we supported several green measures in an effort to reduce our Company's carbon footprint in our corporate office. We continue to evaluate ways to enhance these and other sustainability measures as we make plans to build out our business.

Governance: We have adopted a Code of Business Conduct and Ethics (the "Code") which applies to all of our employees, officers and directors and outlines our commitment to ethical and compliant business practices. We promote compliance with all relevant government laws, rules and regulations; honest and ethical conduct; protection of company assets; and fair dealings and timely and accurate disclosures in all company reporting. All employees are required to understand, comply with and report any suspected violations of the Code, and the Code is reviewed periodically to ensure it is appropriate in scope and achieves the objectives above.

Community Service: We are committed to giving back to our communities. We partake in several employee-led community service initiatives. Through our internal community outreach program – Agile Cares – and we host from time to time team-building events to support causes that are meaningful to our employees and our overall mission.

Code of Business Conduct and Ethics

Our Board has adopted a code of business conduct and ethics. The code of business conduct and ethics ("CBCE") applies to all of our employees, officers and directors. The CBCE provides guidance on fundamental ethical and compliance-related principles and practices such as: accurate record keeping and reporting; avoiding conflicts of interest; protection and proper use of property and information; and compliance with legal and regulatory requirements. The full text of our code of business conduct and ethics is posted on our website at www.agiletherapeutics.com. We intend to disclose, to the extent required by applicable rules and regulations, future amendments to, or waivers of, our code of business conduct and ethics, at the same location on our website identified above or in public filings we will make with the SEC. Information contained on our website is not incorporated by reference, and you should not consider information contained on our website to be part of this prospectus.

Hedging and Pledging Policies

We have adopted an insider trading policy that includes a provision that restricts our directors, officers and employees from engaging in hedging or monetization transactions involving our securities, and from engaging in short sales of our securities. Our insider trading policy also prohibits our directors, officers and employees from holding our securities in margin accounts or otherwise pledging our securities as collateral for loans without prior written approval.

Board Composition

Our business affairs are managed under the direction of our Board, which is currently composed of six (6) members. Five (5) of our six (6) directors are independent within the meaning of the listing rules of the Nasdaq Capital Market, or Nasdaq. Our Board is divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. As a result, only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Each director's term continues until the election and qualification of his or her successor, or the earlier of his or her death, resignation or removal. The classification of our Board may have the effect of delaying or preventing changes in our control or management.

Board Leadership Structure

Al Altomari is the Chairperson of our Board, and Seth H.Z. Fischer is our Lead Independent Director. Our Lead Independent Director chairs the executive sessions of our Board meetings, oversees the Board's annual self-evaluation process, provides feedback to the Chief Executive Officer, and works with the Chief Executive Officer to set agendas for Board meetings. We have a separate chairperson for each committee of our Board, all of whom are independent directors. The chairpersons of each committee report on the activities of their committees in fulfilling their responsibilities at the meetings of our Board.

Our Board has concluded that our current leadership structure is appropriate at this time. However, our Board will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Board Committees

Our Board has established an audit committee, a compensation committee, a nominating and corporate governance committee, and a science and technology committee, each of which operates pursuant to a charter adopted by our Board. The composition and functioning of all of our committees complies with all applicable requirements of the Sarbanes-Oxley Act of 2002, Nasdaq and SEC rules and regulations.

Audit committee. Ms. Barbari, Mr. Fischer and Dr. Hubbard currently serve on the audit committee, which is chaired by Ms. Barbari. Our Board has determined that each member of the audit committee is "independent" for audit committee purposes as that term is defined in the rules of the SEC and the applicable Nasdaq rules, and has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our Board has determined that Ms. Barbari qualifies as an "audit committee financial expert," as defined under the applicable rules of the SEC. The audit committee operates under a written charter that satisfies the applicable standards of the SEC and Nasdaq and which is available on our website at www.agiletherapeutics.com. The inclusion of our website address here and elsewhere in this prospectus does not include or incorporate by reference the information on our website into this prospectus. Our audit committee met eight (8) times during the year ended December 31, 2023. The audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm on an annual basis;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with the independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and the independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending based upon the audit committee's review and discussions with management and the independent registered public accounting firm whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;

- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and approving all such transactions;
- reviewing the Company's risk assessment and risk management policies and procedures, and discussing with management the Company's significant financial risk exposures and the actions management has taken to limit, monitor or control such exposures, including, but not limited to, reviewing, on an on-going basis, cybersecurity; and
- reviewing quarterly earnings releases.

Compensation committee. Mr. Fischer, Dr. Carson and Sharon Barbari currently serve on the compensation committee, which is chaired by Mr. Fischer. Dr. Carson replaced Dr. Shetty on the committee when Dr. Shetty did not stand for re-election to the Board at the Company's annual meeting of stockholders on June 8, 2023. Our Board has determined that each member of the compensation committee is "independent" as defined in applicable Nasdaq rules. The compensation committee operates under a written charter that satisfies the applicable standards of Nasdaq and which is available on our website at www.agiletherapeutics.com. The inclusion of our website address here and elsewhere in this prospectus does not include or incorporate by reference the information on our website into this prospectus. Our compensation committee met six (6) times during the year ended December 31, 2023. The compensation committee's responsibilities include:

- annually reviewing and making recommendations to the Board with respect to corporate goals and objectives relevant to the compensation of our Chief Executive Officer;
- evaluating the performance of our chief executive officer in light of such corporate goals and objectives and making recommendations to the Board with respect to the compensation of our Chief Executive Officer;
- reviewing and approving the compensation of our other executive officers;
- reviewing and establishing our overall management compensation philosophy and policy;
- overseeing and administering our compensation and similar plans;
- reviewing and approving our policies and procedures for the grant of equity-based awards;
- reviewing and making recommendations to the Board with respect to director compensation;
- reviewing and discussing with management the compensation discussion and analysis, if any, to be included in our annual proxy statement or Annual Report on Form 10-K; and
- reviewing and discussing with the Board corporate succession plans for the Chief Executive Officer and other key officers.

Certain of our executive officers may provide information and assist our compensation committee in carrying out its functions, however, the Committee considers potential compensation actions and makes decisions independently. Our compensation committee has engaged the services of Pay Governance LLC, a compensation consulting firm, to advise the compensation committee regarding the amount and types of compensation that we provide to our executives and directors and how our compensation practices compare to the compensation practices of other companies. Pay Governance LLC reports directly to the compensation committee. Pay Governance LLC does not provide any services to us other than the services provided to the compensation committee. The compensation committee believes that Pay Governance LLC does not have any conflicts of interest in advising the compensation committee under applicable SEC rules or Nasdaq listing standards.

Nominating and corporate governance committee. Dr. Hubbard, Ms. Barbari, Dr. Carson, and Ms. Torrente currently serve on the nominating and corporate governance committee, which is chaired by Dr. Hubbard. Our Board has determined that each member of the nominating and corporate governance committee is “independent” as defined in applicable Nasdaq rules. The nominating and corporate governance committee operates under a written charter that satisfies the applicable standards of Nasdaq and which is available on our website at www.agiletherapeutics.com. The inclusion of our website address here and elsewhere in this prospectus does not include or incorporate by reference the information on our website into this prospectus. Our nominating and corporate governance committee met three (3) times during the year ended December 31, 2023. The nominating and corporate governance committee’s responsibilities include:

- developing and recommending to the Board criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- reviewing the size and composition of the Board to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- identifying individuals qualified to become members of the Board;
- recommending to the Board the persons to be nominated for election as directors and to each of the Board’s committees;
- developing and recommending to the Board a code of business conduct and ethics and a set of corporate governance guidelines;
- developing a mechanism by which violations of the code of business conduct and ethics can be reported in a confidential manner;
- overseeing the evaluation of the Board and management; and
- reviewing and reporting to the Board concerning our corporate social responsibility and sustainability efforts, including the impact of environmental and social issues on our company.

Science and Technology Committee. Ms. Torrente, Dr. Carson, and Dr. Hubbard currently serve on the science and technology committee, which is chaired by Ms. Torrente. Dr. Hubbard replaced Dr. Shetty on the committee when Dr. Shetty did not stand for re-election to the Board at the Company’s annual meeting of stockholders on June 8, 2023. The science and technology committee operates under a written charter, which is available on our website at www.agiletherapeutics.com. The inclusion of our website address here and elsewhere in this prospectus does not include or incorporate by reference the information on our website into this prospectus. Our science and technology committee met two (2) times during the year ended December 31, 2023. The science and technology committee’s responsibilities include:

- identifying and discussing new and emerging trends in pharmaceutical science, technology, pharmaceutical regulation and manufacturing, and, as necessary, reporting to the Board on such trends and the committee’s deliberations;
- reviewing, evaluating and advising the Board regarding the quality, direction and competitiveness of our research and development and manufacturing programs;
- reviewing, evaluating and advising the Board regarding our progress in achieving our long-term strategic research and development goals and objectives; reviewing and making recommendations to the Board on our internal and external investments in science, technology and manufacturing. For any external investments in research and development (e.g., potential acquisitions, alliances, collaborations, equity investments, contracts and grants) that require approval by the Board, the committee provides the Board with its recommendation prior to any action by the Board unless time does not permit;

- regularly reviewing our pipeline of product candidates and clinical development performance;
- providing assistance to the compensation committee in setting any pipeline or development performance metric(s) under our incentive compensation programs and reviewing the performance results;
- evaluating its own performance annually and delivering a report to the Board setting forth the results of the evaluation;
- reviewing and reassessing the adequacy of its charter annually and recommending any proposed changes to the Board for its approval; and
- performing any other activities consistent with its charter, our amended and restated bylaws and governing law or regulation, as the committee or the Board deems necessary or appropriate.

In December 2020, the board established an ad hoc finance committee to act on its behalf on matters relating to potential transactions to raise capital and to review potential business development transactions. Ms. Barbari, Mr. Fischer and Dr. Hubbard serve on the committee, which is chaired by Ms. Barbari. The committee met one (1) time during the year ended December 31, 2023. Our Board may from time to time establish other committees.

Meetings of the Board of Directors

The full Board met twelve (12) times during the year ended December 31, 2023. No director attended fewer than 75% of the total number of meetings of the Board and of any committees of the Board of which he or she was a member during our year ended December 31, 2023.

It is our policy that directors are invited and encouraged to attend our annual meetings of stockholders. We have scheduled our Annual Meeting on the same day as a regularly scheduled Board meeting in order to facilitate attendance by the members of our Board. All of our directors at the time of our 2023 Annual Meeting of Stockholders attended the 2023 Annual Meeting of Stockholders.

Board Oversight of Risk

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including risks relating to our operations, strategic direction and intellectual property as more fully discussed under “Risk Factors” in this prospectus. Management is responsible for the day-to-day management of risks we face, while our Board, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our Board has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The role of the Board in overseeing the management of our risks is conducted primarily through committees of the Board, as disclosed in the descriptions of each of the committees above and in the charters of each of the committees. For example, our audit committee is responsible for overseeing the management of risks associated with our financial reporting, accounting and auditing matters, regulatory and legal compliance, and cyber-security; our compensation committee oversees major risks associated with our compensation policies and programs; and our nominating and governance committee oversees the management of risks associated with director independence, conflicts of interest, composition and organization of our Board and director succession planning. The full Board (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management our major risk exposures, their potential impact on Agile, and the steps we take to manage them. When a Board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chairperson of the relevant committee reports on the discussion to the full Board during the committee reports portion of the next Board meeting. This enables the Board and its committees to coordinate the risk oversight role, particularly with respect to risk interrelationships.

EXECUTIVE OFFICERS AND DIRECTORS

The following table provides information concerning our executive officers and directors as of February 6, 2024:

Name	Age	Position
Alfred (Al) Altomari	65	Chairperson, Chief Executive Officer and Director
Scott M. Coiante	57	Senior Vice President, Chief Financial Officer
Robert G. Conway	67	Senior Vice President, Chief Corporate Planning & Supply Chain Officer
Geoffrey P. Gilmore	57	Senior Vice President, Chief Administrative Officer
Paul Korner	58	Senior Vice President, Chief Medical Officer
Amy Welsh	52	Senior Vice President, Chief Commercial Officer
Sharon Barbari	69	Director
Sandra Carson, M.D., FACOG	70	Director
Seth H.Z. Fischer	67	Director
John Hubbard, Ph.D., FCP	67	Director
Josephine Torrente	57	Director

Al Altomari. Alfred Altomari has served as our Chairperson of the Board and Chief Executive Officer since October 2016 and has been a member of our Board since February 2004. Mr. Altomari served as President and Chief Executive Officer from 2010 to 2016. Previously Mr. Altomari served as Agile's Executive Chairperson from 2004 to 2010. From 2003 to 2008, Mr. Altomari held multiple senior management positions at Barrier Therapeutics, Inc., including Chief Commercial Officer, Chief Operating Officer, and Chief Executive Officer. In 2008, in his role as Chief Executive Officer and as a member of Barrier's Board of Directors, Mr. Altomari completed the successful sale of Barrier to Stiefel Laboratories, which was subsequently acquired by GlaxoSmithKline plc. From 1982 to 2003, Mr. Altomari held numerous executive roles in general management, commercial operations, business development, product launch preparation, and finance with Johnson & Johnson. Mr. Altomari also serves on the Board of Directors of Insmed Inc. He previously served on the Board of Directors of Recro Pharm, Inc. and Baudax Bio. Mr. Altomari received an M.B.A. from Rider University and his B.S. from Drexel University. He currently serves as a Trustee of Drexel University and is on the LeBow College of Business Advisory Board and the Board of the Charles D. Close School of Entrepreneurship at Drexel University. We believe Mr. Altomari's qualifications to sit on our Board of Directors include his extensive pharmaceutical industry leadership and operations experience.

Scott M. Coiante. Mr. Coiante has been our Chief Financial Officer since August of 2023. He joined the Company from Aprea Therapeutics, Inc. where he served as the Chief Financial Officer from August 2019 until January 2023 and remained as an employee through March 31, 2023. Prior to joining Aprea Therapeutics, Inc., Mr. Coiante served as our Senior Vice President and Chief Financial Officer from 2010 to August 2019. From 2002 to 2010, Mr. Coiante was Vice President of Finance and Treasurer at Medarex, Inc., formerly a Nasdaq listed biotech company that was acquired in 2009 by Bristol Myers Squibb. From 1989 to 2002, Mr. Coiante held management positions of increasing responsibility at Ernst & Young LLP. Mr. Coiante received a B.S. in Accounting from Villanova University.

Robert G. Conway. Mr. Conway has served as our Senior Vice President and Chief Corporate Planning and Supply Chain Officer since November 2022. Prior to that, he served as our Senior Vice President and Chief Supply Chain Officer since January 2020, as our Senior Vice President, Enterprise Planning and Information Management from 2017 to 2020, as our Senior Vice President of Operations from 2014 to 2017 and as our Chief Development Officer and Vice President of Operations from 2004 to 2014. Mr. Conway has over thirty years of practice in U.S. and international operations with an extensive background in the medical device, pharmaceutical and consumer products industries. Mr. Conway has also previously served as Principal of R. G. Conway and Associates, an independent engineering and project management-consulting firm. Prior to consulting in 1997, Mr. Conway began his career in healthcare with Johnson & Johnson and later joined a Johnson & Johnson supported venture-backed medical device company operating as President and Chief Operating Officer. Mr. Conway holds a B.S. degree in Mechanical Engineering from New Jersey Institute of Technology.

Geoffrey P. Gilmore. Mr. Gilmore has been our Senior Vice President and Chief Administrative Officer since November 2022. Prior to that, Mr. Gilmore served as our General Counsel since August 2014. From 2012 to April 2016, Mr. Gilmore was a principal of Life Sciences Advisory Services, providing consulting services to the pharmaceutical and life science industries. He served as Senior Vice President, General Counsel and Corporate Secretary of Amicus

Therapeutics, Inc., a public bio-pharmaceutical company, from 2008 to 2012. Prior to joining Amicus, Mr. Gilmore spent 10 years at Bristol-Myers Squibb where he held roles of increasing responsibility in the legal department with the Commercial, Intellectual Property, and R&D legal groups, served in the Office of the Corporate Secretary and then reported to the General Counsel as Vice-President and Senior Counsel, Corporate Securities. Mr. Gilmore began his legal career in the business and finance groups at Philadelphia based law firms, Ballard Spahr LLP and Montgomery McCracken Walker & Rhoads LLP. Mr. Gilmore received his B.A. degree from Franklin and Marshall College and his J.D. from the University of Michigan Law School.

Paul Korner. Dr. Korner has been our Chief Medical Officer since August 2020. He has served in various leadership positions of increasing responsibility at several global companies focused on female reproductive health, including Solvay Pharmaceuticals, Wyeth Research, Bayer, and Ferring Pharmaceuticals. Dr. Korner has led more than 50 clinical trials that include multiple engagements with the U.S. Food and Drug Administration, European Medicines Agency, Pharmaceuticals and Medical Devices Agency in Japan, and Health Canada. Most recently Dr. Korner brought his clinical and development acumen to the gene therapy space as a Senior Vice President of Clinical Development & Medical Affairs at Axovant Gene Therapies, Ltd. He currently serves on the Laidlaw Venture Partners Scientific Advisory Board and the Board of Directors of Voltron Therapeutics as an Independent Director. Dr. Korner received his MD from the Stritch School of Medicine at Loyola University and also holds an MBA from the Michael J. Coles College of Business at Kennesaw State University.

Amy Welsh. Amy Welsh has been our Senior Vice President and Chief Commercial Officer since November 2022. Prior to that Ms. Welsh served as our Vice President, Marketing since May 2020. She brings over 25 years of industry marketing experience to Agile with a proven track record in product launch and lifecycle management. Prior to joining Agile, Ms. Welsh served for 3 years as the Vice President of Marketing at Antares Pharma Inc., a public specialty pharmaceutical company, where she oversaw the launch of its flagship brand XYOSTED, as well as the commercialization of products, strategic planning of developmental assets, as well as new M&A opportunities. Before Antares, she spent over eight years at AstraZeneca in brand management and marketing roles of increasing responsibility. Ms. Welsh also brings perspective and experience from her time working at a digital advertising agency dedicated to serving the life sciences industry. Ms. Welsh earned a dual B.A. degree in Marketing Communications and English Literature from LaSalle University.

Sharon Barbari. Ms. Barbari has served as a member of our Board since June 2020. Ms. Barbari has over 40 years of pharmaceutical and biotechnology experience. From 2004 to 2017, she was Chief Financial Officer at Cytokinetics. From 2002 to 2004, she was employed as Chief Financial Officer and Senior Vice President of Finance and Administration at InterMune. Ms. Barbari spent four years from 1998 to 2002 in senior financial roles at Gilead Sciences, including Chief Financial Officer. In this capacity, she led the finance, accounting, and information technology functions during a period of significant growth for Gilead. Ms. Barbari was also employed as Vice President of Strategic Planning at Foote, Cone & Belding Healthcare. She began her career at Syntex Corporation/Roche Pharmaceuticals, where she held various roles of increasing responsibility from 1972 to 1996. Ms. Barbari currently serves as a board member for Vyne Therapeutics (formerly Menlo Pharmaceuticals and Foamix Pharmaceuticals). She previously was a board member for the Association of Bioscience Finance Officers Northern California Chapter and Phytogen Life Sciences. In 2017, Ms. Barbari was a recipient of the YWCA Silicon Valley Tribute to Women Awards. She received her B.S. in accounting from San Jose State University. We believe Ms. Barbari's qualifications to sit on our Board include her extensive pharmaceutical industry leadership and financial operations experience.

Sandra Carson, M.D., FACOG. Dr. Carson has served as a member of our Board since June 2020. Dr. Carson is a Professor of Obstetrics, Gynecology and Reproductive Sciences and Director, Reproductive Endocrinology and Infertility at Yale University. Most recently, she served as the Emeritus Vice President for Education at the American College of Obstetricians & Gynecologists (ACOG) from August 2018 to February 2019 and Vice President for Education from March 2013 to August 2018. Prior to joining ACOG she served as Professor and Director of the Division of Reproductive Endocrinology and Infertility at Brown University from January 2007 to February 2013. She had previously directed the Assisted Reproductive Technology programs at the University of Tennessee (1986-1998) and the Baylor College of Medicine from October 1998 to June 2007. Dr. Carson is one of the foremost leaders in the field of reproductive endocrinology and infertility and she has published over 150 papers, received numerous competitive grants and had a major impact on the field. She has held multiple national leadership positions including President of the American Society for Reproductive Medicine (ASRM), Member of the council of the National Institutes of Child Health and Human Development, Head of the Reproductive Endocrinology and Infertility Division of the American Board of Obstetrics and

Gynecology (ABOG), Director and Vice President of the ABOG board and Vice President of ACOG. Dr. Carson served on the U. S. Food and Drug Administration's Fertility and Maternal Health Drugs Advisory Committee from July 1992 to July 1996 and then from 2007 to 2009. Dr. Carson is a board-certified OB/GYN. She received her Doctor of Medicine degree and completed her residency fellowship training at Northwestern University Medical School and fellowship training at Michael Reese Hospital Medical Center, University of Chicago. We believe Dr. Carson's qualifications to sit on our Board include her extensive medical and clinical experience in the area of Obstetrics, Gynecology and Reproductive Sciences and her significant educational background.

Seth H.Z. Fischer. Mr. Fischer has served as a member of our Board since July 2016, and as our Lead Independent Director since June 2020. Mr. Fischer currently serves as a member of the Board of Directors of Marinus Pharmaceuticals, Inc., Spectrum Pharmaceuticals, Inc., and Esperion Therapeutics, Inc. and is also an advisor to MedHab, LLC. Previously, from 2013 to 2017, Mr. Fischer served as the Chief Executive Officer and as a Director of Vivus, Inc., a publicly traded biopharmaceutical company commercializing and developing innovative, next-generation therapies to address unmet needs. He has served in positions of increasing responsibility with Johnson & Johnson from 1983 until his retirement in 2012. Most recently, Mr. Fischer served as Company Group Chairman, Johnson & Johnson and Worldwide Franchise Chairman, Cordis Corporation from 2008 to 2012, and as Company Group Chairman, North America Pharmaceuticals from 2004 to 2007, which included responsibilities for Ortho-McNeil Pharmaceuticals, Janssen and Scios. Prior to that, Mr. Fischer served as President of Ortho-McNeil Pharmaceuticals from 2000 to 2004. His operating responsibilities encompassed the commercialization of products in multiple therapeutic categories including Topamax® for epilepsy and migraine and products in the analgesic, anti-infective, cardiovascular, neurologic, psychiatric and women's health areas, including ORTHO EVRA®, one of the most successful contraceptive launches in the U.S. and the first ever contraceptive patch. He earned a Bachelor of General Studies from Ohio University and served as a captain in the U.S. Air Force. We believe Mr. Fischer's qualifications to sit on our Board include his extensive pharmaceutical industry leadership and operations experience.

John Hubbard, Ph.D., FCP. Dr. Hubbard has served as a member of our Board since November 2014. Dr. Hubbard currently serves on the Strategic Advisory Board of Genstar Capital and is responsible for advising the private equity firm on investments in the area of healthcare. He is the Chairman of Precision Medicine Group, a privately owned clinical research organization, and of Signant Health, a privately owned specialty clinical trials and technology service provider. He also serves as a non-Executive Director on the Board of Directors of Science 37 Holdings, Inc., a public telemedicine and clinical trial technology provider and Advarra, a privately owned institutional review board. Dr. Hubbard was President and the Chief Executive Officer of BioClinica, a leading privately owned provider of medical imaging, clinical technology and research services until January 1, 2018. Prior to joining BioClinica, he was Senior Vice President and Worldwide Head of Development Operations for Pfizer Inc. and was responsible for the global clinical trial operations and management of more than 450 clinical projects from Phase I to IV. He was a founding member of the Board of Directors of TransCelerate Biopharma, Inc., a leading biopharma industry consortium, and served on the Executive, Audit and Finance Committees. Dr. Hubbard has been leading pharmaceutical research and development activity for over thirty years and held positions of increasing responsibility in the biopharmaceutical and clinical research and development services industries. Prior to joining Pfizer in 2010, he was Group President, Global Clinical Research Services at ICON plc, a leading global clinical research organization, where he was responsible for the global business and operations. He is an Executive Committee Member Emeritus on the Clinical Trials Transformation Initiative, former Board Member of Life Sciences Pennsylvania and former Chairman of the Board of the Association of Clinical Research Organizations (ACRO). During his career, Dr. Hubbard has been directly responsible for drug discovery and non clinical pharmacology, clinical pharmacology, project management, product development optimization, commercial assessment of new chemical entities, and clinical development operations. He has led several drug development teams to successful commercialization of new chemical entities and has participated at FDA meetings to support end of Phase II and end of Phase III data presentations for psychiatric, neurological, cardiovascular, and anti infective drugs. Dr. Hubbard received a Bachelor of Science degree in Biopsychology from the University of Santa Clara and a Doctorate from the University of Tennessee, with a research focus on the genetic basis of hypertension and autonomic dysfunction. He was a National Institute of Health Postdoctoral Fellow in Cardiovascular and Clinical Pharmacology at the University of Texas Health Sciences Center. We believe Dr. Hubbard's qualifications to sit on our Board include his extensive pharmaceutical experience leading research operations and his significant educational background.

Josephine Torrente. Ms. Torrente has served as a member of our Board since October 2021. Ms. Torrente has more than 30 years of experience in the pharmaceutical industry, and is currently a Director at Hyman, Phelps & McNamara PC, a law firm focused on advising clients on FDA matters, where she has practiced since 1998. In addition to her time at Hyman, Phelps & McNamara, Ms. Torrente has worked at Sprout Pharmaceuticals as Executive Vice President,

Corporate and Regulatory Affairs, and Wyeth-Ayerst Research, where she managed U.S. regulatory affairs and conducted discovery research. Ms. Torrente received her B.S. with honors from Case Western Reserve University, her M.S. from the University of Alabama at Birmingham, and her J.D. summa cum laude from Temple University School of Law. We believe Ms. Torrente's qualifications to sit on our Board include her extensive pharmaceutical experience advising Companies on FDA regulatory and drug development matters and her significant educational background.

EXECUTIVE COMPENSATION

Compensation Philosophy and Programs

We are a “smaller reporting company” as defined in Rule 405 of the Securities Act of 1933, as amended (the “Securities Act”), and Item 10 of Regulation S-K, and in accordance with relevant SEC rules and guidance. We have elected, with respect to the disclosures required by Item 402 (Executive Compensation) of Regulation S-K, to comply with the disclosure requirements applicable to smaller reporting companies. Our intent with this overview is to enhance our stockholders’ understanding of our compensation philosophy and programs for our executive officers as well as the compensation committee’s role in the design and administration of these programs and as it relates to specific compensation decisions for our named executive officers.

Our executive compensation philosophy is centered around attracting and retaining talented executives who are essential for our continued growth and success and aligning the interests of these executives with those of our stockholders so that we can build long-term stockholder value. To achieve this objective, in addition to annual base salaries, our executive compensation program utilizes a combination of annual incentives through structured cash bonuses based on pre-defined goals as well as long-term incentives through equity-based compensation. On the whole, we follow a “market median” target compensation philosophy approach, reviewing each compensation component (base salary, target AIP and LTI awards) against the market median with flexibility to target an individual’s base and/or total compensation opportunity above or below the market median based on performance, critical skills and recognition for current and/or anticipated future contributions. In establishing overall executive compensation levels, our compensation committee may consider the following factors, including (i) the executive’s scope of responsibilities, (ii) the strategic importance of the executive’s role, (iii) relevant peer group data, (iv) attainment of individual and overall company performance objectives, (v) recruitment and/or retention concerns, and (vi) the results of the advisory vote of the stockholders on the “say-on-pay” proposal at the prior years’ annual meeting of the stockholders. A substantial portion of executive compensation is directly tied to the achievement of corporate performance objectives, and the contribution of these individuals to build a profitable business and stockholder value over time.

Our executive compensation program is administered by the compensation committee of our Board (the “Compensation Committee”), with guidance and input from our Chief Executive Officer and our independent compensation consultant, Pay Governance LLC (“Pay Governance”). The Compensation Committee oversees the governance, design and administration of our executive compensation programs and evaluates these programs against competitive practice, legal and regulatory developments and corporate governance trends. We are committed to continuing to incorporate leading design and governance practices into our compensation programs. The Compensation Committee, in addition to other activities mentioned above, establishes the new performance objectives for the upcoming fiscal year and approves merit, bonus and equity awards for the current year. The Compensation Committee solicits and considers evaluations and recommendations submitted by the Chief Executive Officer for the Compensation Committee’s review and approval. In the case of the Chief Executive Officer, the evaluation of his performance is conducted by the Compensation Committee in consultation with the Board, and the Compensation Committee approves any adjustments to his compensation as well as equity awards to be granted. The Compensation Committee obtains and considers input from Pay Governance, including benchmarking data discussed below. Mr. Altomari, our Chief Executive Officer, plays no role in determining his own salary, annual cash performance bonus or equity compensation.

Our Peer Group and the Use of Peer Group Compensation Data

Since 2016, the Compensation Committee has periodically engaged Pay Governance as its independent consultant to assist the Compensation Committee in evaluating its executive compensation program. The Compensation Committee has assessed the independence of Pay Governance, considering the factors required by the Nasdaq Global Market Listing Rules and concluded that Pay Governance is independent from the Company and there are no conflicts of interest.

Each year the Compensation Committee has engaged Pay Governance LLC to provide compensation market data, provide updates on executive compensation trends and regulatory development and provide recommendations to be used to establish compensation levels and plans for our executive officers for the following year. In doing so, Pay Governance develops a relevant peer group of companies (described below) in order to perform a thorough compensation review and analysis of our executive compensation levels and plans when compared to this group of peers, including base salary, annual cash bonus and long-term equity incentive awards.

In August 2023, at the recommendation of Pay Governance, the Compensation Committee approved modest changes to the peer group to align with our evolution as a commercial organization, and removed two companies that were either acquired, restructured, or had fallen outside the financial evaluation criteria, and added one company at similar commercial stage. In 2023 our peer group consisted of the following 19 companies:

AcelRx Pharmaceuticals	Femays	Spectrum Pharmaceuticals
Aziyo Biologics	Kala Pharma	Sutro Biopharma
Aytu BioPharma	Lipocine Inc.	Trevena
Baudex Bio, Inc.	Marinus Pharmaceuticals	VYNE Therapeutics
Cidara Therapeutics, Inc.	OptiNose Inc.	Zynerba Pharma
Dare Bioscience	Palatin Technologies	
Evoform Biosciences	SCYNEXIS	

We believe that our selected peer group provides useful information to help us establish competitive compensation practices and levels of compensation that allow us to attract, retain and motivate a talented executive team and, at the same time, aligns the interests of our executives with those of our stockholders. We believe our executive compensation must be competitive within such peer groups, yet fully aligned with our current stage of development and our responsibilities to stockholders.

While the target goal for annual cash salary, annual cash bonus and long-term equity remains around or at the 50th percentile of our peer group, given our need to preserve cash, the Board and Compensation Committee did not award performance-based bonuses to our Named Executive Officers for the 2022 fiscal year, as further described below. Annual bonuses which were approved at 70% of the target were also not awarded as the Company did not have sufficient funds available to pay them. For the 2023 fiscal year, the Board and the Compensation Committee have deferred any decision on performance-based bonuses and/or annual bonuses until the Committee meets to review 2023 performance against corporate goals and assess available funds. The Named Executive Officers will need to be employed on the date any such payment is made. The Board and Committee did award annual equity grants in the normal course in June 2023. No merit based salary adjustments were awarded to our Named Executive Officers in 2023 given our need to preserve cash, although Messrs. Altomari and Gilmore elected to take salary increases in the form of restricted stock unit (“RSU”) awards. A decision has not been taken yet on merit based salary adjustments for 2024.

Summary Compensation Table

The following table provides information concerning the compensation paid to our President and Chief Executive Officer, and our other three most highly compensated individuals, for the fiscal years ended December 31, 2023 and 2022. We refer to these individuals as our named executive officers.

Name and Principal Position	Year	Salary	Restricted Stock Unit Awards (RSU) ⁽²⁾	Option Awards ⁽¹⁾	All Other Compensation	Total
Al Altomari	2023	\$ 600,554	115,228	\$ 26,958	\$ 45,978 ⁽³⁾	\$ 788,718
<i>Chairperson & Chief Executive Officer</i>	2022	\$ 600,554		\$ 196,396	\$ 43,842	\$ 840,762
Geoffrey P. Gilmore	2023	\$ 450,000	50,136	\$ 9,705	\$ 44,851 ⁽⁴⁾	\$ 554,692
<i>Sr. VP, Chief Administrative Officer</i>	2022	429,492		\$ 65,458	\$ 49,428	\$ 544,378
Paul Korner	2023	\$ 442,000	33,480	\$ 9,705	\$ 52,596 ⁽⁵⁾	\$ 537,781
<i>Chief Medical Officer</i>	2022	442,000		65,458	38,402	545,860
Scott M. Coiante	2023	\$ 161,250	42,000		13,148 ⁽⁶⁾	216,398
<i>Chief Financial Officer</i>	2022	\$ —	—	—	—	—

⁽¹⁾ In accordance with SEC rules, this column reflects the aggregate grant date fair value of the option awards granted computed in accordance with Financial Accounting Standard Board Accounting Codification Topic 718 for stock-based compensation transactions (ASC 718). Assumptions used in the calculation of these amounts are included in Note 11 to the financial statements as of December 31, 2022. These amounts do not reflect the actual economic

- value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.
- (2) Represents total grant date value of RSUs that were granted on June 28, 2023, which is based on the closing price of Agile common stock on the grant date and the total number of restricted stock units granted. 37,500 RSU awards for Mr. Altomari and 13,500 RSU awards for Mr. Gilmore are expected to vest 25% on each four year anniversary. This amount does not reflect the actual economic value that will be realized by the named executive officer. 8,963 RSU awards for Mr. Altomari, and 6716 RSU awards for Mr. Gilmore are each expected to vest in one year, June 28, 2024 and were awarded in lieu of a cash increase in their base salaries.
 - (3) Represents \$29,112 for premiums paid by us for health and group life insurance, \$12,200 paid by us for safe harbor match and \$4,666 paid by us for life insurance.
 - (4) Represents \$31,581 for premiums paid by us for health and group life insurance, \$12,200 paid by us for safe harbor match and \$1,070 paid by us for life insurance.
 - (5) Represents \$39,589 for premiums paid by us for health and group life insurance, \$12,200 paid by us for safe harbor match and \$807 paid by us for life insurance.
 - (6) Represents base salary and \$13,148 for premiums paid by us for health and group life insurance for time worked from September through December 2023. Mr. Coiante joined Agile Therapeutics on August 16, 2023, so no data is available for 2022.

Narrative Explanation of Certain Aspects of the Summary Compensation Table

Pursuant to employment agreements entered into with us, each of our named executive officers is eligible to receive (i) a base salary and (ii) an annual performance bonus payable in cash, stock or a combination of both at the discretion of the compensation committee of the Board. The target amount of each named executive officer’s annual performance bonus is a percentage of his or her base salary, as set forth in the table below, and the actual amount payable is based on the achievement of individual and corporate objectives.

On August 16, 2023, Mr. Coiante became our Senior Vice President, Chief Financial Officer (“CFO”). In connection with his appointment as CFO, Mr. Coiante entered into an employment agreement and was awarded a grant of an RSU for 20,000 shares of the Company’s common stock vesting over four years. Pursuant to the terms of his employment agreement, Mr. Coiante will receive an initial annual base salary of \$430,000 and will be eligible to participate in the Company’s benefit and compensation plans, including the Company’s annual bonus plan and the 2023 Equity Incentive Compensation Plan. Mr. Coiante’s target annual bonus is 45% of his base salary, which, for 2023, shall be pro-rated for Mr. Coiante’s actual period of service in 2023.

Base Salary and Annual Performance Bonus

The base salary and target annual performance bonus for each of our named executive officers for our fiscal year ended December 31, 2023, is listed in the table below:

Name	2023 Base Salary	2023 Target Performance Bonus
AI Altomari	600,554	60 %
Scott M. Coiante	430,000	45 %
Geoffrey P. Gilmore	450,000	45 %
Paul Korner	442,000	45 %

For 2022, the Compensation Committee, based on a recommendation from management, did not approve a merit-based increase in base salary for any officer in connection with our overall performance. The Compensation Committee had initially intended to award bonus payments for our named executive officers to reflect the commercial performance of Twirla, the management of our financial resources and progress on the Company’s Phase 4 commitments in 2021 at 50% of each executive’s target. However, given our need to preserve cash, the named executive officers were not granted these bonuses. In addition, the long-term equity incentives were reduced in value compared to the awards granted in 2021 because of the reduced number of shares available in the Company’s incentive plan. Mr. Altomari’s long-term equity incentive grants were reduced by 88%, Mr. Gilmore’s grants were reduced by 89% and Dr. Korner’s grants were reduced by 84% in 2022. In November 2022, Mr. Gilmore was promoted to Senior Vice President, Chief Administrative Officer and his salary was increased to \$450,000.

For 2023, the Compensation Committee, based on a recommendation from management, again did not approve a merit-based increase in base salary for any officer based on our continued need to preserve cash. Messrs. Altomari and Gilmore elected to take salary increases in the form of restricted stock unit (“RSU”) awards and were granted RSUs for 8,963 shares and 6,716 shares respectively. Objectives for the named executive officers’ target bonuses for our fiscal year ending December 31, 2022 included three general categories: (1) the commercial performance of Twirla, as measured by net revenue, weighted at 50% of the total bonus potential; (2) management of our financial position for the 2022 fiscal year, as measured by our pre-tax earnings and cash position, collectively weighted at 40% of the total bonus potential; and (3) activities related to evaluating its pipeline and implementing the post approval commitments to the FDA in connection with the FDA’s approval of Twirla, and business development activity either through acquisition of additional product or similar transaction, both collectively weighted at 10% of the total bonus potential.

Objectives for the 2022 named executive officer target bonuses were deemed to be achieved at 70%, which at the discretion of the Compensation Committee reflected that we had (i) not met our net revenue target, (ii) partially achieved our goals to raise capital but had successfully managed our expenses, (iii) met the objectives for evaluating our pipeline and fully met the timelines for our obligations to the FDA, and (iv) reviewed and identified multiple business development candidates throughout the course of the year. The Compensation Committee, based on a recommendation from management did not approve bonuses for our named executive officers in a continued effort to conserve cash.

For fiscal year ending December 31, 2023, the Compensation Committee had established the following goals which must be achieved in order for the named executive officers to fully realize their potential annual cash bonus targets:

- *Twirla Growth*: Achieving growth of Twirla net revenue as measured by established targets;
- *Financial Management*: Reducing our loss and financing the Company’s operations through 2023 as measured by targets for pre-tax earnings and cash; and
- *Building Agile*: Pursuing business development opportunities to grow our business and meet our Phase 4 commitments to the U.S. Food and Drug Administration for 2023.

The Compensation Committee plans to meet in the first quarter of 2024 to review our performance against the Company’s corporate goals and the achievement of any merit-based salary increase. In a continued effort to conserve cash, management, has asked the Compensation Committee to not award bonuses to our named executive officers for the Company’s performance in 2023.

Equity Compensation

We have historically offered stock options as the primary long-term incentive vehicle to our employees, including our named executive officers, as the long-term incentive component of our compensation program. Stock options allow employees to purchase shares of our common stock at a price per share equal to the fair market value of our common stock on the date of grant and may or may not be intended to qualify as “incentive stock options” for U.S. federal income tax purposes. We typically grant stock options to new hires upon their commencing employment with us. Awards to newly hired employees generally vest with respect to 25% of the total number of option shares on the first anniversary of the grant date and in equal monthly installments over the following 36 months.

As part of an annual compensation evaluation of our named executive officers at the beginning of each year, the compensation committee of the Board considers granting stock options and other long-term incentive vehicles to our named executive officers based on such executive’s individual performance for the preceding year and as an incentive for future performance. Stock options are granted under our 2023 Equity Incentive Compensation Plan, or the 2023 Plan, and generally vest with respect to 25% of the total number of option shares on the first anniversary of the grant date and in equal monthly installments over the following 36 months. RSUs can also be granted under the 2023 Plan, and generally vest with respect to 25% of the total number of restricted stock units on the first four anniversaries of the grant date.

Effective January 19, 2022, the Compensation Committee granted each of Mr. Altomari, Mr. Gilmore, and Dr. Korner options to purchase shares of our common stock in the amount of 337, 112, and 112 (respectively), each at an exercise price of \$684 per share, which was the closing price of our common stock on January 19, 2022. The Compensation

Committee made its decision to grant stock options to our named executive officers based on (i) their individual performance for 2021 and contribution to the Company's performance against its corporate goals in 2021 and (ii) to incentivize future performance.

On November 9, 2022, the Compensation Committee approved an off-cycle grant for all active employees, including our named executive officers. The Compensation Committee granted each of Mr. Altomari, Mr. Gilmore, and Dr. Korner options to purchase shares of our common stock in the amount of 600, 200 and 200 (respectively), each at an exercise price of \$10.22 per share, which was the closing price of our common stock on November 9, 2022.

On June 28, 2023, following the Company's Annual Meeting, the Compensation Committee approved an annual grant for all active employees including our named executive officers. The Compensation Committee granted each of Mr. Altomari, Mr. Gilmore, and Dr. Korner a mix of options and RSUs. The options to purchase shares of our common stock were in the amount of 12,500, 4,500 and 4,500 (respectively) at an exercise price of \$2.48 per share, which was the closing price of our common stock on June 28, 2023. The RSUs were granted under the 2023 Plan equivalent to shares of the Company's common stock in the amount of 37,500, 13,500 and 13,500 (respectively). At the same time, Messrs. Altomari and Gilmore were awarded RSUs in the amount of 8,963 shares and 6,716 shares, respectively, in lieu of cash salary increases.

On October 3, 2023, Scott Coiante was granted an equity award ("Inducement Grant") in the form of an RSU for 20,000 shares of the Company's common stock ("Shares"). The Inducement Grant is governed by the terms of an individual award agreement, and the 2023 Equity Incentive Compensation Plan. The Inducement Grant will vest on a four-year vesting schedule, with 25% of the Shares subject to the option vesting on the first four anniversaries of the date that the Inducement Grant is granted, subject to Mr. Coiante's continued employment with the Company on each vesting date and subject to accelerated vesting in the event of a change in control.

As described under "Outstanding Equity Awards as of December 31, 2023" below, all outstanding and unvested equity awards held by our named executive officers are subject to accelerated vesting in the event we experience a change in control and the equity awards are not assumed by the successor corporation, or at the discretion of the Board. In addition, all outstanding equity awards held by our named executive officers are subject to accelerated vesting in the event of a termination without cause or resignation for good reason that occurs in connection with a change in control, as described under "Severance and Change in Control Benefits" below.

Outstanding Equity Awards as of December 31, 2023

The following table sets forth information regarding each outstanding equity award held by each of our named executive officers as of December 31, 2023. The number of shares subject to each award and, where applicable, the exercise price per share, reflect all changes as a result of our capitalization adjustments.

Name	Grant Date ⁽¹⁾	Option Awards				Stock Awards	
		Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price (\$) ⁽²⁾	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$) ⁽³⁾
Al Altomari	6/24/2014	36	—	\$ 21,500	6/23/2024		
	2/19/2015	45	—	\$ 18,900	2/18/2025		
	2/19/2015	45	—	\$ 21,500	2/18/2025		
	2/8/2016	49	—	\$ 11,860	2/7/2026		
	1/25/2017	120	—	\$ 4,520	1/24/2027		
	1/24/2018	127	—	\$ 6,920	1/23/2028		
	6/20/2018	75	—	\$ 1,160	6/19/2028		
	1/29/2019	269	—	\$ 1,680	1/28/2029		
	1/29/2019	76	—	\$ 5,000	1/28/2029		
	1/22/2020	407	8	\$ 5,660	1/21/2030		
	1/27/2021	255	90	\$ 5,640	1/26/2031		
	1/19/2022	163	174	\$ 684	1/18/2032		
	11/9/2022	164	435	\$ 10.22	11/8/2032		
	6/28/2023	—	12,500	2.48	6/27/2033		
	6/28/2023					46,463	90,603
Scott M. Coiante	10/3/2023					20,000	39,000
Geoffrey P. Gilmore	8/1/2014	15	—	\$ 12,000	7/31/2024		
	2/19/2015	10	—	\$ 18,900	2/18/2025		
	2/8/2016	14	—	\$ 11,860	2/7/2026		
	4/18/2016	14	—	\$ 12,920	4/17/2026		
	1/25/2017	69	—	\$ 4,520	1/24/2027		
	1/24/2018	53	—	\$ 6,920	1/23/2028		
	6/20/2018	75	—	\$ 1,160	6/19/2028		
	1/29/2019	86	—	\$ 1,680	1/28/2029		
	1/29/2019	19	—	\$ 5,000	1/28/2029		
	7/3/2019	75	—	\$ 2,960	7/2/2029		
	1/22/2020	154	3	\$ 5,660	1/21/2030		
	1/27/2021	101	28	\$ 5,640	1/26/2031		
	1/19/2022	59	53	\$ 684	1/18/2032		
	11/9/2022	56	143	\$ 10.22	11/8/2032		
	6/28/2023	—	4,500	2.48	6/27/2033		
	6/28/2023					20,216	39,421
Paul Korner	8/17/2020	67	7	\$ 5,740	8/16/2030		
	1/27/2021	68	17	\$ 5,640	1/26/2031		
	1/19/2022	59	53	\$ 684	1/18/2032		
	11/9/2022	56	143	\$ 10.22	11/8/2032		
	6/28/2023	—	4,500	2.48	6/27/2033		
	6/28/2023					13,500	26,325

- (1) Each of the option awards vest with respect to 25% of the shares one year following the date of grant and with respect to 1/36th of the remaining shares on each monthly anniversary thereafter over the following three years, subject to the executive's continuous service with us through the vesting date.
- (2) All of the option awards listed in the table above were granted with a per share exercise price equal to or above the fair market value of our common stock on the date of grant.
- (3) Market value is based on the closing price of \$1.95 on December 29, 2023, the last trading day of 2023.

Severance and Change in Control Benefits

Each of our named executive officers is eligible to receive certain benefits if his or her employment is terminated under certain circumstances, as described under “Severance and Change in Control Benefits” below.

Al Altomari

We entered into an employment agreement with Mr. Altomari on October 11, 2010, which was amended on December 18, 2012, April 12, 2016, and amended and restated on August 14, 2020, and November 22, 2022. Pursuant to the terms of the agreement, Mr. Altomari is entitled to receive certain benefits in the event his employment is terminated.

Payments Upon Termination Absent a Change in Control.

If Mr. Altomari terminates his employment for good reason or if we terminate his employment without reasonable cause (other than due to death or disability), in either case in the absence of a change in control, he is entitled to receive the following severance benefits: (i) base salary continuation for a period of 12 months, and (ii) reimbursement of Mr. Altomari’s health insurance premiums for a period of 12 months following the date of his termination or until Mr. Altomari obtains other employment, whichever is sooner. In the event of a change in control following his termination, any base salary continuation payments still due to Mr. Altomari shall be paid in full upon the change in control.

In the event Mr. Altomari’s employment terminates as a result of his disability, he will be entitled to receive (i) base salary continuation for a period of 12 months following the date of his termination, and (ii) reimbursement of Mr. Altomari’s health insurance premiums for a period of 12 months following the date of his termination due to his disability or until Mr. Altomari obtains other employment, whichever is sooner.

Payments Upon Termination in Connection with a Change in Control.

If Mr. Altomari terminates his employment for good reason or if we terminate his employment without reasonable cause (other than due to death or disability), in either case upon or within 12 months following a change in control, he is entitled to receive the following severance benefits: (i) a lump-sum cash payment in the amount of 2.0 times his then annual rate of base salary, (ii) a lump sum cash payment equal to Mr. Altomari’s target annual bonus for the year in which his termination occurs, (iii) reimbursement of Mr. Altomari’s health insurance premiums for a period of 24 months following the date of his termination or until Mr. Altomari obtains other employment, whichever is sooner and (iv) each outstanding equity award shall automatically vest in full.

Notwithstanding the foregoing, any payments and benefits that would otherwise be paid to Mr. Altomari (whether or not under his employment agreement) in connection with a change in control of the Company will be reduced to the extent necessary to ensure that he is not subject to any excise tax under Internal Revenue Code Section 4999 in connection with any change in control of the Company or his subsequent termination of employment. However, such reduction will not be made if Mr. Altomari would be better off (on an after-tax basis) receiving all payments and benefits and paying all excise and income taxes under Internal Revenue Code Section 4999.

Under Mr. Altomari’s employment agreement, the terms below are generally defined as follows:

“Change in Control” means (i) a merger or consolidation in which more than 50% of the voting securities of the Company are transferred and the composition of the board after such transaction constitutes less than 50% of the members of the board prior to the transaction; (ii) any acquisition, directly or indirectly, of beneficial ownership of more than 50% of the total combined voting power of the Company, other than in a capital-raising transaction; or (iii) the sale, transfer, exclusive worldwide license or other disposition of all or substantially all of the assets of the Company.

“Good reason” means Mr. Altomari’s resignation following notice to the Company of, and failure by the Company to cure, the occurrence of any of the following: (i) an office relocation of more than 50 miles; (ii) failure by the Company to comply with any material term of the employment agreement; or (iii) the demotion to a lesser position or substantial diminution of authority, duties or responsibilities, except for a reduction in title, position, responsibilities or duties solely by virtue of the Company being acquired and made part of, or operated as a

subsidiary of, a larger company, so long as the new duties and responsibilities are reasonably commensurate with Mr. Altomari's experience.

"Reasonable cause" means (i) an act or omission that constitutes dishonesty, disloyalty, fraud, deceit, gross negligence, willful misconduct or recklessness, including, but not limited to Mr. Altomari's willful violation of the Company's bylaws or code of conduct, and that is directly or indirectly materially detrimental to the Company's best interest; (ii) intentional failure to perform any lawful duties assigned by the board after receiving notice and an opportunity to cure; (iii) the commission of any act that constitutes a felony; or (iv) any material breach of certain sections of the employment agreement.

The payment of any severance compensation described above is subject to Mr. Altomari's execution and non-revocation of a general release of claims against the Company, and his compliance with non-competition and non-solicitation restrictive covenants for a 24-month period after his termination without cause or for good reason upon or within 12 months following a change of control and a 12-month period following his termination date in all other cases.

Geoffrey P. Gilmore

We entered into an employment agreement with Mr. Gilmore on April 12, 2016, which was amended on July 3, 2019, August 14, 2020, and November 1, 2022. Pursuant to the terms of the agreement, as amended, Mr. Gilmore is entitled to receive certain benefits in the event his employment is terminated.

Payments Upon Termination Absent a Change in Control.

If Mr. Gilmore terminates his employment for good reason or if we terminate his employment without reasonable cause (other than due to death or disability), in either case in the absence of a change in control, he is entitled to receive the following severance benefits: (i) base salary continuation for a period of 12 months, and (ii) reimbursement of Mr. Gilmore's health insurance premiums for a period of 12 months following the date of his termination or until he obtains other employment, whichever is sooner. In the event of a change in control following his termination, any base salary continuation payments still due to Mr. Gilmore shall be paid in full upon the change in control.

In the event Mr. Gilmore's employment terminates as a result of his disability, he will be entitled to receive (i) base salary continuation for a period of 12 months following the date of his termination, and (ii) reimbursement of his health insurance premiums for a period of 12 months following the date of his termination due to his disability or until he obtains employment, whichever is sooner.

Payments Upon Termination in Connection with a Change in Control.

If Mr. Gilmore terminates his employment for good reason or if we terminate his employment without reasonable cause (other than due to death or disability), in either case upon or within 12 months following a change in control, he is entitled to receive the following severance benefits: (i) a lump-sum cash payment in the amount of 1.5 times his then annual rate of base salary, (ii) a lump sum cash payment equal to his target annual bonus for the year in which his termination occurs, (iii) reimbursement of his health insurance premiums for a period of 18 months following the date of his termination or until he obtains other employment, whichever is sooner and (iv) each outstanding equity award shall automatically vest in full.

Notwithstanding the foregoing, any payments and benefits that would otherwise be paid to Mr. Gilmore (whether or not under his employment agreement) in connection with a change in control of the Company will be reduced to the extent necessary to ensure that he is not subject to any excise tax under Internal Revenue Code Section 4999 in connection with any change in control of the Company or his subsequent termination of employment. However, such reduction will not be made if Mr. Gilmore would be better off (on an after-tax basis) receiving all payments and benefits and paying all excise and income taxes under Internal Revenue Code Section 4999.

Under Mr. Gilmore's employment agreement, the terms below are generally defined as follows:

"Change in Control" means (i) a merger or consolidation in which more than 50% of the voting securities of the Company are transferred and the composition of the board after such transaction constitutes less than 50%

of the members of the board prior to the transaction; (ii) any acquisition, directly or indirectly, of beneficial ownership of more than 50% of the total combined voting power of the Company, other than in a capital-raising transaction; or (iii) the sale, transfer, exclusive worldwide license or other disposition of all or substantially all of the assets of the Company.

“Good reason” means Mr. Gilmore’s resignation following notice to the Company of, and failure by the Company to cure, the occurrence of any of the following: (i) an office relocation of more than 50 miles; (ii) failure by the Company to comply with any material term of the employment agreement; or (iii) the demotion to a lesser position or substantial diminution of authority, duties or responsibilities, except for a reduction in title, position, responsibilities or duties solely by virtue of the Company being acquired and made part of, or operated as a subsidiary of, a larger company, so long as the new duties and responsibilities are reasonably commensurate with Mr. Gilmore’s experience.

“Reasonable cause” means (i) an act or omission that constitutes dishonesty, disloyalty, fraud, deceit, gross negligence, willful misconduct or recklessness, including, but not limited to Mr. Gilmore’s willful violation of the Company’s bylaws or code of conduct, and that is directly or indirectly materially detrimental to the Company’s best interest; (ii) intentional failure to perform any lawful duties assigned by the Board after receiving notice and an opportunity to cure; (iii) the commission of any act that constitutes a felony; or (iv) any material breach of certain sections of the employment agreement.

The payment of any severance compensation described above is subject to Mr. Gilmore’s execution and non-revocation of a general release of claims against the Company, and his compliance with non-competition and non-solicitation restrictive covenants for an 12-month period after his termination without cause or for good reason upon or within 18 months following a change of control.

Paul Korner, M.D.

We entered into an employment agreement with Dr. Korner on August 17, 2020, which was amended on November 1, 2022. Pursuant to the terms of the agreement, Dr. Korner is entitled to receive certain benefits in the event his employment is terminated.

Payments Upon Termination Absent a Change in Control.

If Dr. Korner terminates his employment for good reason or if we terminate his employment without reasonable cause (other than due to death or disability), in either case in the absence of a change in control, he is entitled to receive the following severance benefits: (i) base salary continuation for a period of 12 months, and (ii) reimbursement of his health insurance premiums for a period of 12 months following the date of his termination or until he obtains other employment, whichever is sooner. In the event of a change in control following his termination, any base salary continuation payments still due to Dr. Korner shall be paid in full upon the change in control.

In the event Dr. Korner’s employment terminates as a result of his disability, he will be entitled to receive (i) base salary continuation for a period of 12 months following the date of his termination, and (ii) reimbursement of his health insurance premiums for a period of 12 months following the date of his termination due to his disability or until he obtains employment, whichever is sooner.

Payments Upon Termination in Connection with a Change in Control.

If Dr. Korner terminates his employment for good reason or if we terminate his employment without reasonable cause (other than due to death or disability), in either case upon or within 12 months following a change in control, he is entitled to receive the following severance benefits: (i) a lump-sum cash payment in the amount of 1.5 times his then annual rate of base salary, (ii) a lump sum cash payment equal to his target annual bonus for the year in which his termination occurs, (iii) reimbursement of his health insurance premiums for a period of 18 months following the date of his termination or until he obtains other employment, whichever is sooner and (iv) each outstanding equity award shall automatically vest in full.

Notwithstanding the foregoing, any payments and benefits that would otherwise be paid to Dr. Korner (whether or not under his employment agreement) in connection with a change in control of the Company will be reduced to the extent necessary to ensure that he is not subject to any excise tax under Internal Revenue Code Section 4999 in connection with any change in control of the Company or his subsequent termination of employment. However, such reduction will not be made if Dr. Korner would be better off (on an after-tax basis) receiving all payments and benefits and paying all excise and income taxes under Internal Revenue Code Section 4999.

Under Dr. Korner's employment agreement, the terms below are generally defined as follows:

"Change in Control" means (i) a merger or consolidation in which more than 50% of the voting securities of the Company are transferred and the composition of the board after such transaction constitutes less than 50% of the members of the board prior to the transaction; (ii) any acquisition, directly or indirectly, of beneficial ownership of more than 50% of the total combined voting power of the Company, other than in a capital-raising transaction; or (iii) the sale, transfer, exclusive worldwide license or other disposition of all or substantially all of the assets of the Company.

"Good reason" means Dr. Korner's resignation following notice to the Company of, and failure by the Company to cure, the occurrence of any of the following: (i) an office relocation of more than 50 miles; (ii) failure by the Company to comply with any material term of the employment agreement; or (iii) the demotion to a lesser position or substantial diminution of authority, duties or responsibilities, except for a reduction in title, position, responsibilities or duties solely by virtue of the Company being acquired and made part of, or operated as a subsidiary of, a larger company, so long as the new duties and responsibilities are reasonably commensurate with Dr. Korner's experience.

"Reasonable cause" means (i) an act or omission that constitutes dishonesty, disloyalty, fraud, deceit, gross negligence, willful misconduct or recklessness, including, but not limited to Dr. Korner's willful violation of the Company's bylaws or code of conduct, and that is directly or indirectly materially detrimental to the Company's best interest; (ii) intentional failure to perform any lawful duties assigned by the board after receiving notice and an opportunity to cure; (iii) the commission of any act that constitutes a felony; or (iv) any material breach of certain sections of the employment agreement.

The payment of any severance compensation described above is subject to Dr. Korner's execution and non-revocation of a general release of claims against the Company, and his compliance with non-competition and non-solicitation restrictive covenants for a 12-month period after his termination without cause or for good reason upon or within 18 months following a change of control.

Scott M. Coiante.

We entered into an employment agreement with Mr. Coiante on August 16, 2023. Pursuant to the terms of the agreement, Mr. Coiante is entitled to receive certain benefits in the event his employment is terminated.

Payments Upon Termination Absent a Change in Control.

If Mr. Coiante terminates his employment for good reason or if we terminate his employment without reasonable cause (other than due to death or disability), in either case in the absence of a change in control, he is entitled to receive the following severance benefits: (i) base salary continuation for a period of 12 months, and (ii) reimbursement of his health insurance premiums for a period of 12 months following the date of his termination or until he obtains other employment, whichever is sooner. In the event of a change in control following his termination, any base salary continuation payments still due to Mr. Coiante shall be paid in full upon the change in control.

In the event Mr. Coiante's employment terminates as a result of his disability, he will be entitled to receive (i) base salary continuation for a period of 12 months following the date of his termination, and (ii) reimbursement of his health insurance premiums for a period of 12 months following the date of his termination due to his disability or until he obtains employment, whichever is sooner.

Payments Upon Termination in Connection with a Change in Control.

If Mr. Coiante terminates his employment for good reason or if we terminate his employment without reasonable cause (other than due to death or disability), in either case upon or within 12 months following a change in control, he is entitled to receive the following severance benefits: (i) a lump-sum cash payment in the amount of 1.5 times his then annual rate of base salary, (ii) a lump sum cash payment equal to his target annual bonus for the year in which his termination occurs, (iii) reimbursement of his health insurance premiums for a period of 18 months following the date of his termination or until he obtains other employment, whichever is sooner and (iv) each outstanding equity award shall automatically vest in full.

Notwithstanding the foregoing, any payments and benefits that would otherwise be paid to Mr. Coiante (whether or not under his employment agreement) in connection with a change in control of the Company will be reduced to the extent necessary to ensure that he is not subject to any excise tax under Internal Revenue Code Section 4999 in connection with any change in control of the Company or his subsequent termination of employment. However, such reduction will not be made if Mr. Coiante would be better off (on an after-tax basis) receiving all payments and benefits and paying all excise and income taxes under Internal Revenue Code Section 4999.

Under Mr. Coiante's employment agreement, the terms below are generally defined as follows:

"Change in Control" means (i) a merger or consolidation in which more than 50% of the voting securities of the Company are transferred and the composition of the board after such transaction constitutes less than 50% of the members of the board prior to the transaction; (ii) any acquisition, directly or indirectly, of beneficial ownership of more than 50% of the total combined voting power of the Company, other than in a capital-raising transaction; or (iii) the sale, transfer, exclusive worldwide license or other disposition of all or substantially all of the assets of the Company.

"Good reason" means Mr. Coiante's resignation following notice to the Company of, and failure by the Company to cure, the occurrence of any of the following: (i) an office relocation of more than 50 miles; (ii) failure by the Company to comply with any material term of the employment agreement; or (iii) the demotion to a lesser position or substantial diminution of authority, duties or responsibilities, except for a reduction in title, position, responsibilities or duties solely by virtue of the Company being acquired and made part of, or operated as a subsidiary of, a larger company, so long as the new duties and responsibilities are reasonably commensurate with Mr. Coiante's experience.

"Reasonable cause" means (i) an act or omission that constitutes dishonesty, disloyalty, fraud, deceit, gross negligence, willful misconduct or recklessness, including, but not limited to Mr. Coiante's willful violation of the Company's bylaws or code of conduct, and that is directly or indirectly materially detrimental to the Company's best interest; (ii) intentional failure to perform any lawful duties assigned by the board after receiving notice and an opportunity to cure; (iii) the commission of any act that constitutes a felony; or (iv) any material breach of certain sections of the employment agreement.

The payment of any severance compensation described above is subject to Mr. Coiante's execution and non-revocation of a general release of claims against the Company, and his compliance with non-competition and non-solicitation restrictive covenants for a 12-month period after his termination without cause or for good reason upon or within 18 months following a change of control.

Employee Benefits and Perquisites

We also provide group life insurance, health, vision, and dental care insurance to all employees, including our named executive officers. These benefits do not discriminate in scope, terms, or operation in favor of the named executive officers. All such benefits terminate at the time each individual is no longer employed with us or as otherwise provided in the applicable employment agreement. All our named executive officers are eligible to participate in all of our employee benefit plans, in each case on the same basis as other employees. We maintain a 401(k) defined contribution plan, which is our primary retirement benefit for employees, including executives. We make a safe-harbor contribution of 100% of the first 3% of an employee's elected salary deferral, plus 50% of the next 2% of salary deferral subject to Internal Revenue Service limitations. Although permitted under the plan, we have not matched employee contributions to the 401(k) plan.

We provide a life insurance benefit for our named executive officers in an amount equal to up to twice the named executive officer's base salary and target bonus capped at \$1,000,000.

We do not generally provide our named executive officers with perquisites or other personal benefits (other than severance benefits, and the life insurance benefit, as described above).

DIRECTOR COMPENSATION

During our fiscal year ended December 31, 2023, our non-employee directors who served on our Board were entitled to receive cash fees and were granted restricted stock units (RSUs) and options to purchase shares of our common stock for their service. A non-employee director is a director who is not employed by us and who does not receive compensation from us (other than for services as a director) or has a business relationship with us that would require disclosure under certain SEC rules. Due to our cash constraints, we paid the directors their cash fees for the first quarter of 2023 but did not pay the directors their fees for the rest of 2023. Mr. Altomari, our Chief Executive Officer and Chairperson of our Board, did not receive any compensation from us during our fiscal year ended December 31, 2023 for his service as a director and is not included in the table below.

Name	Fees Earned or Paid in Cash ⁽⁴⁾	Option Awards ⁽¹⁾⁽²⁾	Restricted Stock Awards ⁽¹⁾⁽²⁾	Total
Sharon Barbari	\$ 77,500	\$ 3,344	\$ 3,345	\$ 84,190
Sandra Carson, M.D., FACOG	\$ 55,000	\$ 3,344	\$ 3,345	\$ 61,690
Seth H.Z. Fischer	\$ 95,000	\$ 3,344	\$ 3,345	\$ 101,690
John Hubbard, Ph.D.	\$ 65,000	\$ 3,344	\$ 3,345	\$ 71,690
Ajit S. Shetty, Ph.D. ⁽³⁾	\$ 14,375	\$ —	\$ —	\$ 14,375
Josephine Torrente	\$ 55,000	\$ 3,344	\$ 3,345	\$ 61,690

(1) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the awards granted computed in accordance with Financial Accounting Standard Board Accounting Codification Topic 718 for stock-based compensation transactions (ASC 718). Assumptions used in the calculation of these amounts are included in Note 11 to the financial statements as of December 31, 2022. These amounts do not reflect the actual economic value that will be realized by the director upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.

(2) As of December 31, 2023, our non-employee directors held the following aggregate number of shares under outstanding stock options (representing unexercised option awards—both exercisable and unexercisable) and unvested restricted stock unit awards:

Name	Aggregate Number of Shares Underlying Option Awards	Aggregate Number of Shares Underlying RSU Awards
Sharon Barbari	1,117	935
Sandra Carson, M.D., FACOG	1,117	935
Seth H.Z. Fischer	1,185	935
John Hubbard, Ph.D.	1,199	935
Ajit S. Shetty, Ph.D. ⁽³⁾	127	0
Josephine Torrente	1,129	948

(3) The compensation provided for Mr. Shetty represents payment until June 8, 2023, when he did not stand for re-election to the Board at the Company's annual meeting of stockholders.

(4) The amounts represent the fees earned by Board members in 2023; however, in an effort to preserve cash, the Company has only paid a portion of the fees for 2023 at this time.

Non-Employee Director Compensation

During 2023, each non-employee member of our Board is entitled to receive the following cash compensation for board services, as applicable:

- \$45,000 per year for service as a Board member;
- \$25,000 per year for service as lead independent director;
- \$20,000 per year for service as chairperson of the audit committee;

- \$15,000 per year for service as chairperson of the compensation committee;
- \$12,500 per year for service as chairperson of the finance committee;
- \$10,000 per year for service as chairperson of the nominating and corporate governance committee;
- \$12,500 per year for service as chairperson of the science and technology committee; and
- \$5,000 per year for service as a member on each committee, except each member of the compensation committee is entitled to receive \$7,500 per year for service in that role and each member of the audit committee is entitled to receive \$10,000 per year for service in that role.

Non-employee members of our Board receive automatic grants of equity awards under our 2023 Equity Incentive Compensation Plan (the “2023 Plan”). Each non-employee director joining our Board will automatically be granted equity awards totaling \$150,000 in value split equally between a non-statutory stock option to purchase shares of common stock with an exercise price equal to the fair market value of our common stock on the grant date and a restricted stock unit, or RSU. The shares subject to each initial option grant and RSU will vest in three successive equal annual installments over the 3-year period measured from the date of the non-employee director’s election to our Board, subject to the non-employee director’s continued board service through each vesting date and provided that the director attends at least 75% of the board meetings held during each respective year of board service.

In addition, on the date of each annual meeting of our stockholders, each non-employee director will automatically be granted equity awards totaling \$75,000 in value split equally between a non-statutory stock option to purchase shares of our common stock on that date with an exercise price equal to the fair market value of our common stock on the grant date and an RSU. In 2023, because of the limited number of shares of common stock available for issuance pursuant to the 2023 Plan, each non-employee director received equity awards totaling approximately \$6,690 each, which was evenly split into (i) a stock option to purchase 1,065 shares of common stock, which shares will vest on the first anniversary of the grant date, subject to the non-employee director’s continued board service through such date and provided that the non-employee director attends at least 75% of the board meetings held during such year of board service, and (ii) 935 RSUs, which will vest on the first anniversary of the grant date, subject to the non-employee director’s continued board service through such date and provided that the non-employee director attends at least 75% of the board meetings held during such year of board service. The decision to establish a value of equity awards and to equally split the awards between stock option shares and RSUs was based on a review of director equity compensation by our Board that included participation by the Compensation Committee’s independent compensation advisor, Pay Governance LLC. In making this determination, our Board considered our business plan, our stock price and potential dilution to stockholders, and the need to adequately compensate our directors for their service.

The shares subject to each option grant or RSU under the director compensation policy will immediately vest upon (i) an acquisition of the Company by merger or asset sale, (ii) the successful completion of a tender offer for more than 50% of our outstanding voting stock or (iii) a change in the majority of our Board effected through one or more proxy contests for board membership, or a Change in Control. All automatic director options have a maximum term of ten years.

We will also continue to reimburse our non-employee directors for their reasonable out-of-pocket expenses incurred in attending board and committee meetings.

Director Independence

Our common stock is listed on Nasdaq. The listing rules of this stock exchange generally require that a majority of the members of a listed company’s Board be independent. In addition, the rules of Nasdaq require that, subject to specified exceptions, each member of a listed company’s audit, compensation, and nominating and corporate governance committees be independent. The Nasdaq director independence definition includes a series of objective tests, such as that the director is not also one of our employees and has not engaged in various types of business dealings with us. In addition, as further required by Nasdaq rules, our Board has made a subjective determination as to each independent director that no relationships exist, which, in the opinion of our Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our directors reviewed and discussed

information provided by the directors and us regarding each director's business and personal activities as they may relate to us and our management.

Our Board has determined that none of our non-employee directors or director nominees has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of our current non-employee directors is "independent" as that term is defined under Nasdaq rules. The independent members of our Board hold separate regularly scheduled executive session meetings at which only independent directors are present.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the Board, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries; or be an affiliated person of the listed company or any of its subsidiaries. Each of the current members of our audit committee, Sharon Barbari, Seth H.Z. Fischer, and John Hubbard, Ph.D., FCP, qualifies as an independent director pursuant to Rule 10A-3.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of December 31, 2023 (except as otherwise noted) for:

- based on reports filed with the SEC, each person, or group of persons, who beneficially owns more than five percent (5%) of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules of the SEC. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the table below have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership is based on 2,963,657 shares of common stock outstanding at December 31, 2023. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to options or warrants held by that person or entity that are currently exercisable or that will become exercisable or releasable within 60 days of December 31, 2023. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Agile Therapeutics, Inc., 500 College Road East, Suite 310, Princeton, New Jersey 08540.

Name of Beneficial Owner ⁽¹⁾	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Named Executive Officers and Directors		
Al Altomari ⁽²⁾	3,178	0.1 %
Scott M. Coiante ⁽³⁾	80	*
Geoffrey P. Gilmore ⁽⁴⁾	851	*
Paul Korner, M.D. ⁽⁵⁾	270	*
Sharon Barbari ⁽⁶⁾	90	*
Sandra Carson, M.D., FACOG ⁽⁷⁾	90	*
Seth H.Z. Fischer ⁽⁸⁾	160	*
John Hubbard, Ph.D., FCP ⁽⁹⁾	174	*
Josephine Torrente ⁽¹⁰⁾	88	*
All current executive officers and directors as a group (11 persons) ⁽¹¹⁾	5,662	0.2 %

* Represents beneficial ownership of less than 1% of the outstanding shares of our common stock.

(1) This table is based upon information supplied by officers, directors and stockholders known by us to be beneficial owners of more than five percent of our common stock as well as Schedules 13G or 13D and Section 16 reports filed with the SEC. We have not independently verified such information.

(2) Includes (a) 1,286 shares of common stock owned by Mr. Altomari and (b) 1,892 shares of common stock that Mr. Altomari has the right to acquire from us within 60 days of December 31, 2023.

(3) Represents 80 shares of common stock owned by Mr. Coiante.

(4) Includes (a) 30 shares of common stock owned by Mr. Gilmore and (b) 821 shares of common stock that Mr. Gilmore has the right to acquire from us within 60 days of December 31, 2023.

(5) Includes (a) zero shares of common stock owned by Dr. Korner and (b) 270 shares of common stock that Dr. Korner has the right to acquire from us within 60 days of December 31, 2023.

(6) Includes (a) 38 shares of common stock owned by Ms. Barbari and (b) 52 shares of common stock that Ms. Barbari has the right to acquire from us within 60 days of December 31, 2023.

- (7) Includes (a) 38 shares of common stock owned by Dr. Carson and (b) 52 shares of common stock that Dr. Carson has the right to acquire from us within 60 days of December 31, 2023.
- (8) Includes (a) 40 shares of common stock owned by Mr. Fischer and (b) 120 shares of common stock that Mr. Fischer has the right to acquire from us within 60 days of December 31, 2023.
- (9) Includes (a) 40 shares of common stock owned by Dr. Hubbard and (b) 134 shares of common stock that Dr. Hubbard has the right to acquire from us within 60 days of December 31, 2023.
- (10) Includes (a) 39 shares of common stock owned by Ms. Torrente and (b) 49 shares of common stock that Ms. Torrente has the right to acquire from us within 60 days of December 31, 2023.
- (11) Includes (a) 1,632 shares of common stock owned and (b) 4,030 shares of common stock that these individuals have the right to acquire from us within 60 days of December 31, 2023.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In addition to the cash and equity compensation arrangements of our directors and named executive officers discussed under “Director Compensation” and “Executive Compensation,” the following is a description of transactions since December 31, 2022, to which we have been a party in which the amount involved exceeded or will exceed \$120,000 and in which any of our directors, executive officers, beneficial holders of more than 5% of our capital stock, or entities affiliated with or immediate family members of any of the foregoing, had or will have a direct or indirect material interest.

Employment Agreements

We have entered into employment agreements with certain of our executive officers. For more information regarding these agreements, see the section of this prospectus entitled “Executive Compensation.”

Equity Awards and Payments to Executive Officers and Directors

We have granted stock options to our executive officers and certain of our directors and paid fees to certain of our directors as more fully described in the section entitled “Director Compensation” and “Executive Compensation.”

Credit Agreement and Guaranty

In February 2020, we entered into a Credit Agreement and Guaranty with Perceptive Credit Holdings III, LP (“Perceptive”), an affiliate of a beneficial holder of more than 5% of our capital stock, 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 tranche was to be available to us based on the achievement of a revenue milestone by December 31, 2021, which was not achieved. The other tranches of debt under the Amended Perceptive Credit Agreement are no longer available to us. On January 7, 2022, we prepaid \$5.0 million of the outstanding debt, and Perceptive waived the prepayment premium. On July 8, 2022, we prepaid \$5.0 million of the outstanding debt, and Perceptive waived the prepayment premium. On July 25, 2022, we entered into a fifth amendment to the Amended Perceptive Credit Agreement, as amended (the “Fifth Amendment”). Pursuant to the Fifth Amendment, Perceptive agreed to release its security interest in certain assets being transferred from us to Corium in connection with an amendment to our Manufacturing and Commercialization Agreement with Corium and waive our obligations to comply with certain financial covenants through the end of 2022. In exchange, we agreed to prepay \$7.0 million of outstanding principal under the Amended Perceptive Credit Agreement using the proceeds of recent sales under our ATM program with H.C. Wainwright & Co., LLC. Such payment was made on July 25, 2022. On March 21, 2023, we entered into a sixth amendment to the Amended Perceptive Credit Agreement (the “Sixth Amendment”). The Sixth Amendment waived the our obligations to (1) comply with certain financial covenants relating to minimum revenue requirements and minimum liquidity through June 30, 2023, and (2) file financial statements along with our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 that are not subject to any “going concern” qualification. On October 30, 2023, we entered into a seventh amendment to the Perceptive Credit Agreement (the “Seventh Amendment”). The Seventh Amendment: (1) amends our obligations to comply with certain financial covenants relating to minimum revenue requirements, (2) amends and waives our obligations to comply with certain financial covenants relating to minimum liquidity through December 31, 2023, and (3) requires us to make principal payments on its outstanding loan balance of \$150,000 per month beginning on December 1, 2023.

The facility will mature on February 10, 2024 (“Maturity Date”). Pursuant to the Amended Perceptive Credit Agreement, beginning August 31, 2022, we began making monthly principal payments in an amount equal to \$75,000. Beginning on December 1, 2023 and pursuant to the Seventh Amendment, we began making monthly payments of \$150,000, and will continue to do so until the Maturity Date, at which time all remaining principal amount outstanding is due.

Borrowings under the Amended Perceptive Credit Agreement will accrue interest at an annual rate equal to the Secured Overnight Financing Rate, or SOFR, plus 10.25%, provided that SOFR shall not be less than 1.5%. The rate of interest in effect as of December 31, 2023 was 15.6%. Upon the occurrence and during the continuance of any event of default under the Fifth Amendment, the interest rate automatically increases by 3.0% per annum. We may prepay any outstanding loans in whole or in part. Any such prepayment of the loans is subject to a prepayment premium of 2.0%.

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

In connection with the Perceptive Credit Agreement, we issued to Perceptive two warrants to purchase an aggregate of 700 shares of our common stock (together, the “2020 Perceptive Warrants”). The first warrant is exercisable for 350 shares of common stock at an exercise price of \$7,480.00 per share. The second warrant is exercisable for 350 shares of common stock at an exercise price of \$9,340.00 per share. The 2020 Perceptive Warrants expire on February 10, 2027. In connection with the Perceptive Credit Agreement, we issued to Perceptive a warrant to purchase 225 shares of our common stock (the “2021 Perceptive Warrant” and, together with the 2020 Perceptive Warrants, the “Perceptive Warrants”) at an exercise price of \$5,740.00 per share. The 2021 Perceptive Warrant expires on February 26, 2028. The Perceptive Warrants contain anti-dilution provisions and other warrant holder protections and are not exercisable to the extent that Perceptive would beneficially own more than 19.99% of the Company’s common stock because of the exercise. In connection with the Sixth Amendment and Seventh Amendments, we amended and restated the Perceptive Warrants to reset the strike price of the Perceptive Warrants.

Review and Approval of Related Party Transactions

Our Audit Committee Charter requires that our Audit Committee review and approve or ratify transactions involving us and any executive officer, director, director nominee, 5% stockholder and certain of their immediate family members, also referred to herein as a related person. The policy and procedures cover any transaction involving a related person, also referred to herein as a related person transaction, in which the related person has a material interest, and which does not fall under an explicitly stated exception set forth in the applicable disclosure rules of the SEC.

A related person transaction will be considered approved or ratified if it is authorized by the Audit Committee after full disclosure of the related person’s interest in the transaction. In considering related person transactions, the Audit Committee will consider any information considered material to investors and the following factors:

- the related person’s interest in the transaction;
- the approximate dollar value of the transaction;
- whether the transaction was undertaken in the ordinary course of our business;
- whether the terms of the transaction are no less favorable to us than terms that we could have reached with an unrelated third party; and
- the purpose and potential benefit to us of the transaction.

DESCRIPTION OF CAPITAL STOCK

The following description is a general summary of the terms of the shares of common stock or shares of preferred stock, does not include all of the terms of the shares of common stock or shares of preferred stock and should be read together with our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, copies of which have been filed previously with the SEC. For more information on how you can obtain copies of our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, see “Where You Can Find More Information” on page 130 of this prospectus.

Common Stock

General

Our Amended and Restated Certificate of Incorporation, as amended, provides the authority to issue 300,000,000 shares of common stock, par value \$0.0001 per share. At December 31, 2023, there were 2,963,657 shares of common stock outstanding. Each share of our common stock has the same relative rights and is identical in all respects to each other share of our common stock. The rights, preferences and privileges of holders of our common stock are subject to the rights, preferences and privileges of the holders of shares of any series of preferred stock that we have issued or may issue in the future.

Voting Rights

The holders of our common stock are entitled to one vote per share on any matter to be voted upon by our stockholders. Our Amended and Restated Certificate of Incorporation does not permit cumulative voting in connection with the election of directors.

Dividends

The holders of our common stock are entitled to dividends, if any, as our Board may declare from time to time from funds legally available for that purpose, subject to the holders of other classes of stock, if any, at the time outstanding having prior rights as to dividends, if any.

Liquidation Rights

Upon any voluntary or involuntary liquidation, dissolution, or winding up of our affairs, the holders of our common stock are entitled to share ratably in all assets remaining after the payment of creditors, subject to any prior liquidation distribution rights of holders of other classes of stock, if any, at the time outstanding.

Miscellaneous

Holders of our common stock have no preemptive, conversion, redemption or sinking fund rights. The outstanding shares of our common stock are, and the shares of common stock to be offered hereby when issued will be, validly issued, fully paid and non-assessable.

Nasdaq Listing

Our common stock is listed on the Nasdaq Capital Market under the symbol “AGRX.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Broadridge Corporate Issuer Solutions, Inc. whose address is 51 Mercedes Way, Edgewood, New York 11717.

Preferred Stock

Our Amended and Restated Certificate of Incorporation, as amended, authorizes the issuance of up to 10,000,000 shares of preferred stock, par value \$0.0001 per share, none of which are issued and outstanding as of the date of this

prospectus. We may issue, from time to time in one or more series, the terms of which may be determined at the time of issuance by our Board, without further action by our stockholders, shares of preferred stock and such shares may include voting rights, preferences as to dividends and liquidation, conversion rights, redemption rights and sinking fund provisions. The shares of each series of preferred stock shall have preferences, limitations and relative rights, including voting rights, identical with those of other shares of the same series and, except to the extent provided in the description of such series, of those of other series of preferred stock.

Delaware Law and Certain Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws Provisions

Our Amended and Restated Certificate of Incorporation, as amended, and Amended and Restated Bylaws, as amended, to be in effect upon completion of this offering contain provisions that could delay or prevent a change of control of our company or changes in our Board 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 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, as amended, Amended and Restated Bylaws, as amended, and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our Board 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 could cause the market price of our common stock to decline.

Indemnification

Our Amended and Restated Certificate of Incorporation, as amended, contains provisions permitted under the General Corporation Law of Delaware relating to the liability of directors. The provisions eliminate, to the extent legally permissible, a director's liability for monetary damages for a breach of fiduciary duty, except in circumstances involving wrongful acts, such as the breach of a director's duty of loyalty or acts or omissions that involve intentional misconduct or a knowing violation of law. The limitation of liability described above does not alter the liability of our directors and officers under federal securities laws. Furthermore, our Amended and Restated Certificate of Incorporation, as amended, contains provisions to indemnify our directors and officers to the fullest extent permitted by the General Corporation Law of Delaware. These provisions do not limit or eliminate our right or the right of any stockholder of ours to seek non-monetary relief, such as an injunction or rescission in the event of a breach by a director or an officer of his or her duty of care to us. We believe that these provisions assist us in attracting and retaining qualified individuals to serve as directors.

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering up to _____ shares of common stock, together with Series E-1 warrants to purchase up to _____ shares of common stock (the “Series E-1 warrants”) and Series E-2 warrants to purchase up to _____ shares of common stock (the “Series E-2 warrants”, and together with the Series E-1 warrants, the “Series E warrants”). We are also offering up to _____ pre-funded warrants (the “Series F pre-funded warrants” and collectively with the Series E warrants, the “warrants”) to those purchasers, whose purchase of shares of common stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering in lieu of the shares of our common stock that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%). Each Series F pre-funded warrant will be exercisable for one share of common stock. Each Series F pre-funded warrant is being issued together with the same Series E warrants described above being issued with each share common stock. The shares of common stock or Series F pre-funded warrants, as the case may be, and the Series E warrants, can only be purchased together in this offering, but the Series F pre-funded warrants and Series E warrants are immediately separable and will be issued separately in this offering. We are also registering the shares of common stock and the shares of common stock issuable from time to time upon exercise of the Series F pre-funded warrants and Series E warrants offered hereby.

Common Stock

The description of our common stock under the section “Description of Our Capital Stock” in this prospectus is incorporated herein by reference.

Series F Pre-Funded Warrants

The following summary of certain terms and provisions of the Series F pre-funded warrants that are being issued hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Series F pre-funded warrant, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Series F pre-funded warrant for a complete description of the terms and conditions of the Series F pre-funded warrants.

Duration and Exercise Price

Each Series F pre-funded warrant offered hereby will have an initial exercise price per share equal to \$0.0001. The Series F pre-funded warrants will be immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The Series F pre-funded warrants will be issued separately from the accompanying Series E warrants with Series F pre-funded warrants.

Exercisability

The Series F pre-funded warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Series F pre-funded warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days’ prior notice from the holder to us, the holder may increase the amount of beneficial ownership of outstanding stock after exercising the holder’s Series F pre-funded warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Series F pre-funded warrants and in accordance with the rules and regulations of the SEC. Purchasers of Series F pre-funded warrants in this offering may also elect prior to the issuance of the Series F pre-funded warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock.

Cashless Exercise

In lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Series F pre-funded warrants.

Transferability

Subject to applicable laws, a Series F pre-funded warrant may be transferred at the option of the holder upon surrender of the Series F pre-funded warrant to us together with the appropriate instruments of transfer.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the Series F pre-funded warrants. Rather, the number of shares of common stock to be issued will be rounded to the nearest whole number.

Trading Market

There is no trading market available for the Series F pre-funded warrants on any securities exchange or nationally recognized trading system, and we do not expect a trading market to develop. We do not intend to list the Series F pre-funded warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the Series F pre-funded warrants will be extremely limited. The common stock issuable upon exercise of the Series F pre-funded warrants is currently listed on the Nasdaq Capital Market.

Right as a Stockholder

Except as otherwise provided in the Series F pre-funded warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the Series F pre-funded warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their Series F pre-funded warrants. The Series F pre-funded warrants will provide that holders have the right to participate in distributions or dividends paid on our common stock.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Series F pre-funded warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of more than 50% of the voting power represented by our outstanding common stock, the holders of the Series F pre-funded warrants will be entitled to receive upon exercise of the Series F pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Series F pre-funded warrants immediately prior to such fundamental transaction.

Series E Warrants

The following summary of certain terms and provisions of the Series E warrants included with the shares of common stock and the Series F pre-funded warrants that are being issued hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Series E warrants, the forms of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the forms of Series E warrants for a complete description of the terms and conditions of the Series E warrants. The Series E-1 warrants and Series E-2 warrants have the same terms and provisions, other than the exercise period of each, as described below.

Duration and Exercise Price

Each Series E warrant offered hereby will have an initial exercise price equal to \$ _____ per share of common stock. The Series E-1 warrants will be exercisable beginning on the Initial Exercise Date and will expire five years from

the Initial Exercise Date. The Series E-2 warrants will be exercisable beginning on the Initial Exercise Date and will expire eighteen months from the Initial Exercise Date. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The Series E warrants will be issued separately from the common stock, or the Series F pre-funded warrants, as the case may be.

We intend to promptly, and in no event later than 90 days after the consummation of this offering, seek stockholder approval for the issuance of shares of common stock issuable upon exercise of the Series E warrants but we cannot assure you that such stockholder approval will be obtained, provided, however, that, if and only if the Pricing Conditions are met, then we will not seek Warrant Stockholder Approval. We have agreed with the investors in this offering that, if we do not obtain stockholder approval for the issuance of the shares of common stock upon exercise of the warrants at the first stockholder meeting for such purpose after this offering, we will call a stockholder meeting every 90 days thereafter until the earlier of the date we obtain such approval or the warrants are no longer outstanding, provided, however, that, if and only if the Pricing Conditions are met, then we will not seek Warrant Stockholder Approval.

Exercisability

The Series E warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Series E warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of beneficial ownership of outstanding stock after exercising the holder's Series E warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Series E warrants and in accordance with the rules and regulations of the SEC.

Cashless Exercise

If, at the time a holder exercises its Series E warrants, a registration statement registering the issuance of the shares of common stock underlying the Series E warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Series E warrants.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the Series E warrants. Rather, the number of shares of common stock to be issued will be rounded to the nearest whole number.

Transferability

Subject to applicable laws, a Series E warrant may be transferred at the option of the holder upon surrender of the Series E warrant to us together with the appropriate instruments of transfer.

Trading Market

There is no trading market available for the Series E warrants on any securities exchange or nationally recognized trading system, and we do not expect a trading market to develop. We do not intend to list the Series E warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the Series E warrants will be extremely limited. The common stock issuable upon exercise of the Series E warrants is currently listed on the Nasdaq Capital Market.

Right as a Stockholder

Except as otherwise provided in the Series E warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the Series E warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their Series E warrants.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Series E warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of more than 50% of the voting power represented by our outstanding common stock, the holders of the Series E warrants will be entitled to receive upon exercise of the Series E warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Series E warrants immediately prior to such fundamental transaction. In addition, in the event of a fundamental transaction which is approved by our Board, the holders of the Series E warrants have the right to require us or a successor entity to redeem the Series E warrant for cash in the amount of the Black-Scholes value of the unexercised portion of the Series E warrant on the date of the consummation of the fundamental transaction. In the event of a fundamental transaction which is not approved by our Board, the holders of the Series E warrants have the right to require us or a successor entity to redeem the Series E warrant for the consideration paid in the fundamental transaction in the amount of the Black Scholes value of the unexercised portion of the Series E warrant on the date of the consummation of the fundamental transaction.

Placement Agent Warrants

The following summary of certain terms and provisions of the Placement Agent Warrants that are being issued hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Placement Agent Warrants, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Placement Agent Warrant for a complete description of the terms and conditions of the Placement Agent Warrant.

Duration and Exercise Price

Each Placement Agent Warrant offered hereby will have an initial exercise price equal to \$ _____ per share of common stock (125% of the combined public offering price per share of common stock and Series E warrants). The Placement Agent Warrants will be exercisable beginning on the Initial Exercise Date and will expire five years from the commencement of sales in this offering. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price.

Exercisability

The Placement Agent Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Placement Agent Warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of beneficial ownership of outstanding stock after exercising the holder's Placement Agent Warrant up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Placement Agent Warrants and in accordance with the rules and regulations of the SEC.

Cashless Exercise

If, at the time a holder exercises its Placement Agent Warrants, a registration statement registering the issuance of the shares of common stock underlying the Placement Agent Warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to

us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Placement Agent Warrants.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the Placement Agent Warrants. Rather, the number of shares of common stock to be issued will be rounded to the nearest whole number.

Transferability

Subject to applicable laws, a Placement Agent Warrant may be transferred at the option of the holder upon surrender of the Placement Agent Warrant to us together with the appropriate instruments of transfer.

Trading Market

There is no trading market available for the Placement Agent Warrants on any securities exchange or nationally recognized trading system, and we do not expect a trading market to develop. We do not intend to list the Placement Agent Warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the Placement Agent Warrants will be extremely limited. The common stock issuable upon exercise of the Placement Agent Warrants is currently listed on the Nasdaq Capital Market.

Right as a Stockholder

Except as otherwise provided in the Placement Agent Warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the Placement Agent Warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their Placement Agent Warrants.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Placement Agent Warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of more than 50% of the voting power represented by our outstanding common stock, the holders of the Placement Agent Warrants will be entitled to receive upon exercise of the Placement Agent Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Placement Agent Warrants immediately prior to such fundamental transaction. In addition, in the event of a fundamental transaction which is approved by our Board, the holders of the Placement Agent Warrants have the right to require us or a successor entity to redeem the Placement Agent Warrant for cash in the amount of the Black-Scholes value of the unexercised portion of the Placement Agent Warrant on the date of the consummation of the fundamental transaction. In the event of a fundamental transaction which is not approved by our Board, the holders of the Placement Agent Warrants have the right to require us or a successor entity to redeem the Placement Agent Warrants for the consideration paid in the fundamental transaction in the amount of the Black Scholes value of the unexercised portion of the Placement Agent Warrant on the date of the consummation of the fundamental transaction.

MATERIAL U.S. FEDERAL TAX CONSIDERATIONS FOR HOLDERS OF OUR COMMON STOCK, SERIES F PRE-FUNDED WARRANTS AND SERIES E WARRANTS

The following discussion describes certain material U.S. federal income tax consequences of the acquisition, ownership and disposition of our common stock, Series F pre-funded warrants and Series E warrants acquired in this offering. This discussion is based on the current provisions of the Internal Revenue Code of 1986, as amended (referred to as the “Code”), existing and proposed U.S. Treasury regulations promulgated thereunder, and administrative rulings and court decisions in effect as of the date hereof, all of which are subject to change at any time, possibly with retroactive effect. No ruling has been or will be sought from the Internal Revenue Service, or IRS, with respect to the matters discussed below, and there can be no assurance the IRS will not take a contrary position regarding the tax consequences of the acquisition, ownership or disposition of our common stock, Series F pre-funded warrants or Series E warrants, or that any such contrary position would not be sustained by a court.

We assume in this discussion that the shares of our common stock, Series F pre-funded warrants and Series E warrants will be held as capital assets (generally, property held for investment). This discussion does not address all aspects of U.S. federal income taxes, does not discuss the potential application of the Medicare contribution tax and does not deal with state or local taxes or U.S. federal gift and estate tax laws, or any non-U.S. tax consequences that may be relevant to holders in light of their particular circumstances. This discussion also does not address the special tax rules applicable to particular holders, such as:

- a bank, insurance company, or other financial institution;
- a tax-exempt entity, organization, or arrangement;
- a government or any agency, instrumentality, or controlled entity thereof;
- a real estate investment trust;
- an S corporation or other pass-through entity (or an investor in an S corporation or other pass-through entity);
- a regulated investment company;
- a “controlled foreign corporation” or a “passive foreign investment company”;
- a dealer or broker in stocks and securities, or currencies;
- a trader in securities that elects mark-to-market treatment or any other holder subject to mark-to-market treatment;
- a holder of our common stock, Series F pre-funded warrants, or Series E warrants that is liable for the alternative minimum tax;
- a holder of our common stock, Series F pre-funded warrants, or Series E warrants that received such security through the exercise of options, warrants, or similar derivative securities or otherwise as compensation;
- a holder of our common stock, Series F pre-funded warrants, or Series E warrants that holds such security in a tax-deferred account (such as an individual retirement account or a plan qualifying under Section 401(k) of the Code);
- a holder of our common stock, Series F pre-funded warrants, or Series E warrants that has a functional currency other than the U.S. dollar;

- a holder of our common stock, Series F pre-funded warrants, or Series E warrants that holds such security as part of a hedge, straddle, constructive sale, conversion or other integrated transaction;
- a holder of our common stock, Series F pre-funded warrants, or Series E warrants required to accelerate the recognition of any item of gross income with respect to such security, as a result of such income being recognized on an applicable financial statement;
- a holder of our common stock, Series F pre-funded warrants, or Series E warrants that is a U.S. expatriate or former citizen or long-term resident of the United States;
- a holder of our common stock, Series F pre-funded warrants, or Series E warrants that does not hold such security as a capital asset within the meaning of Section 1221 of the Code (generally, for investment purposes);
- a holder of our common stock, Series F pre-funded warrants, or Series E warrants whose security may constitute “qualified small business stock” under Section 1202 of the Code or “Section 1244 stock” for purposes of Section 1244 of the Code; or
- a holder of our common stock, Series F pre-funded warrants, or Series E warrants that acquired such security in a transaction subject to the gain rollover provisions of Section 1045 of the Code;

In addition, this discussion does not address the tax treatment of partnerships or other pass-through entities or of persons who hold our common stock, Series F pre-funded warrants or Series E warrants through partnerships or other entities which are pass-through entities for U.S. federal income tax purposes. A partner in a partnership or other pass-through entity that will hold our common stock, Series F pre-funded warrants or Series E warrants should consult his, her or its own tax advisor regarding the tax consequences of the ownership and disposition of our common stock, Series F pre-funded warrants or Series E warrants through a partnership or other pass-through entity, as applicable.

The discussion of U.S. federal income tax considerations is for information purposes only and is not tax advice. Investors should consult their own tax advisors regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of acquiring, holding and disposing of our common stock, Series F pre-funded warrants and Series E warrants.

For the purposes of this discussion, a “U.S. Holder” means a beneficial owner of our common stock, Series F pre-funded warrants or Series E warrants that is for U.S. federal income tax purposes (a) an individual citizen or resident of the United States, (b) a corporation (or other entity treated as a corporation for U.S. federal income tax purposes), organized in or under the laws of the United States, any state thereof or the District of Columbia, (c) an estate the income of which is includable in gross income for U.S. federal income tax purposes regardless of its source, or (d) a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons (within the meaning of Section 7701(a)(30) of the Code) has the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person. A “Non-U.S. Holder” is, for U.S. federal income tax purposes, a beneficial owner of common stock, Series F pre-funded warrants or Series E warrants (other than a partnership or other entity or arrangement classified as a partnership for U.S. federal income tax purposes) that is not a U.S. Holder.

Treatment of Series F Pre-Funded Warrants

Although it is not entirely free from doubt, we believe a Series F pre-funded warrant should be treated as a share of our common stock for U.S. federal income tax purposes and a holder of Series F pre-funded warrants should generally be taxed in the same manner as a holder of common stock as described below. Accordingly, for U.S. federal income tax purposes, no gain or loss should be recognized upon the exercise of a Series F pre-funded warrant, and upon exercise, the holding period of the share of common stock received should include the holding period of the Series F pre-funded warrant. Similarly, the tax basis of a share of common stock received upon exercise of a Series F pre-funded warrant should include the tax basis of the Series F pre-funded warrant (discussed below) increased by the exercise price of \$0.0001. The balance of this discussion generally assumes that the characterization described above is respected for U.S. federal income tax purposes.

Allocation of Purchase Price to Common Stock, Series F Pre-Funded Warrants and Series E Warrants

For U.S. federal income tax purposes, a holder's acquisition of the Series E warrants and common stock or Series F pre-funded warrants, as applicable, will be treated as the acquisition of an "investment unit" consisting of one share of common stock (or one Series F pre-funded warrant, as applicable) and a Series E-1 warrant and a Series E-2 warrant, each to acquire one share of our common stock, subject to adjustment. The purchase price for each investment unit will be allocated between these two components in proportion to their relative fair market values at the time the investment unit is purchased by the holder. This allocation of the purchase price for each investment unit will establish the holder's initial tax basis for U.S. federal income tax purposes in the common stock (or Series F pre-funded warrant, as applicable) and the Series E warrants included in each investment unit. The separability of the share of common stock (or Series F pre-funded warrant, as applicable) and the Series E warrants included in each investment unit should not in itself result in the recognition of income or gain for U.S. federal income tax purposes. Each holder should consult his, her or its own tax advisor regarding risks associated with the acquisition of an investment unit pursuant to this offering (including potential alternative characterizations and the allocation of purchase price for an investment unit).

Tax Considerations Applicable to U.S. Holders

Exercise and Expiration of Series E Warrants

In general, a U.S. Holder will not recognize gain or loss for U.S. federal income tax purposes upon exercise of a Series E warrant. The U.S. Holder will take a tax basis in the shares acquired on the exercise of a Series E warrant equal to the exercise price of the Series E warrant, increased by the U.S. Holder's adjusted tax basis in the Series E warrant exercised (as determined pursuant to the rules discussed above). The U.S. Holder's holding period in the shares of our common stock acquired on exercise of the Series E warrant will begin on the date of exercise of the Series E warrant, and will not include any period for which the U.S. Holder held the Series E warrant.

In certain limited circumstances, a U.S. Holder may be permitted to undertake a cashless exercise of Series E warrants into our common stock. The U.S. federal income tax treatment of a cashless exercise of Series E warrants into our common stock is unclear, and the tax consequences of a cashless exercise could differ from the consequences upon the exercise of a Series E warrant described in the preceding paragraph. U.S. Holders should consult their own tax advisors regarding the U.S. federal income tax consequences of a cashless exercise of Series E warrants.

The lapse or expiration of a Series E warrant will be treated as if the U.S. Holder sold or exchanged the Series E warrant and recognized a capital loss equal to the U.S. Holder's tax basis in the Series E warrant. The deductibility of capital losses is subject to limitations.

Certain Adjustments to and Distributions on the Series E Warrants

Under Section 305 of the Code, an adjustment to the number of shares of common stock issued on the exercise of the Series E warrants, or an adjustment to the exercise price of the Series E warrants, may be treated as a constructive distribution to a U.S. Holder of the Series E warrants if, and to the extent that, such adjustment has the effect of increasing such U.S. Holder's proportionate interest in our "earnings and profits" or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property. In addition, if we were to make a distribution in cash or other property with respect to our common stock after the issuance of the Series E warrants, then we may, in certain circumstances, make a corresponding distribution to a Series E warrant holder. The taxation of a distribution received with respect to a Series E warrant is unclear. It is possible such a distribution would be treated as a distribution (or constructive distribution), although other treatments are possible. For more information regarding the tax considerations related to distributions, see the discussion below regarding "Distributions." U.S. Holders should consult their tax advisors regarding the proper treatment of any adjustments to and distributions on the Series E warrants.

Distributions

As discussed above in the section captioned "Dividend Policy", we currently anticipate that we will retain all available funds and any future earnings for use in the operation of our business and do not anticipate declaring or paying

any cash dividends on our common stock for the foreseeable future. In the event that we do make distributions on our common stock or Series F pre-funded warrants to a U.S. Holder, those distributions generally will constitute dividends for U.S. tax purposes to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Distributions to a U.S. Holder that are not derived from our current or accumulated earnings and profits will constitute a return of capital that is applied against and reduces, but not below zero, the U.S. Holder's adjusted tax basis in our common stock or Series F pre-funded warrant, as applicable, and to the extent in excess of such basis, will be treated as gain realized on the sale or exchange of our common stock or Series F pre-funded warrants, as applicable, as described below under the section titled "Disposition of Our Common Stock, Series F Pre-Funded Warrants or Series E Warrants."

Disposition of Our Common Stock, Series F Pre-Funded Warrants or Series E Warrants

Upon a sale or other taxable disposition of our common stock, Series F pre-funded warrants or Series E warrants, a U.S. Holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. Holder's adjusted tax basis in the applicable common stock, Series F pre-funded warrants or Series E warrants. Capital gain or loss will constitute long-term capital gain or loss if the U.S. Holder's holding period for the applicable common stock, Series F pre-funded warrant or Series E warrant exceeds one year. The deductibility of capital losses is subject to certain limitations. U.S. Holders who recognize losses with respect to a disposition of our common stock, Series F pre-funded warrants or Series E warrants should consult their own tax advisors regarding the tax treatment of such losses.

Information Reporting and Backup Withholding

Information reporting requirements generally will apply to payments of dividends (including constructive dividends) on our common stock, Series F pre-funded warrants and Series E warrants and to the proceeds of a sale or other disposition of common stock, Series E warrants and Series F pre-funded warrants by a U.S. Holder unless such U.S. Holder is an exempt recipient, such as a corporation. Backup withholding will apply to those payments if the U.S. Holder fails to provide the holder's taxpayer identification number, or certification of exempt status, or if the holder otherwise fails to comply with applicable requirements to establish an exemption. Backup withholding is not an additional tax. Rather, amounts withheld as backup withholding may be credited against a person's U.S. federal income tax liability, and a holder generally may obtain a refund of any excess amounts withheld under the backup withholding rules by timely filing the appropriate claim for refund with the IRS and furnishing any required information.

Tax Considerations Applicable to Non-U.S. Holders

Exercise and Expiration of Series E Warrants

In general, a Non-U.S. Holder will not be subject to U.S. federal income tax on the exercise of the Series E warrants into shares of common stock. As described under "U.S. Holders — Exercise and Expiration of Series E Warrants," the U.S. federal income tax treatment of a cashless exercise of Series E warrants into our common stock is unclear. A Non-U.S. Holder should consult his, her, or its own tax advisor regarding the U.S. federal income tax consequences of a cashless exercise of Series E warrants.

The expiration of a Series E warrant will be treated as if the Non-U.S. Holder sold or exchanged the Series E warrant and recognized a capital loss equal to the Non-U.S. Holder's tax basis in the Series E warrant. However, a Non-U.S. Holder will not be able to utilize a loss recognized upon expiration of a Series E warrant against the Non-U.S. Holder's U.S. federal income tax liability unless the loss is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if an income tax treaty applies, is attributable to a permanent establishment or fixed base in the United States) or is treated as a U.S.-source loss and the Non-U.S. Holder is an individual nonresident and present 183 days or more in the taxable year of disposition in the United States and certain other conditions are met.

Certain Adjustments to and Distributions on the Series E Warrants

As described under "U.S. Holders — Certain Adjustments to and Distributions on the Series E Warrants," an adjustment to the Series E warrants could result in a constructive distribution to a Non-U.S. Holder, which would be treated as described under "Distributions" below, and the tax treatment of a distribution on a Series E warrant is unclear. Any resulting withholding tax attributable to deemed dividends would be collected from other amounts payable or distributable

to the Non-U.S. Holder. Non-U.S. Holders should consult their tax advisors regarding the proper treatment of any adjustments to or distributions on the Series E warrants.

Distributions

As discussed above in the section captioned “Dividend Policy”, we currently anticipate that we will retain all available funds and any future earnings for use in the operation of our business and do not anticipate declaring or paying any cash dividends on our common stock for the foreseeable future. In the event that we do make distributions on our common stock or Series F pre-funded warrants to a Non-U.S. Holder, those distributions generally will be treated as dividends, as return of capital or as gain on the sale or exchange of common stock or Series F pre-funded warrants for U.S. federal income tax purposes as described in “U.S. Holders — Distributions.”

Subject to the discussions below under the sections titled “Information Reporting and Backup Withholding” and “Foreign Accounts,” any distribution (including constructive distributions) on our common stock or Series F pre-funded warrants that is treated as a dividend paid to a Non-U.S. Holder that is not effectively connected with the holder’s conduct of a trade or business in the United States will generally be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and the Non-U.S. Holder’s country of residence. To obtain a reduced rate of withholding under a treaty, a Non-U.S. Holder generally will be required to provide the applicable withholding agent with a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E or other appropriate form, certifying the Non-U.S. Holder’s entitlement to benefits under that treaty. Such form must be provided prior to the payment of dividends and must be updated periodically and when otherwise required by law.

We generally are not required to withhold tax on dividends paid (or constructive dividends deemed paid) to a Non-U.S. Holder that are effectively connected with such holder’s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment or fixed base that the holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to us. In general, such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates applicable to U.S. persons. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional “branch profits tax,” which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder’s effectively connected earnings and profits, subject to certain adjustments.

Distributions to a Non-U.S. Holder that are not derived from our current or accumulated earnings and profits generally will be treated as a return of capital that will be applied against and reduce (but not below zero) the Non-U.S. Holder’s basis in its common stock or Series F pre-funded warrants, as applicable, and to the extent in excess of such basis, will be treated as gain from the sale or exchange of such common stock or Series F pre-funded warrants, as applicable, as described under “Disposition of Our Common Stock, Series F Pre-Funded Warrants or Series E Warrants” below.

If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the holder’s behalf, the holder will be required to provide appropriate documentation to such agent. The holder’s agent may then be required to provide certification to the applicable withholding agent, either directly or through other intermediaries.

Disposition of Our Common Stock, Series F Pre-Funded Warrants or Series E Warrants

Subject to the discussions below under the sections titled “Information Reporting and Backup Withholding” and “Foreign Accounts,” a Non-U.S. Holder generally will not be subject to U.S. federal income or withholding tax with respect to gain realized on a sale or other disposition of our common stock, Series F pre-funded warrants or Series E warrants unless:

- the gain is effectively connected with the Non-U.S. Holder’s conduct of a trade or business in the United States (and, if required by an applicable income tax treaty between the United States and such Non-U.S. Holder’s country of residence, the gain is attributable to a permanent establishment or fixed base maintained by the Non-U.S. Holder in the U.S.), in which case the Non-U.S. Holder will be taxed on a net income basis at the regular rates and in the manner applicable to U.S. persons, and if the Non-U.S. Holder is a corporation, an additional branch profits tax at a rate of 30%, or a lower rate as may be specified by an applicable income tax treaty, may also apply;

- the Non-U.S. Holder is a nonresident alien present in the United States for 183 days or more in the taxable year of the disposition and certain other requirements are met, in which case the Non-U.S. Holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) on the net gain derived from the disposition, which may be offset by certain U.S.-source capital losses of the Non-U.S. Holder, if any, provided that the Non-U.S. Holder has timely filed U.S. federal income tax returns reporting those losses; or
- we are, or have been, a "United States real property holding corporation," or USRPHC, for U.S. federal income tax purposes during the five-year period preceding such disposition (or the Non-U.S. Holder's holding period, if shorter). We do not believe that we are or have been a USRPHC and, even if we are or were a USRPHC, as long as our common stock is regularly traded on an established securities market, dispositions will not be subject to tax for a Non-U.S. Holder that has not held more than 5% of our common stock, actually or constructively, during the five-year period preceding such Non-U.S. Holder's disposition (or the Non-U.S. Holder's holding period, if shorter). Special rules may apply to the determination of the 5% threshold in the case of a holder of a Series F pre-funded warrant or Series E warrant.

See the sections titled "Information Reporting and Backup Withholding" and "Foreign Accounts" below for additional information regarding withholding rules that may apply to proceeds of a disposition of our common stock, Series F pre-funded warrants or Series E warrants paid to foreign financial institutions or non-financial foreign entities.

Information Reporting and Backup Withholding

We must report annually to the IRS and to each Non-U.S. Holder the gross amount of the distributions (including constructive distributions) on our common stock, Series F pre-funded warrants or Series E warrants paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. Holders may have to comply with specific certification procedures to establish that the holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate, currently 24%. Generally, a Non-U.S. Holder will comply with such procedures if it provides a properly executed applicable IRS Form W-8 or by otherwise establishing an exemption. Dividends paid to Non-U.S. Holders subject to withholding of U.S. federal income tax, as described above under the heading "Distributions," will generally be exempt from U.S. backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock, Series F pre-funded warrants or Series E warrants by a Non-U.S. Holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the Non-U.S. Holder certifies its status as a Non-U.S. Holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a non-U.S. broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. Holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the Non-U.S. Holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a Non-U.S. Holder can be refunded or credited against the Non-U.S. Holder's U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

Foreign Accounts

Legislation commonly referred to as the "Foreign Account Tax Compliance Act," or "FATCA," generally imposes a 30% withholding tax on dividends on common stock, Series F pre-funded warrants and Series E warrants if paid to a non-U.S. entity unless (i) if the non-U.S. entity is a "foreign financial institution," the non-U.S. entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the non-U.S. entity is not a "foreign

financial institution,” the non-U.S. entity identifies certain of its U.S. investors, if any, or (iii) the non-U.S. entity is otherwise exempt under FATCA.

Intergovernmental agreements between the United States and foreign countries with respect to FATCA may significantly modify the requirements described in this section for Non-U.S. Holders. Holders should consult their own tax advisors regarding the possible implications of FATCA on their investment in our common stock, Series F pre-funded warrants or Series E warrants.

The preceding discussion of material U.S. federal tax considerations is for information only. It is not tax advice. Prospective investors should consult their own tax advisors regarding the particular U.S. federal, state, local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, Series F pre-funded warrants or Series E warrants, including the consequences of any proposed changes in applicable laws.

PLAN OF DISTRIBUTION

We engaged (“ ” or the “placement agent”) to act as our exclusive placement agent to solicit offers to purchase the securities offered by this prospectus on a reasonable best efforts basis. The placement agent is not purchasing or selling any securities, nor are they required to arrange for the purchase and sale of any specific number or dollar amount of securities, other than to use their “reasonable best efforts” to arrange for the sale of the securities by us. Therefore, we may not sell the entire amount of securities being offered.

There is no minimum amount of proceeds that is a condition to closing of this offering. The placement agent does not guarantee that it will be able to raise new capital in this offering. Investors purchasing securities offered hereby will have the option to execute a securities purchase agreement with us. In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers which enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. The ability to pursue a claim for breach of contract is material to larger purchasers in this offering as a means to enforce the following covenants uniquely available to them under the securities purchase agreement: (i) a covenant to not enter into variable rate financings for a period of one year following the closing of the offering, subject to an exception; and (ii) a covenant to not enter into any equity financings for () days from closing of the offering, subject to certain exceptions. The placement agent may engage one or more sub-placement agents or selected dealers to assist with the offering.

The nature of the representations, warranties and covenants in the securities purchase agreements shall include:

- standard issuer representations and warranties on matters such as organization, qualification, authorization, no conflict, no governmental filings required, current in SEC filings, no litigation, labor or other compliance issues, environmental, intellectual property and title matters and compliance with various laws such as the Foreign Corrupt Practices Act;
- standard issuer representations and warranties on matters such as organization, qualification, authorization, no conflict, no governmental filings required, current in SEC filings, no litigation, labor or other compliance issues, environmental, intellectual property and title matters and compliance with various laws such as the Foreign Corrupt Practices Act; and
- covenants regarding matters such as registration of warrant shares, no integration with other offerings, filing of an 8-K to disclose entering into these securities purchase agreements, no shareholder rights plans, no material nonpublic information, use of proceeds, indemnification of purchasers, reservation and listing of common stock, and no subsequent equity sales for () days, subject to certain exceptions.

Fees and Expenses

The following table shows the per share and Series E warrants placement agent fees and total placement agent fees we will pay in connection with the sale of the securities in this offering, assuming the purchase of all of the securities we are offering.

Per share and Series E warrants placement agent cash fees	\$
Per Series F pre-funded warrant and Series E warrants placement agent cash fees	\$
Total	\$

We have agreed to pay the placement agent a total cash fee equal to 7.0% of the gross proceeds of this offering and a management fee equal to 1.0% of the gross proceeds raised in this offering. We will also pay the placement agent a non-accountable expense allowance of \$10,000, \$15,950 for the expenses of its clearing firm, and will reimburse the placement agent’s legal fees and expenses in an amount up to \$100,000. We estimate the total offering expenses of this offering that will be payable by us, excluding the placement agent fees and expenses, will be approximately \$ million. After deducting the placement agent fees and our estimated offering expenses, we expect the net proceeds from this offering to be approximately \$ million.

Placement Agent Warrants

We have agreed to grant placement agent warrants to the placement agent, or its designees, (the “Placement Agent Warrant”) to purchase a number of shares of our common stock equal to 5.0% of the aggregate number of shares of common stock and Series F pre-funded warrants sold to the investors in this offering. The placement agent warrants will have an exercise price of \$ (125% of the combined public offering price per share of common stock and Series E warrants) and will terminate on the five year anniversary of commencement of sales in this offering. The Placement Agent Warrants and the shares of common stock exercisable under the Placement Agent Warrants are registered on the registration statement of which this prospectus is a part. The form of the Placement Agent Warrant will be included as an exhibit to this registration statement of which this prospectus forms a part.

Tail

We have also agreed to pay the placement agent a tail fee equal to the cash and warrant compensation in this offering, if any investor, who was contacted or introduced to us by the placement agent during the term of its engagement, provides us with capital in any public or private offering or other financing or capital raising transaction during the 12-month period following expiration or termination of our engagement of the placement agent.

Determination of Offering Price

The combined public offering price per share and Series E warrants and the combined public offering price per Series F pre-funded warrant and Series E warrants we are offering and the exercise prices and other terms of the warrants were negotiated between us and the investors, in consultation with the placement agent based on the trading of our common stock prior to this offering, among other things. Other factors considered in determining the public offering prices of the securities we are offering and the exercise prices and other terms of the warrants include the history and prospects of our company, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

Lock-up Agreements

We and each of our officers and directors have agreed with the placement agent to be subject to a lock-up period of () days following the date of this prospectus. This means that, during the applicable lock-up period, we and such persons may not offer for sale, contract to sell, or sell any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock subject to certain customary exceptions. The placement agent may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements. In addition, we have agreed to not issue any securities that are subject to a price reset based on trading prices of our common stock or upon a specified or contingent event in the future, or enter into an agreement to issue securities at a future determined price, until one (1) year following the closing date of this offering, subject to an exception. The placement agent may waive this prohibition in its sole discretion and without notice.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Broadridge Corporate Issuer Solutions, Inc. whose address is 51 Mercedes Way, Edgewood, New York 11717.

Nasdaq Listing

Our common stock is currently listed on the Nasdaq Capital Market under the symbol “AGRX.” On , 2024, the reported closing price per share of our common stock was \$. We do not plan to list the warrants on the Nasdaq Capital Market or any other securities exchange or trading market.

Indemnification

We have agreed to indemnify the placement agent against certain liabilities, including liabilities under the Securities Act of 1933, as amended (the “Securities Act”), or to contribute to payments the placement agent may be required to make with respect to any of these liabilities.

Regulation M

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act and any fees received by it and any profit realized on the sale of the securities by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The placement agent will be required to comply with the requirements of the Securities Act and the Exchange Act of 1934, as amended (the “Exchange Act”), including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the placement agent. Under these rules and regulations, the placement agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until they have completed their participation in the distribution.

Electronic Offer, Sale and Distribution of Securities

A prospectus in electronic format may be made available on the websites maintained by the placement agent, if any, participating in this offering and the placement agent may distribute prospectuses electronically. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or the placement agent, and should not be relied upon by investors.

LEGAL MATTERS

The validity of the securities being offered in this offering will be passed upon for us by Morgan, Lewis & Bockius LLP, Princeton, New Jersey.

EXPERTS

The financial statements of Agile Therapeutics, Inc. at December 31, 2022 and 2021, and for each of the three years in the period ended December 31, 2022, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon, which contains explanatory paragraphs describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 1 to the financial statements and describing the restatement of the 2021 financial statements as described in Note 2 to the financial statements appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus forms part of a registration statement on Form S-1 that we filed with the SEC. This prospectus does not contain all of the information set forth in the registration statement and the exhibits to the registration statement. For further information with respect to us and the securities that we are offering under this prospectus, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement. You should rely only on the information contained in this prospectus. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the cover page of this prospectus, regardless of the time of delivery of this prospectus or any sale of the securities offered hereby. We file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains a website that contains reports, proxy statements and other information regarding issuers that file electronically with the SEC, including Agile Therapeutics. The address of the SEC website is www.sec.gov.

We maintain a website at www.agiletherapeutics.com. Information contained in or accessible through our website does not constitute a part of this prospectus.

**Agile Therapeutics, Inc.
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For the Year Ended December 31, 2022**

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Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Agile Therapeutics, Inc. (the “Company”) as of December 31, 2022 and 2021, the related statements of operations and comprehensive loss, changes in stockholders’ equity, and cash flows for each of the three years in the period ended December 31, 2022, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

The Company’s Ability to Continue as a Going Concern

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

Restatement of 2021 Financial Statements

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

Basis for Opinion

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

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

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

Critical Audit Matter

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

on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenues, net

Description of the Matter The Company sells approved product primarily to wholesale distributors. As discussed in Note 3, revenue is recorded net of reserves for applicable variable consideration. When recognizing revenue, the Company estimates the transaction price and assesses whether to constrain variable consideration. Limited historical data is available for use in developing such estimates.

The Company’s estimates of Medicaid rebates, chargebacks, and copayment assistance depend on the identification of key customer contract terms and conditions, as well as estimates of sales volumes to different classes of payers. Auditing the Company’s net revenues was complex due to the Company’s limited history of product sales, and the revenue recognition process involves significant judgment to identify and assess the terms and conditions of customer agreements and related government regulations.

How We Addressed the Matter in Our Audit Among other procedures performed to test management’s estimates of Medicaid rebates, chargebacks, and co-payment assistance, we developed an independent expectation of the reserve based on the relevant terms of the customer contracts and/or obtained management’s calculations of the respective reserve and tested management’s estimate by tracing relevant inputs to the customer contracts and underlying sales data. We obtained and reviewed the Company’s estimated channel and payer mix, compared relevant inputs to underlying sales data and analyzed the impact of changes to the inputs on the estimate. We also evaluated credits and adjustments subsequent to the balance sheet date, if any, and tested the underlying sales data by confirming a sample of receivable balances directly with the Company’s customers and performed alternative procedures for confirmations not received.

/s/ Ernst & Young LLP

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

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

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

See accompanying notes.

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

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

See accompanying notes.

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

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Other Comprehensive Income</u>	<u>Accumulated Deficit</u>	<u>Net Stockholders' Equity</u>
	<u>Number of Shares</u>	<u>Amount</u>	<u>Number of Shares</u>	<u>Amount</u>				
Balance December 31, 2019	—	\$ —	1,745,264	\$ —	\$ 306,115	\$ —	\$ (260,370)	\$ 45,745
Share-based compensation — stock options and RSUs	—	—	—	—	2,818	—	—	2,818
Proceeds from issuance of common stock in public offering, net of expenses	—	—	431,250	—	48,435	—	—	48,435
Issuance of common stock upon exercise of stock options	—	—	12,586	—	610	—	—	610
Warrants issued in connection with long- term debt	—	—	—	—	3,570	—	—	3,570
Unrealized net gain on marketable securities	—	—	—	—	—	3	—	3
Net loss	—	—	—	—	—	—	(51,853)	(51,853)
Balance December 31, 2020	—	\$ —	2,189,100	\$ —	\$ 361,548	\$ 3	\$ (312,223)	\$ 49,328
Share-based compensation - stock options and RSUs	—	—	—	—	3,338	—	—	3,338
Issuance of common stock pursuant to at-the-market stock sales, net of expenses	—	—	172,879	—	9,266	—	—	9,266
Issuance of common stock in public offering, net of expenses (Restated)	—	—	666,666	—	11,898	—	—	11,898
Issuance of common stock upon exercise of stock options	—	—	3,160	—	75	—	—	75
Vesting of RSUs	—	—	3,096	—	—	—	—	—
Warrants issued in connection with long- term debt	—	—	—	—	1,080	—	—	1,080
Unrealized net gain on marketable securities	—	—	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	—	—	(71,067)	(71,067)
Balance December 31, 2021 (Restated)	—	\$ —	3,034,901	\$ —	\$ 387,205	\$ —	\$ (383,290)	\$ 3,915
Share-based compensation - stock options and RSUs	—	—	—	—	2,492	—	—	2,492
Issuance of common stock pursuant to at-the-market stock sales, net of expenses	—	—	12,655,773	1	13,456	—	—	13,457
Issuance of series A and B convertible preferred stock in a registered direct offering (Note 10)	4,850	—	—	—	—	—	—	—
Conversion of series A convertible preferred stock	(2,425)	—	303,125	—	—	—	—	—
Conversion of series B convertible preferred stock	(2,425)	—	303,125	—	—	—	—	—
Issuance of common stock in public offering, net of expenses	—	—	26,666,666	3	—	—	—	3
Vesting of RSUs	—	—	6,555	—	—	—	—	—
Fractional shares retired as a result of reverse split	—	—	(11)	—	—	—	—	—
Net loss	—	—	—	—	—	—	(25,412)	(25,412)
Balance December 31, 2022	—	\$ —	42,970,134	\$ 4	\$ 403,153	\$ —	\$ (408,702)	\$ (5,545)

See accompanying notes.

Agile Therapeutics, Inc.
Statements of Cash Flows

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

See accompanying notes.

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

1. Organization and Description of Business

Nature of Operations

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

The Company’s sole approved product, Twirla, also known prior to its approval as AG200-15, is a once-weekly prescription contraceptive patch that received approval from the U.S. Food and Drug Administration, or FDA, in February 2020 and was commercially launched in early December 2020. Substantially all of the Company’s resources are currently dedicated to commercializing Twirla in the United States. The Company has generated minimal product revenue to date and is subject to a number of risks similar to those of other early stage commercial companies, including, but not limited to, dependence on key individuals, the difficulties and uncertainties inherent in the development of commercially usable products, market acceptance of products, protection of proprietary technology, the potential need to obtain additional capital necessary to fund the development of its products, reliance on a consistent supply chain both for Twirla and in general, macroeconomic factors such as inflation, competition from larger companies, and compliance with FDA and other government regulations. If the Company does not successfully commercialize Twirla, it will be unable to generate recurring product revenue or achieve profitability. The Company has incurred operating losses and negative cash flows from operating activities each year since inception. As of December 31, 2022, the Company had an accumulated deficit of approximately \$408 million.

The Company expects to continue to incur significant operating expenses for the foreseeable future in connection with its ongoing activities, as the Company:

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

The Company has financed its operations to date primarily through the issuance and sale of its common stock in both public and private offerings (see Note 10), private placements of its convertible preferred stock, venture loans, and non-dilutive grant funding.

Going Concern

As of December 31, 2022, the Company had cash and cash equivalents of \$5.2 million and a \$2.0 million working capital deficit. The Company’s current liquidity is sufficient to fund operations only into the second quarter of 2023. The Company closely monitors its cash and cash equivalents and will need to raise additional funds to meet its projected operating requirements, including the continued commercialization of Twirla, and exploring the advancement of its existing pipeline and its possible expansion through business development activities.

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

The Company has generated losses since inception, used substantial cash in operations, has a working capital deficit at December 31, 2022 and anticipates it will continue to incur net losses for the foreseeable future. The Company's future success depends on its ability to obtain additional capital and/or implement various strategic alternatives, and there can be no assurance that any financing can be realized by the Company, or if realized, what the terms of any such financing may be, or that any amount that the Company is able to raise will be adequate. Based upon the foregoing, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern through the 12 months following the date on which the Company's Annual Report on Form 10-K is filed.

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

The audited financial statements as of December 31, 2022 have been prepared under the assumption that the Company will continue as a going concern for the next 12 months. The Company's ability to continue as a going concern is dependent upon its uncertain ability to obtain additional capital, reduce expenditures and/or execute on its business plan and successfully launch Twirla. The audited financial statements as of December 31, 2022 do not include any adjustments that might result from the outcome of this uncertainty. If the Company is unable to continue as a going concern, it may have to liquidate its assets and may receive less than the value at which those assets are carried on the financial statements.

2. Restatement of Previously Issued Financial Statements

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

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

Impact of the Restatement

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

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

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

Balance Sheet

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

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

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

Statement of Operations and Comprehensive Loss

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

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

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

Statement of Changes in Stockholders' Equity

	Common Stock		Additional	Accumulated	Accumulated	Net
	Number of	Amount	Paid-in	Other Comprehensive	Deficit	Stockholders'
	Shares *		Capital *	Income		Equity
As Previously Reported						
Balance December 31, 2020	2,189,100	\$ —	\$ 361,548	\$ 3	\$ (312,223)	\$ 49,328
Share-based compensation - stock options and RSUs	—	—	3,338	—	—	3,338
Issuance of common stock pursuant to at-the-market stock sales, net of expenses	172,879	—	9,266	—	—	9,266
Issuance of common stock in public offering, net of expenses	666,666	—	21,081	—	—	21,081
Issuance of common stock upon exercise of stock options	3,160	—	75	—	—	75
Vesting of RSUs	3,096	—	—	—	—	—
Warrants issued in connection with long-term debt	—	—	1,080	—	—	1,080
Unrealized net gain on marketable securities	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	(74,894)	(74,894)
Balance December 31, 2021	<u>3,034,901</u>	<u>\$ —</u>	<u>\$ 396,388</u>	<u>\$ —</u>	<u>\$ (387,117)</u>	<u>\$ 9,271</u>
Adjustment						
Balance December 31, 2020	—	—	—	—	—	—
Share-based compensation - stock options and RSUs	—	—	—	—	—	—
Issuance of common stock pursuant to at-the-market stock sales, net of expenses	—	—	—	—	—	—
Issuance of common stock in public offering, net of expenses	—	—	(9,183)	—	—	(9,183)
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—
Vesting of RSUs	—	—	—	—	—	—
Warrants issued in connection with long-term debt	—	—	—	—	—	—
Unrealized net gain on marketable securities	—	—	—	—	3,827	3,827
Net loss	—	—	—	—	—	—
Total adjustment December 31, 2021	<u>—</u>	<u>\$ —</u>	<u>\$ (9,183)</u>	<u>\$ —</u>	<u>\$ 3,827</u>	<u>\$ (5,356)</u>
As Restated						
Balance December 31, 2020	2,189,100	\$ —	\$ 361,548	\$ 3	\$ (312,223)	\$ 49,328
Share-based compensation - stock options and RSUs	—	—	3,338	—	—	3,338
Issuance of common stock pursuant to at-the-market stock sales, net of expenses	172,879	—	9,266	—	—	9,266
Issuance of common stock in public offering, net of expenses	666,666	—	11,898	—	—	11,898
Issuance of common stock upon exercise of stock options	3,160	—	75	—	—	75
Vesting of RSUs	3,096	—	—	—	—	—
Warrants issued in connection with long-term debt	—	—	1,080	—	—	1,080
Unrealized net gain on marketable securities	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	(71,067)	(71,067)
Balance December 31, 2021 (Restated)	<u>3,034,901</u>	<u>\$ —</u>	<u>\$ 387,205</u>	<u>\$ —</u>	<u>\$ (383,290)</u>	<u>\$ 3,915</u>

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

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Statement of Cash Flows

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

3. Summary of Significant Accounting Policies

Basis of Presentation

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

Use of Estimates

The preparation of the Company’s financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company bases its estimates and judgments on historical experience and various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company’s balance sheets and the amounts of revenue and expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, revenue recognition, costs of product revenues, the accounting for

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common stock warrants, stock-based compensation, and accounting for research and development costs. As future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates.

Risks and Uncertainties

While Twirla has been approved by the FDA, other potential product candidates developed by the Company will require approval from the FDA prior to commercial sales. There can be no assurance that the Company's other product candidates will receive the required approval. If the Company is denied approval or such approval is delayed, or is unable to obtain the necessary financing to complete development and approval, there could be a material adverse impact on the Company's financial condition and results of operations.

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

Cash and Cash Equivalents

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

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

Trade Accounts Receivable and Allowances

Trade accounts receivable are amounts owed to the Company by its customers for product that has been delivered. The trade accounts receivable are recorded at the invoice amount, less prompt pay and other discounts, chargebacks, and an allowance for credit losses, if any. The allowance for credit losses is the Company's estimate of losses over the life of the receivables. The Company evaluates forward looking economic factors and uses professional judgment to determine the allowance for credit losses. The credit loss reserves are reviewed and adjusted periodically. Credit loss reserves were not material as of December 31, 2022 and 2021, respectively.

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

Fair Value of Financial Instruments

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

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

Inventory

Inventory is valued utilizing the weighted average costing method. The Company records an inventory reserve for losses associated with dated, expired, excess or obsolete items. This reserve is based on management’s current knowledge with respect to inventory levels, planned production and sales volume assumptions. During the year ended December 31, 2021, the Company established a reserve of approximately \$5.3 million for inventory not expected to be sold prior to its shelf-life date. As of December 31, 2022 inventory reserves approximated \$0.6 million.

Property and Equipment

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

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

Long-Lived Assets

In accordance with ASC 360, *Property, Plant and Equipment*, the Company’s policy is to review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Management does not believe that there has been any impairment of the carrying value of any long-lived assets as of December 31, 2022.

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.

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Advertising Costs

The Company has elected to expense advertising costs when incurred. Advertising costs totaled \$8.2 million, \$13.8 million and \$5.5 for the years ended December 31, 2022 and 2021 and 2020, respectively.

Deferred Financing Costs

Costs directly attributable to the Company's term loan (see Note 9) are deferred and reported as a reduction of the related term loan. These costs represent legal fees and other costs related to the term loan and are being amortized utilizing the straight-line method over the term of the loan. Amortization of deferred financing costs charged to interest expense was approximately \$342,000, \$277,000 and \$231,000 for the years ended December 31, 2022, 2021 and 2020, respectively.

Concentrations of Credit Risk

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

Major customers of the Company are defined as those constituting greater than 10% of its total revenue. In 2022, the Company had sales to four customers that individually accounted for more than 10% of its total revenue. These customers had sales of \$2.9 million, \$2.7 million, \$2.6 million and \$1.2 million, respectively, which represented 86% of total revenues in the aggregate. In 2021, the Company had sales to three customers that individually accounted for more than 10% of our total revenue. These customers had sales of \$1.3 million, \$1.3 million, and \$1.2 million, respectively, which represented 93% of total revenues in the aggregate. Accounts receivable related to the four comprised 28%, 29%, 25% and 15%, respectively.

Revenue Recognition

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

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

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

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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.

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

Product returns – Customers have the right to return product that is within six months or less of the labeled expiration date or that is past the expiration date by no more than twelve months. Twirla was commercially launched in December 2020 and with limited historical sales data, an estimate for product returns as of December 31, 2022 was made based on industry standard data and trend analysis. Estimated product returns are recorded as contra trade accounts receivable on the balance sheet.

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

Rebates – The Company will be subject to mandatory discount obligations under the Medicaid and Tricare programs. The rebate amounts for these programs are determined by statutory requirements or contractual arrangements. Rebates are owed after the product has been dispensed to an end user and the Company has been invoiced. Rebates for Medicaid and Tricare are typically invoiced in arrears. The Company estimates the amount in rebates based on the expected number of claims and related cost that is associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Rebate estimates are recorded as other current liabilities in accrued expenses on the balance sheet.

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

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

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

Warrants

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

In connection with entering into a senior secured term loan facility in February 2020, the Company issued warrants to purchase 35,000 shares of its common stock to the lender, Perceptive Credit Holdings III, L.P. (“Perceptive”). In connection with an amendment to that facility in February 2021, the Company issued warrants to purchase 11,250 shares of the Company’s common stock (collectively, the “Perceptive Warrants”). The Perceptive Warrants qualify for equity classification and have been allocated based upon the relative fair value of the base instrument and the warrant. The Perceptive Warrants were subject to repricing in the event of an offering of securities at a price lower than the existing strike price before December 31, 2022. In connection with the Sixth Amendment, we amended and restated the Perceptive Warrants to reset the strike price of the Perceptive Warrants. See Notes 9 and 10 for additional information.

In connection with an underwritten public offering completed in October 2021, the Company issued warrants to purchase 333,333 shares of its common stock. This offering also triggered an adjustment to the exercise price of the Perceptive Warrants, which resulted in a reduction of the strike price for these warrants. This reduction resulted in an immaterial increase to additional paid-in-capital. See Notes 9 and 10 for additional information.

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In connection with a registered direct offering completed in March 2022, the Company issued warrants to purchase 1,242,813 shares of its common stock. This offering also triggered an adjustment to the exercise price of the Perceptive Warrants, which resulted in a reduction of the strike price for these warrants. This reduction resulted in an immaterial increase to additional paid-in-capital. See Notes 9 and 10 for additional information.

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

In connection with a public offering completed in July 2022, the Company issued warrants to purchase 54,666,665 shares of its common stock. This offering also triggered an adjustment to the exercise price of the Perceptive Warrants, which resulted in a reduction of the strike price for these warrants.

Income Taxes

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

The Company has adopted the authoritative guidance on accounting for and disclosure of uncertainty in tax positions which prescribes a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. The Company has no uncertain tax positions as of December 31, 2022 that qualify for either recognition or disclosure in the financial statements under this guidance.

Stock-Based Compensation

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

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

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating and reporting segment, which is the business of commercializing its transdermal patch for use in contraception.

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Net Loss Per Share

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

The following table sets forth the outstanding potentially dilutive securities that have been excluded from the calculation of diluted net loss per share for the years ended December 31, 2022, 2021 and 2020, respectively, because to do so would be anti-dilutive (in common equivalent shares):

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

Recent Accounting Pronouncements

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

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

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

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

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

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4. Fair Value Measurements

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

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

- Level 1—Quoted prices in active markets for identical assets and liabilities. The Company’s Level 1 assets consist of cash and cash equivalents. The Company has no Level 1 liabilities.
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted market prices for similar assets or liabilities in active markets or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets and liabilities. The Company has no Level 2 assets or liabilities.
- Level 3—Unobservable inputs that are supported by little or no market data and which require internal development of assumptions about how market participants price the fair value of the assets or liabilities. The Company’s level 3 liabilities consist of warrant liability. The Company has no level 3 assets.

The following tables set forth the Company’s financial instruments measured at fair value by level within the fair value hierarchy as of December 31, 2022 and 2021:

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
December 31, 2022			
Assets:			
Cash and cash equivalents	\$ 5,246	\$ —	\$ —
Total assets at fair value	<u>\$ 5,246</u>	<u>\$ —</u>	<u>\$ —</u>
Liabilities:			
Warrant Liability	\$ —	\$ —	\$ 5,934
Total assets at fair value	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 5,934</u>
	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3 (Restated)</u>
December 31, 2021			
Assets:			
Cash and cash equivalents	\$ 19,143	\$ —	\$ —
Total assets at fair value	<u>\$ 19,143</u>	<u>\$ —</u>	<u>\$ —</u>
Liabilities:			
Warrant Liability (Restated)	\$ —	\$ —	\$ 5,356
Total assets at fair value	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 5,356</u>

The significant assumptions used in preparing the option pricing model for valuing the Company’s warrants as of December 31, 2022 include (i) volatility 136.8% - 137.4%, (ii) risk-free interest rate 4.2%, (iii) strike price for the common warrants \$0.90, (iv) strike price for the preferred warrants (10.40), (v) fair value of common stock \$0.23, and (vi) expected life 4.3 – 4.5 years. The significant assumptions used in preparing the option pricing model for valuing

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the Company's warrants as of December 31, 2021 include (i) volatility 136.4%, (ii) risk-free interest rate 1.1%, (iii) strike price for the common warrants \$34.08, (iv) fair value of common stock \$31.63, and (v) expected life 4.98 years.

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

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

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

5. Prepaid Expenses

Prepaid expenses consist of the following:

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

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:

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

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

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

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7. Accrued Liabilities

Accrued liabilities consist of the following:

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

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 has no finance leases and one operating lease for its corporate headquarters in Princeton, NJ. The current lease commenced on December 1, 2021 and terminates on March 31, 2025. The lease provides the Company with an option to extend the lease for an additional five years. Under the terms of the lease, the Company pays base annual rent subject to a fixed dollar amount increase each year, a fixed monthly charge for electricity, and other normal operating expenses such as taxes, repairs, and maintenance. The Company evaluates renewal options at lease inception and on an ongoing basis and includes renewal options that it is reasonably certain to exercise in its expected lease terms when classifying leases and measuring lease liabilities. The lease does not require variable lease payments, residual value guarantees or restrictive covenants.

The lease does not provide an implicit rate, therefore the Company used its incremental borrowing rate as the discount rate when measuring the operating lease liability. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of the lease.

Operating lease expense was \$355,000 and \$180,000 for the years ended December 31, 2022 and 2021, respectively. Operating cash flows used for operating leases during the years ended December 31, 2022 and 2021 were \$175,000 and \$131,000 respectively. As of December 31, 2022, the weighted-average remaining lease term was 2.25 years and the weighted average discount rate was 11.8%.

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

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

9. Credit Agreement and Guaranty

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On February 10, 2020 (the “Closing Date”), the Company entered into a Credit Agreement and Guaranty with Perceptive for a senior secured term loan credit facility of up to \$35.0 million, (the “Perceptive Credit Agreement”). A first tranche of \$5.0 million was funded on execution of the Perceptive Credit Agreement. A second tranche of \$15.0 million was funded as a result of the approval of Twirla by the FDA. Another \$15.0 million tranche was to be available to the Company based on the achievement of a revenue milestone by December 31, 2021, which was not achieved. The other tranches of debt under the Amended Perceptive Credit Agreement are no longer available to the Company. On January 7, 2022, the Company prepaid \$5.0 million of the outstanding debt, and Perceptive waived the prepayment premium. On July 8, 2022, the Company prepaid \$5.0 million of the outstanding debt, and Perceptive waived the prepayment premium. On July 25, 2022, the Company entered into a fifth amendment to the Amended Perceptive Credit Agreement, as amended (the “Fifth Amendment”). Pursuant to the Fifth Amendment, Perceptive agreed to release its security interest in certain assets being transferred from the Company to Corium in connection with an amendment to the Company’s Manufacturing and Commercialization Agreement with Corium and waive the Company’s obligations to comply with certain financial covenants through the end of 2022. In exchange, the Company agreed to prepay \$7.0 million of outstanding principal under the Amended Perceptive Credit Agreement using the proceeds of recent sales under the Company’s ATM program with H.C. Wainwright & Co., LLC. Such payment was made on July 25, 2022.

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

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

The Company may prepay any outstanding loans in whole or in part. Any such prepayment of the loans is subject to a prepayment premium of 4.0% if such prepayment occurs after February 10, 2022 and on or prior to February 10, 2023; and 2.0% if such prepayment occurs after February 10, 2023 and prior to the Maturity Date.

All of the Company’s obligations under the Fifth Amendment are secured by a first-priority lien and security interest in substantially all of the Company’s tangible and intangible assets, including intellectual property. The Amended Perceptive Agreement contains certain representations and warranties, affirmative covenants, negative covenants and conditions that are customary for similar financings. The negative covenants restrict or limit the ability of the Company to, among other things and subject to certain exceptions contained in the Amended Perceptive Credit Agreement, incur new indebtedness; create liens on assets; engage in certain fundamental corporate changes, such as mergers or acquisitions, or changes to the Company’s business activities; make certain investments or restricted payments (each as defined in the Amended Perceptive Credit Agreement); change its fiscal year; pay dividends; repay other certain indebtedness; engage in certain affiliate transactions; or enter into, amend or terminate any other agreements that have the impact of restricting the Company’s ability to make loan repayments under the Amended Perceptive Credit Agreement. In addition, the Company must (i) at all times prior to the Maturity Date maintain a minimum cash balance of \$3.0 million; and (ii) as of the last day of each fiscal quarter commencing with the fiscal quarter ending December 31, 2022, report revenues for the trailing 12-month period that exceed the amounts set forth in the Fifth Amendment which range from \$62.6 million for the fiscal quarter ending March 31, 2023 to \$87.1 million for the fiscal quarter ending December 31, 2023. Pursuant to the Waiver and Sixth Amendment to the Perceptive Credit Agreement (the “Sixth Amendment”), the Company has received a waiver of certain financial covenants through the second quarter of 2023. In the event the Company does not pay off the remainder of the outstanding principal under the facility, the Company will need to negotiate for a waiver of its obligations to comply with the covenants relating to revenue for Twirla in the second quarter of 2023.

In connection with the Perceptive Credit Agreement, the Company issued to Perceptive two warrants to purchase an aggregate of 35,000 shares of the Company’s common stock (together, the “2020 Perceptive Warrants”). The first

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warrant is exercisable for 17,500 shares of common stock at an exercise price of \$149.60 per share. The second warrant is exercisable for 17,500 shares of common stock at an exercise price of \$186.80 per share. The 2020 Perceptive Warrants expire on February 10, 2027. In connection with the Amended Perceptive Credit Agreement, the Company issued to Perceptive a warrant to purchase 11,250 shares of the Company's common stock (the "2021 Perceptive Warrant" and, together with the 2020 Perceptive Warrants, the "Perceptive Warrants") at an exercise price of \$114.80 per share. The 2021 Perceptive Warrant expires on February 26, 2028. The Perceptive Warrants contain anti-dilution provisions that expired on December 31, 2022 and other warrant holder protections and are not exercisable to the extent that Perceptive would beneficially own more than 19.99% of the Company's common stock as a result of the exercise. In connection with the Sixth Amendment, we amended and restated the Perceptive Warrants to reset the strike price of the Perceptive Warrants.

As a result of the public offering of the Company's common stock completed in October 2021 (see Note 10), the antidilution provision of the Perceptive Warrants was triggered, resulting in a reduction of the strike price for the Perceptive Warrants. Warrants to purchase 17,500 shares of common stock that had an exercise price of \$186.80 per share were reduced to \$141.60 per share, warrants to purchase 17,500 shares of common stock that had an exercise price of \$149.60 per share were reduced to \$115.20 per share, and warrants to purchase 11,250 shares of common stock that had an exercise price of \$114.80 per share were reduced to \$90.80 per share.

As a result of the registered direct offering completed in March 2022 (see Note 10), the anti-dilution provision of the Perceptive Warrants was again triggered resulting in a further reduction of the strike price for the Perceptive Warrants. Warrants to purchase 17,500 shares of common stock that had an adjusted exercise price of \$141.60 per share were reduced to \$105.52 per share, warrants to purchase 17,500 shares of common stock that had an adjusted exercise price of \$115.20 per share were reduced to \$86.61 per share, and warrants to purchase 11,250 shares of common stock that had an adjusted exercise price of \$90.80 per share were reduced to \$69.13 per share.

As a result of the public offering of the Company's common stock completed in July 2022 (see Note 10), the antidilution provision of the Perceptive Warrants was again triggered resulting in a reduction of the strike price for the Perceptive Warrants. Warrants to purchase 17,500 shares of common stock that had an exercise price of \$105.52 per share were reduced to \$14.90 per share, warrants to purchase 17,500 shares of common stock that had an exercise price of \$86.61 per share were reduced to \$12.37 per share, and warrants to purchase 11,250 shares of common stock that had an exercise price of \$69.13 per share were reduced to \$10.03 per share.

The Company allocated the proceeds of \$20.0 million in accordance with ASC 470 based on the relative fair values of the debt and the Perceptive Warrants. The relative fair value of the Perceptive Warrants of approximately \$3.6 million at the time of issuance, which was determined using the Black-Scholes option-pricing model, was recorded as additional paid-in capital and reduced the carrying value of the debt. The significant assumptions used in the preparing the option pricing model for valuing the Perceptive Warrants issued include (i) volatility (70.0%), (ii) risk free interest rate of 1.47% (estimated using treasury bonds with a 7-year life), (iii) strike prices of \$149.60 and \$186.80 for the common stock warrants, (iv) fair value of common stock (\$160.40) and (v) expected life (7 years). The fair value of the 2021 Perceptive Warrants of approximately \$1.1 million at the time of issuance, which was determined using the Black-Scholes option-pricing model, was recorded as additional paid-in capital and reduced the carrying value of the debt. The significant assumptions used in preparing the option pricing model for valuing the 2021 Perceptive Warrants issued include (i) volatility (103.5%), (ii) risk free interest rate of 1.15% (estimated using treasury bonds with a 7-year life), (iii) strike price of \$114.80 for the common stock warrant, (iv) fair value of common stock (\$114.80) and (v) expected life (7 years). The fair value of the warrants as well as the debt issue costs incurred in connection with the entry into the Perceptive Credit Agreement, including a facility fee of 1% of the total amount of loans available under the facility, are presented as a direct deduction from the carrying amount of the term loan on the consolidated balance sheet as detailed below (in thousands).

	December 31,		December 31,	
	2022		2021	
Notes payable	\$	2,625	\$	20,000
Debt issuance costs		(209)		(550)

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Warrant discount		(990)	(2,617)
Total debt	\$	1,426	\$ 16,833
Less, current portion		1,426	16,833
Long-term debt, less current portion	\$	—	\$ —

The fair value of the warrants and the debt issue costs are being amortized utilizing the effective interest method over the term of the loan. The Company recorded interest expense for the amortization of the fair value of the warrants and debt issue costs of \$1,969,000, \$1,661,000 and \$1,341,000 for the years ended December 31, 2022, 2021, and 2020 respectively.

10. Stockholders' Equity

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

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

Shelf Registration Statement

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

Public Offerings

In October 2021, the Company completed a public offering of 666,666 shares of its common stock and warrants to purchase 333,333 shares of its common stock at a combined price of \$34.00 per share of common stock and one-half of a warrant to purchase one share of common stock. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses were approximately \$21.1 million.

In July 2022, the Company completed a public offering of (1) 19,148,332 shares of its common stock and warrants to purchase 38,296,664 shares of its common stock at a combined price of \$0.90 per share of common stock and warrants and (2) 7,518,334 pre-funded warrants to purchase 7,518,334 shares of its common stock and warrants to purchase 15,036,668 shares of its common stock at a combined price of \$0.8999 per share of common stock and pre-funded warrant. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses were approximately \$22.0 million.

ATM Sales Agreements

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In March 2021, the Company entered into a common stock sales agreement (the “2021 ATM Agreement”) under which the Company may sell up to an aggregate of \$50.0 million in gross proceeds through the sale of shares of common stock from time to time in “at-the-market” equity offerings (as defined in Rule 415 promulgated under the Securities Act of 1933, as amended). The Company agreed to pay a commission of up to 3% of the gross proceeds of any common stock sold under the 2021 ATM Agreement. During the year ended December 31, 2021, the Company issued and sold 172,879 shares of common stock under the 2021 ATM Agreement resulting in net proceeds to the Company of approximately \$9.3 million.

On January 10, 2022, the Company filed a prospectus supplement to its 2020 Shelf Registration Statement registering an at-the-market offering program (the “January 2022 ATM”) the Company entered into for the sale of up to \$50.0 million of shares of its common stock. The Company agreed to pay a commission of up to 3% of the gross proceeds of any common stock sold under the January 2022 ATM. During the nine months ended September 30, 2022, the Company issued and sold 25,623 shares of common stock under the January 2022 ATM resulting in net proceeds to the Company of approximately \$0.3 million. On April 26, 2022, the Company terminated the January 2022 ATM.

On April 27, 2022, the Company entered into a new at-the-market offering program (“April 2022 ATM”) with H.C. Wainwright LLC and Co. (the “Sales Agent”), under which the Company may, from time to time in its sole discretion, issue and sell through or to the Sales Agent, acting as the Company’s agent, up to \$12,841,000 of shares of the Company’s common stock (the “Placement Shares”). The Company agreed to pay the Sales Agent a commission of up to 3.0% of the gross sales proceeds of any Placement Shares sold under the April 2022 ATM. Through September 30, 2022, the Company issued and sold a total of 8,687,502 shares of common stock under the April 2022 ATM Agreement, representing the entire capacity of the April 2022 ATM, resulting in net proceeds of approximately \$12.2 million.

On August 22, 2022, the Company increased the April 2022 ATM (“August 2022 ATM”). As increased, the Company may now offer and sell, from time to time through the Sales Agent, shares of the Company’s common stock having an aggregate offering price of up to \$75.0 million. During the year ended December 31, 2022, the Company issued and sold 3,942,648 shares of common stock under the August 2022 ATM resulting in net proceeds to the Company of approximately \$0.9 million.

Registered Direct Offering

On March 14, 2022, the Company filed a prospectus supplement to its 2020 Shelf Registration Statement registering a direct offering (the “2022 Preferred Stock Offering”) of 2,425 shares of Series A convertible preferred stock (the “Series A Preferred Stock”) and 2,425 shares of Series B convertible preferred stock (the “Series B Preferred Stock”) and Series A warrants (the “Series A Warrants”) to purchase up to an aggregate of 606,250 shares of the common stock of the Company and Series B warrants (the “Series B Warrants”) to purchase up to an aggregate of 606,250 shares of common stock. Each share of Series A Preferred Stock and Series B Preferred Stock has a stated value of \$1,000 per share and a conversion price of \$8.00 per share. The shares of preferred stock issued in the 2022 Preferred Stock Offering are convertible into an aggregate of 606,250 shares of common stock. The Series A Warrants have an exercise price of \$10.40 per share, will become exercisable six months following the date of issuance, and will expire 5 years following the initial exercise date. The Series B Warrants have an exercise price of \$10.40 per share, will become exercisable six months following the date of issuance, and will expire one and one-half years following the initial exercise date. Proceeds from the 2022 Preferred Stock Offering, net of the placement agent’s fees and offering expenses were approximately \$4.1 million. A portion of the placement agent’s fees included warrants to purchase 30,313 shares of the common stock of the Company at a strike price of \$10.00 per share. The warrants become exercisable six months following the date of issuance and will expire 5 years following the commencement of sales in the 2022 Preferred Stock Offering.

On March 15, 2022, 2,425 shares of the Series A Preferred Stock were converted into 303,125 shares of the Company’s common stock. On April 4, 2022, 2,425 shares of the Series B Preferred Stock were converted into 303,125 shares of the Company’s common stock.

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On April 25, 2022, the Company entered into a letter agreement and waiver (the “Letter Agreement”) with Armistice Capital Master Fund Ltd. (“Armistice”), pursuant to which Armistice consented to the Company entering into and effecting an at-the-market (“ATM”) offering facility. On March 14, 2022, the Company entered into the 2022 Preferred Stock Offering with Armistice, under which agreement, the Company was restricted from entering into and effecting an ATM offering facility until the 180-day anniversary of the Closing Date. Pursuant to the Letter Agreement, the Company issued to Armistice a new common stock purchase warrant (“New Warrant”), on the same terms and conditions as the Series A Warrants, provided that such New Warrant shall be exercisable into 212,188 warrant shares. The Series A Warrants have an exercise price of \$10.40 per share, and will become exercisable six months following the date of issuance, and will expire 5 years following the initial exercise date. The New Warrant is exercisable 6 months after the date of the Letter Agreement.

On July 6, 2022, the Company completed a best efforts public offering (the “Offering”) in which the Company raised net proceeds of \$22.0 million through the sale of 19,148,332 shares of common stock and 7,518,334 pre-funded warrants (“Series B pre-funded warrants”) to purchase 7,518,334 shares of common stock. Both the sales of shares of common stock and pre-funded warrants were accompanied by Series A-1 and Series A-2 warrants (together the “Series A warrants”) to purchase shares of common stock. The Series A-1 warrants are exercisable immediately and will expire five years from the date of issuance, and the Series A-2 warrants are exercisable immediately and will expire thirteen months from the date of issuance. H.C. Wainwright acted as the exclusive placement agent in connection with the Offering and, as compensation, received a cash fee of 7% of the aggregate proceeds raised in the Offering. The Company also issued to certain designees of H.C. Wainwright warrants to purchase up to 1,333,333 shares of common stock with an exercise price of \$1.125 per share.

Common Stock Warrants

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

As a result of the registered direct offering completed in March 2022, the anti-dilution provision of the Perceptive Warrants was again triggered resulting in a further reduction of the strike price for the Perceptive Warrants. Warrants to purchase 17,500 shares of common stock that had an adjusted exercise price of \$141.60 per share were reduced to \$105.52 per share, warrants to purchase 17,500 shares of common stock that had an adjusted exercise price of \$115.20 per share were reduced to \$86.61 per share, and warrants to purchase 11,250 shares of common stock that had an adjusted exercise price of \$90.80 per share were reduced to \$69.13 per share.

As a result of the public offering of the Company’s common stock completed in July 2022, the antidilution provision of the Perceptive Warrants was again triggered resulting in a reduction of the strike price for the Perceptive Warrants. Warrants to purchase 17,500 shares of common stock that had an exercise price of \$105.52 per share were reduced to \$14.90 per share, warrants to purchase 17,500 shares of common stock that had an exercise price of \$86.61 per share were reduced to \$12.37 per share, and warrants to purchase 11,250 shares of common stock that had an exercise price of \$69.13 per share were reduced to \$10.03 per share.

All Perceptive Warrants are accounted for in equity, whereas all warrants associated with our various financings are accounted for as liabilities. In accordance with ASC Topic 815-40, Derivatives and Hedging, Contracts in Entity’s Own Equity, these liabilities are measured at fair value upon issuance, with subsequent changes in fair value reported in the Statement of Operations each reporting period.

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11. Equity Incentive Plans*Stock options*

The Company had granted stock options under an amended and restated 1997 Equity Incentive Plan (the “1997 Plan”) and a 2008 Equity Incentive Plan (the “2008 Plan”). The plans provided for the granting of incentive and non-statutory options and stock awards to consultants, directors, officers and employees. Such options are exercisable for a period of ten years and generally vest over a four-year period. In conjunction with the adoption of the 2008 Plan in April 2008, no additional grants were made from the 1997 Plan and issued options from the 1997 Plan remain outstanding. In 2014, the Board approved the 2014 Incentive Compensation Plan (the “2014 Plan”). The 2014 Plan is the successor to the Company’s 2008 Plan and 1997 Plan. In conjunction with the adoption of the 2014 Plan in 2014, no additional grants were made from the 2008 Plan and options from the 1997 Plan and the 2008 Plan remain outstanding. In June 2018, the 2014 Plan was amended and restated, and the Amended and Restated 2014 Incentive Compensation Plan is now referred to as the Amended 2014 Plan. As of December 31, 2022, there were 314,398 shares available for future grant under the Amended 2014 Plan.

Through December 31, 2022, the Company granted options to certain employees and non-employees to purchase shares of common stock at exercise prices ranging from \$0.20 to \$430.00 per share. The Company recorded noncash stock-based compensation expense for the years ended December 31, 2022, 2021 and 2020 based on the fair market value of the options and shares granted at the grant date. Stock-based compensation expense was as follows:

	Year Ended December 31,		
	2022	2021	2020
Cost of goods sold	\$ 133	\$ 271	\$ 14
Research and development	372	490	651
Selling and marketing	155	148	108
General and administrative	1,833	2,429	2,045
Total	\$ 2,493	\$ 3,338	\$ 2,818

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

	2022	2021	2020
Risk-free interest rate	1.71% - 4.22 %	.66% - 1.51 %	.40% - 1.68 %
Expective volatility	107% - 118 %	105% - 106 %	65% - 106 %
Expected dividend yield	0 %	0 %	0 %
Expected life (in years)	6.25	6.25	6.25

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

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

Expected volatility. The expected volatility assumption was based on volatilities of a peer group of similar companies whose share prices are publicly available until August 2020. The peer group was developed based on comparable companies in the biotechnology and pharmaceutical industries. In August 2020, the Company transitioned to its own expected volatility based on sufficient historical data.

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

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

As of December 31, 2022, the unrecorded deferred stock-based compensation balance related to stock options was approximately \$3.3 million and will be recognized over an estimated weighted-average amortization period of 2.8 years. The weighted average grant date fair value of options granted during the year ended December 31, 2022 was \$3.29.

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

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

Intrinsic value in the tables was calculated as the difference between the Company's stock price at December 31, 2022, of \$0.23 per share, and the exercise price, multiplied by the number of options.

Restricted Stock Units

During the year ended December 31, 2021, the Company granted a total of 1,774 RSUs to certain employees of the Company. These RSUs vested on the one-year anniversary of the grant date. During the year ended December 31, 2021, the Company granted a total of 5,659 RSUs to directors of the Company. These RSUs vest ratably over one and three years.

During the year ended December 31, 2022, the Company granted a total of 4,690 RSUs to directors of the Company. These RSUs vest ratably over one year.

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

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

12. Income Taxes

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

As of December 31, 2022, the Company had available net operating loss carryforwards ("NOLs") of approximately \$390.6 million for federal and \$79.9 million for state income tax reporting purposes. Under the TCJA, the federal NOLs generated after 2017, approximately \$201.7 million, can be carried forward indefinitely, while the NOLs generated through taxable years ending December 31, 2017, approximately \$188.9 million, are available to offset future federal taxable income, if any, through 2037. The Company also has research and development tax credit carryforwards of approximately \$6.4 million and \$0.9 million for federal and state income tax reporting purposes, respectively, which are available to reduce federal income taxes, if any, through 2042 and state income taxes, if any, through 2037.

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

As of December 31, 2022, the Company has not accrued interest or penalties related to uncertain tax positions. The Company's tax returns for the years ended December 31, 2019 through December 31, 2021 are still subject to examination by major tax jurisdictions. However, the Internal Revenue Service ("IRS") and state tax jurisdictions can audit the NOLs generated in prior years in the years that those NOLs are utilized.

For all years through December 31, 2022, the Company generated research credits but has not conducted a study to document the qualified activities. This study may result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the deferred tax asset established for the research and development credit carryforwards and the valuation allowance.

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

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

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

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

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

Sale of New Jersey Net Operating Losses

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

13. Commitments and Contingencies

The Company has several firm purchase commitments, primarily related to the manufacture and supply of Twirla and the supply of a field force of sales representatives to provide certain detailing services, sales operation services, compliance services, and training services. Future firm purchase commitments under these agreements, the last of which ends in 2033, total \$238.2 million. This amount does not represent all of the Company's anticipated purchases in the future, but instead represents only purchases that are the subject of contractually obligated minimum purchases. The minimum commitments disclosed are determined based on non-cancelable minimum spend in 2023 or termination amounts. Additionally, the Company purchases products and services as needed with no firm commitment.

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In April 2020, the Company entered into a manufacturing and commercialization agreement with Corium, (the “Corium Agreement”). Under the Corium Agreement, the Company has a requirement to order quarterly minimum volumes of approximately \$5.6 million of product. In the event that the Company does not order the minimum volume, the Company is required to pay an additional fee equal to twenty-five percent (25%) per unit of the transfer price for all units ordered in that quarter. The Company did not meet the minimum volume order in the first or second quarter of 2022, and has, therefore, paid the additional 25% per unit fee as a penalty for all units ordered during the period. Based on current demand expectations for Twirla, the Company did not expect to meet the minimum volume order for the balance of 2022 and would be subject to the additional fee on future purchases. On July 25, 2022 the Company and Corium entered into Amendment No. 1 to the Corium Agreement (the “Amendment”) that is designed to restructure the contract minimums applicable to the purchase of manufactured Twirla and other services provided by Corium, transfer equipment ownership to Corium to support the manufacture of Twirla and extend the term of the Corium Agreement. Pursuant to the Amendment, the parties agreed to adjust the process for the Company providing Corium certain binding and non-binding forecasts required under the Corium Agreement. Additionally, Corium will not enforce the original quantity minimums in the Corium Agreement, which are waived and replaced by new minimums that are based on Corium’s revenue for product purchased by the Company, expiring raw materials, and other services billed by Corium to support batch production and release. The guaranteed minimum revenue requirement for 2022 is \$5.3 million, for 2023 is \$7.0 million, and is \$22.5 million for 2024 and each year thereafter. In the event that the Company does not meet the guaranteed minimum revenue requirements in any given year, the Company will be required to make additional payments to Corium for the shortfall. The Company agreed to make certain monthly supplemental payments to Corium through December 2023, which payments are eligible to be retroactively reduced based upon product orders placed by the Company during 2022 and 2023 meeting certain designated thresholds. In connection with the supplemental payments, Corium will retain the proceeds for the sale of certain raw materials to which the Company would otherwise have economic right to offset such supplemental payments. Further, the Company agreed to reimburse Corium for any unused raw materials in the event the Company’s actual product requirements are lower than initially forecasted. Pursuant to the Amendment, the term of the Corium Agreement was extended to December 31, 2033. Pursuant to the Amendment, the parties agreed to transfer ownership of certain manufacturing equipment used in the manufacture of Twirla from the Company to Corium under a Bill of Sale dated July 25, 2022.

The Company records a provision for contingent losses when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. An unfavorable outcome to any legal matter, if material, could have an adverse effect on the Company's operations or its financial position. As of December 31, 2022, the Company has not recorded a provision for any contingent losses.

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Notes to Financial Statements (Continued)
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14. Quarterly Financial Information (Unaudited)

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

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Notes to Financial Statements (Continued)
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Balance Sheets

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

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

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Notes to Financial Statements (Continued)
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Quarterly and Year to Date Statements of Operations and Comprehensive Loss

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

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

Agile Therapeutics, Inc.
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Statements of Changes in Stockholders' Equity (Unaudited)

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

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Notes to Financial Statements (Continued)
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Statements of Changes in Stockholders' Equity (Unaudited)

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

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

Statements of Changes in Stockholders' Equity (Unaudited)

Agile Therapeutics, Inc.
Notes to Financial Statements (Continued)
December 31, 2022

(amounts in tables in thousands, except share and per share data)

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

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

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

Statements of Cash Flows

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

15. Subsequent Events

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

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

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

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

On March 21, 2023, the Company and Perceptive entered into the Sixth Amendment. The Sixth Amendment waived the Company's obligations to (1) comply with certain financial covenants relating to minimum revenue requirements and minimum liquidity through June 30, 2023, and (2) file financial statements along with its Annual Report on Form 10-K for the fiscal year ended December 31, 2022 that are not subject to any "going concern" qualification. In connection with the Sixth Amendment to the Perceptive Agreement, we amended and restated the Perceptive Warrants to reset the strike price of the Perceptive Warrants.

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

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,873	\$ 5,246
Accounts receivable, net	3,521	3,377
Inventory, net	2,411	1,332
Prepaid expenses and other current assets	1,259	1,403
Total current assets	10,064	11,358
Property and equipment, net	101	177
Right of use asset	486	695
Other non-current assets	238	2,012
Total assets	\$ 10,889	\$ 14,242
Liabilities and stockholders' deficit		
Current liabilities:		
Long-term debt, current portion	\$ 1,589	\$ 1,426
Notes payable, current portion	379	—
Accounts payable	6,879	7,734
Accrued expenses	8,338	3,908
Lease liability, current portion	353	319
Total current liabilities	17,538	13,387
Lease liabilities, long-term	196	466
Warrant liability	5,566	5,934
Total liabilities	23,300	19,787
Commitments and contingencies (Note 10)		
Stockholders' deficit		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized, 4,850 issued and no shares outstanding at September 30, 2023 and no shares issued and outstanding at December 31, 2022	—	—
Common stock, \$0.0001 par value, 300,000,000 shares authorized, 2,277,657 and 859,402 issued and outstanding at September 30, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	406,288	403,157
Accumulated deficit	(418,699)	(408,702)
Total stockholders' deficit	(12,411)	(5,545)
Total liabilities and stockholders' deficit	\$ 10,889	\$ 14,242

See accompanying notes to unaudited financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues, net	\$ 6,662	\$ 3,002	\$ 15,979	\$ 6,888
Cost of product revenues	2,477	1,425	6,787	5,183
Gross profit	<u>4,185</u>	<u>1,577</u>	<u>9,192</u>	<u>1,705</u>
Operating expenses:				
Research and development	\$ 705	\$ 788	\$ 2,171	\$ 2,901
Selling and marketing	4,800	5,560	14,040	23,523
General and administrative	2,680	2,815	8,813	9,837
Loss on disposition of assets	—	11,122	—	11,122
Total operating expenses	<u>8,185</u>	<u>20,285</u>	<u>25,024</u>	<u>47,383</u>
Loss from operations	<u>(4,000)</u>	<u>(18,708)</u>	<u>(15,832)</u>	<u>(45,678)</u>
Other income (expense)				
Interest income	13	46	61	50
Interest expense	(341)	(1,004)	(1,114)	(2,699)
Unrealized gain on warrant liability	3,529	13,736	6,890	22,171
Total other income, net	<u>3,201</u>	<u>12,778</u>	<u>5,837</u>	<u>19,522</u>
Loss before benefit from income taxes	(799)	(5,930)	(9,995)	(26,156)
Benefit from income taxes	—	—	—	4,675
Net loss and comprehensive loss	<u>\$ (799)</u>	<u>\$ (5,930)</u>	<u>\$ (9,995)</u>	<u>\$ (21,481)</u>
Net loss per share (basic and diluted)	<u>\$ (0.27)</u>	<u>\$ (8.01)</u>	<u>\$ (5.30)</u>	<u>\$ (71.61)</u>
Weighted-average common shares (basic and diluted)	<u>2,950,136</u>	<u>739,957</u>	<u>1,884,793</u>	<u>299,970</u>

See accompanying notes to unaudited financial statements.

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

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated		Total Stockholders' Deficit
	Number of Shares	Amount	Number of Shares	Amount		Other Comprehensive Income	Accumulated Deficit	
Balance December 31, 2022	—	\$ —	859,402	\$ —	\$ 403,157	\$ —	\$ (408,702)	\$ (5,545)
Share-based compensation - stock options and RSUs	—	—	—	—	498	—	—	498
Issuance of common stock pursuant to at-the market stock sales, net of expenses	—	—	72,699	—	1,003	—	—	1,003
Net loss	—	—	—	—	—	—	(5,389)	(5,389)
Balance March 31, 2023	—	\$ —	932,101	\$ —	\$ 404,658	\$ —	\$ (414,091)	\$ (9,433)
Share-based compensation - stock options and RSUs	—	—	—	—	482	—	—	482
Fractional shares retired as a result of reverse split	—	—	—	—	(13)	—	—	(13)
Issuance of common stock pursuant to at-the market stock sales, net of expenses	—	—	105,342	—	652	—	—	652
Issuance of common stock in public offering, net of offering costs	—	—	95,000	—	—	—	—	—
Exercise of pre-funded warrants	—	—	508,286	—	—	—	—	—
Vesting of RSUs	—	—	76	—	—	—	—	—
Net loss	—	—	—	—	—	—	(3,809)	(3,809)
Balance June 30, 2023	—	\$ —	1,640,805	\$ —	\$ 405,779	\$ —	\$ (417,900)	\$ (12,121)
Share-based compensation - stock options and RSUs	—	—	—	—	439	—	—	439
Issuance of common stock pursuant to at-the market stock sales, net of expenses	—	—	29,842	—	70	—	—	70
Exercise of pre-funded warrants	—	—	607,000	—	—	—	—	—
Vesting of RSUs	—	—	10	—	—	—	—	—
Net loss	—	—	—	—	—	—	(799)	(799)
Balance September 30, 2023	—	\$ —	2,277,657	\$ —	\$ 406,288	\$ —	\$ (418,699)	\$ (12,411)

See accompanying notes to unaudited financial statements.

On April 10, 2023, the Company effectuated a one-for-fifty reverse stock split of its outstanding shares of common stock (the "Reverse Stock Split"). The Reverse Stock Split reduces the Company's shares of outstanding common stock, stock options, RSU's, and warrants to buy shares of the Company's common stock. Fractional shares of common stock that would have otherwise resulted from the Reverse Stock Split were rounded down to the nearest whole share, and cash in lieu of payments were made to stockholders. All share and per share data for all periods presented in the accompanying financial statements and the related disclosures have been adjusted retrospectively to reflect the Reverse Stock Split. The number of authorized shares of common stock and the par value per share remains unchanged.

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

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Number of Shares	Amount	Number of Shares	Amount				
Balance December 31, 2021	—	\$ —	60,698	\$ —	\$ 387,205	\$ —	(383,290)\$	3,915
Share-based compensation - stock options and RSUs	—	—	—	—	764	—	—	764
Issuance of common stock pursuant to at-the market stock sales, net of expenses	—	—	512	—	348	—	—	348
Issuance of series A and B convertible preferred stock in a registered direct offering (Note 8)	4,850	—	—	—	—	—	—	—
Conversion of series A convertible preferred stock	—	—	6,063	—	—	—	—	—
Vesting of RSUs	(2,425)	—	35	—	—	—	—	—
Net loss	—	—	—	—	—	—	(10,385)	(10,385)
Balance March 31, 2022	<u>2,425</u>	<u>—</u>	<u>67,308</u>	<u>\$ —</u>	<u>\$ 388,317</u>	<u>\$ —</u>	<u>(393,675)\$</u>	<u>(5,358)</u>
Share-based compensation - stock options and RSUs	—	\$ —	—	—	669	—	—	669
Issuance of common stock pursuant to at-the market stock sales, net of expenses	—	—	173,750	—	12,226	—	—	12,226
Conversion of series B convertible preferred stock	(2,425)	—	6,062	—	—	—	—	—
Vesting of RSUs	—	—	82	—	—	—	—	—
Unrealized net gain on marketable securities	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	(5,168)	(5,168)
Balance June 30, 2022	<u>—</u>	<u>\$ —</u>	<u>\$ 247,202</u>	<u>\$ —</u>	<u>\$ 401,212</u>	<u>\$ —</u>	<u>(398,843)\$</u>	<u>2,369</u>
Share-based compensation - stock options and RSUs	—	—	—	—	536	—	—	536
Issuance of common stock pursuant to a public offering, net of expenses	—	—	533,333	—	—	—	—	—
Net loss	—	—	—	—	—	—	(5,930)	(5,930)
Balance September 30, 2022	<u>—</u>	<u>\$ —</u>	<u>\$ 780,535</u>	<u>\$ —</u>	<u>\$ 401,748</u>	<u>\$ —</u>	<u>(404,773)\$</u>	<u>(3,025)</u>

See accompanying notes to unaudited financial statements.

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

	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (9,995)	\$ (21,481)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	77	1,255
Amortization	209	188
Loss on disposition of assets	—	11,122
Noncash stock-based compensation	1,418	1,969
Noncash amortization of deferred financing costs	838	1,635
Unrealized gain on warrants	(6,890)	(22,171)
Changes in operating assets and liabilities:		
Accounts receivable	(144)	(2,178)
Inventory	(1,079)	(831)
Prepaid expenses and other assets	2,480	(1,551)
Accounts payable and accrued expenses	3,572	(2,213)
Lease liability	(235)	(132)
Net cash used in operating activities	<u>(9,749)</u>	<u>(34,388)</u>
Cash flows from investing activities:		
Acquisition of property and equipment	—	(133)
Net cash used in investing activities	<u>—</u>	<u>(133)</u>
Cash flows from financing activities:		
Proceeds from issuance of preferred stock in registered direct offering, net of offering costs	—	4,129
Proceeds from At-the-Market sales of common stock, net of offering costs	1,725	12,573
Proceeds from the issuance of common stock in public offering, net of offering costs	6,509	21,971
Repayments of long-term debt	(675)	(17,150)
Repayments of note payable	(184)	—
Net cash provided by financing activities	<u>7,375</u>	<u>21,523</u>
Net decrease in cash and cash equivalents	(2,374)	(12,998)
Cash and cash equivalents, beginning of period	5,246	19,143
Cash and cash equivalents, end of period	<u>\$ 2,873</u>	<u>\$ 6,145</u>
Supplemental disclosure of noncash financing activities		
Warrants issued in connection with preferred stock financing	\$ —	\$ 2,101
Conversion of Series A preferred stock into common stock	—	897
Conversion of Series B preferred stock into common stock	—	887
Supplemental cash flow information		
Interest paid	\$ 276	\$ 1,078

See accompanying notes to unaudited financial statements.

1. Organization and Description of Business

Nature of Operations

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

The Company’s sole approved product, Twirla, is a once-weekly prescription contraceptive patch that received approval from the U.S. Food and Drug Administration, or FDA, in February 2020 and was commercially launched in early December 2020. Substantially all of the Company’s resources are currently dedicated to commercializing Twirla in the United States. The Company has generated minimal product revenue to date and is subject to a number of risks similar to those of other early stage commercial companies, including, but not limited to, dependence on key individuals, the difficulties and uncertainties inherent in the development of commercially usable products, market acceptance of products, protection of proprietary technology, the need to obtain additional capital necessary to fund the development of its products, reliance on a consistent supply chain both for Twirla and in general, macroeconomic factors such as inflation, competition from larger companies, and compliance with FDA and other government regulations. If the Company does not continue to successfully commercialize Twirla, it will be unable to generate recurring product revenue or achieve profitability. The Company has incurred operating losses and negative cash flows from operating activities each year since inception. As of September 30, 2023, the Company had an accumulated deficit of approximately \$418.7 million. The Company expects to continue to incur significant operating expenses for the foreseeable future in connection with its ongoing activities, as the Company:

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

The Company has financed its operations to date primarily through the issuance and sale of its common stock in both public and private offerings (see Note 8), private placements of its convertible preferred stock, venture loans, and non-dilutive grant funding.

Going Concern

As of September 30, 2023, the Company had cash and cash equivalents of \$2.9 million and a \$7.5 million working capital deficit. The Company’s current liquidity is sufficient to fund operations into December 2023. The Company closely monitors its cash and cash equivalents and will need to raise additional funds to meet its projected operating requirements, including the continued commercialization of Twirla, and exploring the advancement of its existing pipeline and its possible expansion through business development activities.

The Company has generated losses since inception, used substantial cash in operations, has a working capital deficit as of September 30, 2023, and anticipates it will continue to incur net losses for the foreseeable future. The Company’s future success depends on its ability to obtain additional capital and/or implement various strategic alternatives, and there can be no assurance that any financing can be realized by the Company, or if realized, what the terms of any such financing may be, or that any amount that the Company is able to raise will be adequate. Based upon the foregoing,

management has concluded that there is substantial doubt about the Company's ability to continue as a going concern through the 12 months following the date on which this Quarterly Report on Form 10-Q is filed.

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

The unaudited financial statements as of September 30, 2023 have been prepared under the assumption that the Company will continue as a going concern for the next 12 months. The Company's ability to continue as a going concern is dependent upon its uncertain ability to obtain additional capital, reduce expenditures and/or execute on its business plan and successfully commercialize Twirla. The unaudited financial statements as of September 30, 2023 do not include any adjustments that might result from the outcome of this uncertainty. If the Company is unable to continue as a going concern, it may have to liquidate its assets and may receive less than the value at which those assets are carried on the financial statements.

Basis of Presentation

The accompanying unaudited interim financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") for interim information and pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") for Quarterly Reports on Form 10-Q. Accordingly, certain information and footnote disclosure normally included in financial statements prepared in accordance with U.S. GAAP has been condensed or omitted pursuant to such rules and regulations. These interim financial statements should be read in conjunction with the audited financial statements and related notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 as filed with the SEC on March 23, 2023.

In the opinion of management, the unaudited interim financial statements reflect all adjustments, which are normal recurring adjustments, necessary for the fair presentation of the financial information for the interim periods presented. The results of operations for the three and nine months ended September 30, 2023 are not necessarily indicative of the operating results for the full fiscal year or any future period.

The accompanying unaudited financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company has incurred recurring losses and negative cash flows from operations. If the Company encounters unforeseen factors that impact the Company's current business plan or its ability to generate revenue from the commercialization of Twirla, the Company believes it has the ability to revise its commercial plans, including curtailing sales and marketing spending, to allow it to continue to fund its operations.

2. Summary of Significant Accounting Policies

The Company's complete listing of significant accounting policies is described in Note 2 to the Company's audited financial statements as of December 31, 2022 included in its Annual Report on Form 10-K filed with the SEC on March 23, 2023.

Use of Estimates

The preparation of the Company's financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company bases its estimates and judgments on historical experience and various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheets

and the amounts of revenue and expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, revenue recognition, costs of product revenues, inventory reserves, the accounting for common stock warrants, stock-based compensation, and accounting for research and development costs. As future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates.

Risks and Uncertainties

While Twirla has been approved by the FDA, other potential product candidates developed by the Company will require approval from the FDA prior to commercial sales. There can be no assurance that the Company's other product candidates will receive the required approval. If the Company is denied approval or such approval is delayed, or is unable 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 the possibility of continued public health threats could adversely affect the Company's ongoing or planned business operations. For example, the coronavirus ("COVID-19") pandemic previously resulted in federal, state and local governments and private entities mandating various restrictions, including travel restrictions, access restrictions, restrictions on public gatherings, and stay at home orders. The most significant impacts to the Company's business were encountered by sales representatives promoting Twirla in the field, as some offices limited opportunities for face-to-face interactions with healthcare providers. Re-implementation of COVID-19 restrictions, if necessary in the future, may disrupt the Company's business and/or could adversely affect the Company's commercialization plans and results. 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 the Company 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. Another shutdown necessitating work in a completely remote environment could result in delays to its business activities and commercialization plan. The Company will continue to closely monitor events as they develop, and plan for alternative and mitigating measures that can be implemented 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.

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 represents the Company's estimate of losses over the life of the receivables. The Company evaluates forward-looking economic factors and uses professional judgment to determine the allowance for credit losses. The credit loss reserves are reviewed and adjusted periodically. Credit loss reserves were not material as of September 30, 2023 and December 31, 2022.

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

Fair Value of Financial Instruments

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

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

Inventory

Inventory is valued utilizing the weighted average costing method. The Company records an inventory reserve for losses associated with dated, expired, excess or obsolete items. This reserve is based on management’s current knowledge with respect to inventory levels, planned production and sales volume assumptions. As of September 30, 2023 and December 31, 2022, inventory reserves approximated \$1.4 million and \$0.6 million, respectively.

Long-Lived Assets

In accordance with ASC 360, *Property, Plant and Equipment*, the Company’s policy is to review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Management does not believe the carrying values of any long-lived assets are impaired as of September 30, 2023.

Research and Development Expenses

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

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

Advertising Costs

The Company has elected to expense advertising costs when incurred. Advertising costs totaled zero and \$0.9 million for the three months ended September 30, 2023 and 2022, respectively, and totaled zero and \$6.1 million for the nine months ended September 30, 2023 and 2022, respectively.

Deferred Financing Costs

Costs directly attributable to the Company’s senior secured term loan (see Note 7) 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 \$44,000 and \$146,000 for the three months ended September 30, 2023 and 2022, respectively and was approximately \$146,000 and \$284,000 for the nine months ended September 30, 2023 and 2022, respectively.

Concentrations of Credit Risk

Financial instruments, which potentially subject the Company to credit risk consist principally of cash, cash equivalents, and accounts receivable. The Company invests its cash and cash equivalents in interest-bearing accounts in United States financial institutions, the balances of which exceed federally insured limits. The Company mitigates credit risk by limiting the investment type and maturity to securities that preserve capital, maintain liquidity, and have a high

credit quality. The Company has not recognized any losses from credit risks on such accounts. The Company has no financial instruments with off balance sheet risk of accounting loss.

Major customers of the Company are defined as those constituting greater than 10% of its total revenue. In the three months ended September 30, 2023, the Company had sales to five customers that individually accounted for more than 10% of its total revenue. These customers had sales of \$1.7 million, \$1.3 million, \$1.1 million, \$1.1 million, and \$1.1 million, respectively, which represented 93% of total revenues in the three months ended September 30, 2023. In the nine months ended September 30, 2023, the Company had sales to five customers that individually accounted for more than 10% of its total revenue. These customers had sales of \$3.2 million, \$3.2 million, \$3.2 million, \$3.0 million and \$2.1 million, respectively, which represented 92% of total revenue for the nine months ended September 30, 2023. Accounts receivable related to these five customers comprised 36%, 26%, 18%, 15%, and 0%, of the Company's total accounts receivable, respectively, as of September 30, 2023. In the three months ended September 30, 2022, the Company had sales to three customers that individually accounted for more than 10% of its total revenue. These customers had sales of \$0.7 million, \$0.6 million, and \$0.6 million, respectively, which represented 30% of total revenues in the three months ended September 30, 2022. In the nine months ended September 30, 2022, the Company had sales to three customers that individually accounted for more than 10% of its total revenue. These customers had sales of \$1.9 million, \$1.8 million and \$1.7 million, respectively, which represented 33% of total revenue for the nine months ended September 30, 2022.

Revenue Recognition

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

In accordance with ASC 606, the Company recognizes revenue at the point in time when its performance obligation is satisfied by transferring control of the promised goods or services to a customer. In accordance with the Company's contracts with customers, control of the product is transferred upon the conveyance of title, which occurs when the product is sold to and received by a customer. The Company's customers are located in the United States and consist primarily of wholesale distributors. 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; and
- Co-payment assistance.

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

provisions are analyzed, and adjustments are made if necessary. Any adjustments made to these provisions would affect net product revenue and earnings in the current period.

In accordance with ASC 606, the Company must make 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 continues to become 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.

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

Product returns – Customers have the right to return product that is within six months or less of the labeled expiration date or that is past the expiration date by no more than twelve months. Twirla was commercially launched in December 2020 and with limited historical sales data, an estimate for product returns as of September 30, 2023 was made based on industry standard data and trend analysis. Estimated product returns are recorded as other current liabilities in accrued expenses on the balance sheet.

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

Rebates – The Company will be subject to mandatory discount obligations under the Medicaid and Tricare programs. The rebate amounts for these programs are determined by statutory requirements or contractual arrangements. Rebates are owed after the product has been dispensed to an end user and the Company has been invoiced. Rebates for Medicaid and Tricare are typically invoiced in arrears. The Company estimates the amount in rebates based on the expected number of claims and related cost that is associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Rebate estimates are recorded as other current liabilities in accrued expenses on the balance sheet.

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

Provisions for the revenue reserves described above totaled \$8.5 million and \$3.2 million for the three months ended September 30, 2023 and 2022, respectively, and \$19.3 million and \$6.1 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, reserves on the balance sheet associated with variable consideration were \$7.4 million.

Warrants

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

In connection with entering into a senior secured term loan facility in February 2020 (the “Perceptive Credit Agreement”), the Company issued warrants to purchase 700 shares of its common stock to the lender, Perceptive Credit Holdings III, L.P. (“Perceptive”). In connection with an amendment to that facility in February 2021, the Company issued warrants to purchase 225 shares of the Company’s common stock (collectively, the “Perceptive Warrants”). The Perceptive Warrants qualify for equity classification and have been allocated based upon the relative fair value of the base instrument and the warrant. In March 2023, in connection with the Waiver and Sixth Amendment to the Perceptive Credit Agreement, the Company amended and restated the Perceptive Warrants to reset the strike price of the Perceptive Warrants. In October 2023, in connection with the Seventh Amendment to the Perceptive Credit Agreement, the Company reset the strike price of the Perceptive Warrants. See Notes 7 and 8 for additional information.

In connection with an underwritten public offering completed in October 2021, the Company issued warrants to purchase 6,660 shares of its common stock. These warrants are classified as liabilities, were measured at fair value upon issuance, with subsequent changes in fair value reported in the Statements of Operations and Comprehensive Loss each reporting period. This offering also triggered an adjustment to the exercise price of the Perceptive Warrants, which resulted in a reduction of the strike price for these warrants. This reduction resulted in an immaterial increase to additional paid-in-capital. See Notes 7 and 8 for additional information.

In connection with a registered direct offering completed in March 2022, the Company issued warrants to purchase 24,856 shares of its common stock. These warrants are classified as liabilities, were measured at fair value upon issuance, with subsequent changes in fair value reported in the Statement of Operations each reporting period. This offering also triggered an adjustment to the exercise price of the Perceptive Warrants, which resulted in a reduction of the strike price for these warrants. This reduction resulted in an immaterial increase to additional paid-in-capital. See Notes 7 and 8 for additional information.

In connection with a letter agreement and waiver entered into with an investor on April 2022, the Company issued warrants to purchase 4,243 shares of common stock. These warrants are classified as liabilities, were measured at fair value upon issuance, with subsequent changes in fair value reported in the Statement of Operations each reporting period. See Note 8 for additional information.

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

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

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 September 30, 2023 that qualify for either recognition or disclosure in the financial statements under this guidance.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC 718, *Compensation-Stock Compensation*. The Company grants stock options for a fixed number of shares to employees and non-employees with an exercise price equal to no less than the fair value of the shares at grant date. Compensation cost is recognized for all share-based payments granted and is based on the grant-date fair value estimated using the weighted-average assumption of the Black-Scholes option pricing model based on key assumptions such as stock price, expected volatility and expected term. The Company elects to account for forfeitures when they occur. The equity instrument is not considered to be issued until the instrument vests. As a result, compensation cost is recognized over the requisite service period with an offsetting credit to additional paid-in capital.

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

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 three and nine months ended September 30, 2023 and 2022, respectively, because to do so would be anti-dilutive (in common equivalent shares):

	September 30,	
	2023	2022
Common stock warrants	4,484,077	36,691
Unvested restricted stock units	135,037	142
Common stock options	43,510	5,778
Total	<u>4,662,624</u>	<u>42,611</u>

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 its consolidated financial statements or disclosures.

The Company did not adopt any new accounting pronouncements during the nine months ended September 30, 2023 that had a material effect on its financial statements.

3. Fair Value Measurements

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

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

- Level 1 — Quoted prices in active markets for identical assets or liabilities. The Company’s Level 1 assets consist of cash and cash equivalents. The Company has no Level 1 liabilities.
- Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted market prices for similar assets or liabilities in active markets or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets and liabilities. The Company has no Level 2 assets or liabilities.
- Level 3 — Unobservable inputs that are supported by little or no market data and which require internal development of assumptions about how market participants price the fair value of the assets or liabilities. The Company has no Level 3 assets. Level 3 liabilities consist of warrant liability.

The following table sets forth the Company’s financial instruments measured at fair value by level within the fair value hierarchy as of September 30, 2023 and December 31, 2022 (in thousands):

	Level 1	Level 2	Level 3
September 30, 2023			
Assets:			
Cash and cash equivalents	\$ 2,873	\$ —	\$ —
Total assets at fair value	<u>\$ 2,873</u>	<u>\$ —</u>	<u>\$ —</u>
Liabilities:			
Warrant Liability	\$ —	\$ —	\$ 5,566
Total assets at fair value	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 5,566</u>
December 31, 2022			
Assets:			
Cash and cash equivalents	\$ 5,246	\$ —	\$ —
Total assets at fair value	<u>\$ 5,246</u>	<u>\$ —</u>	<u>\$ —</u>
Liabilities:			
Warrant Liability	\$ —	\$ —	\$ 5,934
Total assets at fair value	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 5,934</u>

The significant assumptions used in preparing the option pricing model for valuing the Company’s warrants as of September 30, 2023 include (i) volatility 86.06% - 123.42%, (ii) risk-free interest rate 4.62% - 5.46%, (iii) strike price for the common warrants of \$3.69, \$45.00 and \$1,700.00, (iv) fair value of common stock \$2.40 and (v) expected life 1.15 - 4.65 years. The significant assumptions used in preparing the option pricing model for valuing the Company’s warrants as of December 31, 2022 include (i) volatility 136.8% - 137.4%, (ii) risk-free interest rate 4.2% - 4.7%, (iii)

strike price for the common warrants \$45.00 and \$1,700, (iv) strike price for the preferred warrants of \$520.00, (v) fair value of common stock \$11.50 and (vi) expected life 0.7 - 4.5 years.

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

Beginning balance at December 31, 2022	\$ 5,934
Warrants issued	10,615
Change in fair value	(10,983)
Ending Balance September 30, 2023	<u>\$ 5,566</u>

There were no transfers between Level 1, 2 or 3 during the nine months ended September 30, 2023 or 2022.

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Prepaid insurance	\$ 697	\$ 628
Other	562	775
Total prepaid expenses and other current assets	<u>\$ 1,259</u>	<u>\$ 1,403</u>

5. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Gross to net accruals	\$ 3,933	\$ 2,332
Accrued compensation	2,721	833
Accrued professional fees and other	1,684	743
Total accrued liabilities	<u>\$ 8,338</u>	<u>\$ 3,908</u>

6. Leases

The Company has no finance leases and one operating lease for its corporate headquarters in Princeton, NJ. The current lease commenced on December 1, 2021 and terminates on March 31, 2025. The lease provides the Company with an option to extend the lease for an additional five years. Under the terms of the lease, the Company pays base annual rent subject to a fixed dollar amount increase each year, a fixed monthly charge for electricity, and other normal operating expenses such as taxes, repairs, and maintenance. The Company evaluates renewal options at lease inception and on an ongoing basis and includes renewal options that it is reasonably certain to exercise in its expected lease terms when classifying leases and measuring lease liabilities. The lease does not require variable lease payments, residual value guarantees, or restrictive covenants.

The lease does not provide an implicit rate, therefore the Company used its incremental borrowing rate as the discount rate when measuring the operating lease liability. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of the lease.

Operating lease expense was \$89,000 and \$90,000 for the three months ended September 30, 2023 and 2022, respectively. Operating lease expense was \$267,000 and \$271,000 for the nine months ended September 30, 2023 and 2022, respectively. Operating cash flows used for operating leases during the nine months ended September 30, 2023

and 2022 were approximately \$235,000 and \$132,000 respectively. As of September 30, 2023, the weighted average remaining lease term was 1.50 years, and the weighted average discount rate was 11.8%.

Future minimum lease payments under non-cancellable leases as of September 30, 2023 were as follows (in thousands):

2023	\$	98
2024		397
2025		101
Total	\$	596
Less: Interest		(47)
Present value of lease liability	\$	<u>549</u>

7. Credit Agreement and Guaranty

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

The facility will mature on February 10, 2024 (“Maturity Date”). Pursuant to the Perceptive Credit Agreement, beginning August 31, 2022, the Company began making monthly principal payments in an amount equal to \$75,000. Beginning on December 1, 2023 and pursuant to the Seventh Amendment, the Company will begin making monthly payments of \$150,000 until the Maturity Date, at which time all remaining principal amount outstanding is due.

Borrowings under the 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 September 30, 2023 was 15.58%. Upon the occurrence and during the continuance of any event of default under the Perceptive Credit Agreement, the interest rate automatically increases by 3.0% per annum.

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

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

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

As a result of the public offering of the Company's common stock completed in October 2021 (see Note 8), the antidilution provision of the Perceptive Warrants was triggered, resulting in a reduction of the strike price for the Perceptive Warrants. Warrants to purchase 350 shares of common stock that had an exercise price of \$9,340 per share were reduced to \$7,080 per share, warrants to purchase 350 shares of common stock that had an exercise price of \$7,480 per share were reduced to \$5,760 per share, and warrants to purchase 225 shares of common stock that had an exercise price of \$5,740 per share were reduced to \$4,540 per share.

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

As a result of the public offering of the Company's common stock completed in July 2022 (see Note 8), the antidilution provision of the Perceptive Warrants was again triggered resulting in a reduction of the strike price for the Perceptive Warrants. Warrants to purchase 350 shares of common stock that had an exercise price of \$5,276 per share were reduced to \$745 per share, warrants to purchase 350 shares of common stock that had an exercise price of \$4,330.50 per share were reduced to \$618.50 per share, and warrants to purchase 225 shares of common stock that had an exercise price of \$3,456.50 per share were reduced to \$501.50 per share.

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

per share were reduced to \$3.69 per share, and warrants to purchase 225 shares of common stock that had an exercise price of \$501.50 per share were reduced to \$3.69 per share.

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

	September 30, 2023	December 31, 2022
Notes payable	\$ 1,950	\$ 2,625
Debt issuance costs	(63)	(209)
Warrant discount	(298)	(990)
Total debt	\$ 1,589	\$ 1,426
Less, current portion	1,589	1,426
Long-term debt, less current portion	\$ —	\$ —

The fair value of the warrants and the debt issue costs are being amortized utilizing the effective interest method over the term of the loan. The Company recorded interest expense for the amortization of the fair value of the warrants and debt issue costs of \$252,000 and \$838,000 for the three months ended September 30, 2023 and 2022, respectively. The Company recorded interest expense for the amortization of the fair value of the warrants and debt issue costs of \$838,000 and \$1,635,000 for the nine months ended September 30, 2023 and 2022, respectively.

8. Stockholders' Deficit

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

Reverse Stock Split

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

Shelf Registration Statement

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

Public Offerings

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

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

In May 2023, the Company completed a best efforts public offering of an aggregate of 95,000 shares of common stock and 1,801,286 pre-funded warrants in lieu of shares of common stock and warrants to purchase a total of 3,792,572 shares of common stock at combined public offering price of \$3.9551 per share. Proceeds from the public offering, net of underwriting discounts, commissions, and offering expenses were approximately \$6.5 million. Through September 30, 2023 at total of 1,115,286 pre-funded warrants have been exercised and 686,000 pre-funded warrants remain available for exercise as of September 30, 2023. H.C. Wainwright acted as the exclusive placement agent in connection with the Offering and, as compensation, received a cash fee of 7% of the aggregate proceeds raised in the Offering. The Company also issued to certain designees of H.C. Wainwright warrants to purchase up to 94,814 shares of common stock with an exercise price of \$4.9439 per share.

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

ATM Sales Agreement

In March 2021, the Company entered into a common stock sales agreement (the “Sales Agreement”) under which the Company may sell up to an aggregate of \$50.0 million in gross proceeds through the sale of shares of common stock from time to time in “at-the-market” equity offerings (as defined in Rule 415 promulgated under the Securities Act of 1933, as amended). The Company agreed to pay a commission of up to 3% of the gross proceeds of any common stock sold under the Sales Agreement. During the year ended December 31, 2021, the Company issued and sold 3,457 shares of common stock under the Sales Agreement resulting in net proceeds to the Company of approximately \$9.3 million.

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

On April 27, 2022, the Company entered into a new at-the-market offering program (the “April 2022 ATM Agreement”) with H.C. Wainwright LLC and Co. (the “Sales Agent”) under which the Company is authorized to sell up to an aggregate of \$12.8 million in gross proceeds through the sale of shares of common stock from time to time. The Company agreed to pay a commission of up to 3.0% of the gross proceeds of any common stock sold under the April 2022 ATM Agreement. Through September 30, 2022, the Company issued and sold a total of 173,750 shares of common stock under the April 2022 ATM Agreement, representing the entire capacity of the April 2022 ATM, resulting in net proceeds of approximately \$12.2 million. On August 22, 2022, the Company increased the April 2022 ATM (“August 2022 ATM”). As increased, the Company was eligible to offer and sell, from time to time through the Sales Agent, shares of its common stock having an aggregate offering price of up to \$75.0 million. During the year ended December 31, 2022, the Company issued and sold 78,852 shares of common stock under the August 2022 ATM resulting in net proceeds of approximately \$0.9 million. During the nine months ended September 30, 2023, the Company issued and sold 207,883 shares for net proceeds of approximately \$1.7 million. On April 12, 2023, the Company filed a prospectus supplement to its registration statement on Form S-3 for the August 2022 ATM verifying that it is now eligible to sell up to \$4.5 million worth of shares through its ATM.

Registered Direct Offering

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

On March 15, 2022, 2,425 shares of the Series A Preferred Stock were converted into 6,025 shares of the Company’s common stock. On April 4, 2022, 2,425 shares of the Series B Preferred Stock were converted into 6,025 shares of the Company’s common stock.

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

Stock-Based Compensation Expense

Stock-based compensation expense was allocated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Cost of goods sold	\$ 12	\$ 29	\$ 69	\$ 104
Research and development	94	90	261	284
Selling and marketing	10	40	73	120
General and administrative	323	377	1,015	1,461
Total	<u>\$ 439</u>	<u>\$ 536</u>	<u>\$ 1,418</u>	<u>\$ 1,969</u>

9. Income Taxes

Sale of New Jersey Net Operating Losses

The Company has participated in the State of New Jersey's Technology Business Tax Certificate Transfer Program (the "Program") sponsored by The New Jersey Economic Development Authority. The Program enables approved biotechnology companies with unused NOLs and unused research and development credits to sell these tax benefits for at least 80% of the value of the tax benefits to unaffiliated, profitable corporate taxpayers in the State of New Jersey. The Program is administered by The New Jersey Economic Development Authority and the New Jersey Department of the Treasury's Division of Taxation. The Company had previously reached the maximum lifetime benefit of \$15.0 million under the historical Program; however, in January 2021 the Program was amended to extend the maximum lifetime benefit to \$20.0 million. The Company received final approval in March 2022 for \$4.7 million of additional cash benefit that was received in April 2022.

10. Commitments and Contingencies

The Company has several firm purchase commitments, primarily related to the manufacture and supply of Twirla and the supply of a field force of sales representatives to provide certain detailing services, sales operation services, compliance services, and training services. Future firm purchase commitments under these agreements, the last of which ends in 2033, total \$230.1 million. This amount does not represent all of the Company's anticipated purchases in the future, but instead represents only purchases that are the subject of contractually obligated minimum purchases. The minimum commitments disclosed are determined based on non-cancelable minimum spend in 2023 or termination amounts. Additionally, the Company purchases products and services as needed with no firm commitment.

In April 2020, the Company entered into a manufacturing and commercialization agreement with Corium (the "Corium Agreement"). Under the Corium Agreement, the Company has a requirement to order quarterly minimum volumes of approximately \$5.6 million of product. In the event that the Company does not order the minimum volume, the Company is required to pay an additional fee equal to twenty-five percent (25%) per unit of the transfer price for all units ordered in that quarter. The Company did not meet the minimum volume order in the first or second quarter of 2022, and has, therefore, paid the additional 25% per unit fee as a penalty for all units ordered during the period. Based on then-current demand expectations for Twirla, the Company did not expect to meet the minimum volume order for the balance of 2022 and would be subject to the additional fee on future purchases. On July 25, 2022 the Company and Corium entered into Amendment No. 1 to the Corium Agreement (the "Amendment") that is designed to restructure the contract minimums applicable to the purchase of manufactured Twirla and other services provided by Corium, transfer equipment ownership to Corium to support the manufacture of Twirla, and extend the term of the Corium Agreement. Pursuant to the Amendment, the parties agreed to adjust the process for the Company providing Corium certain binding and non-binding forecasts required under the Corium Agreement. Additionally, Corium will not enforce the original quantity minimums in the Corium Agreement, which are waived and replaced by new minimums that are based on Corium's revenue for product purchased by the Company, expiring raw materials, and other services billed by Corium to support batch production and release. The guaranteed minimum revenue requirement for 2023 is \$7.0 million, and is \$22.5 million for 2024 and each year thereafter. In the event that the Company does not meet the guaranteed minimum revenue requirements in any given year, the Company will be required to make additional payments to Corium for the shortfall. The Company agreed to make certain monthly supplemental payments to Corium through December 2023, which payments are eligible to be retroactively reduced based upon product orders placed by the Company during 2023 meeting certain designated thresholds. In connection with the supplemental payments, Corium will retain the proceeds for the sale of certain raw materials to which the Company would otherwise have economic right to offset such supplemental payments. Further, the Company agreed to reimburse Corium for any unused raw materials in the event the Company's actual product requirements are lower than initially forecasted. Pursuant to the Amendment, the term of the Corium Agreement was extended to December 31, 2033. Pursuant to the Amendment, the parties agreed to transfer ownership of certain manufacturing equipment used in the manufacture of Twirla from the Company to Corium under a Bill of Sale dated July 25, 2022.

The Company records a provision for contingent losses when it is both probable that a liability has been incurred, and the amount of the loss can be reasonably estimated. An unfavorable outcome to any legal matter, if material, could

have an adverse effect on the Company's operations or its financial position. As of September 30, 2023, the Company has not recorded a provision for any contingent losses.



\$15,000,000

Up to Shares of Common Stock and
Accompanying Series E-1 Warrants to Purchase up to Shares of Common Stock and
Series E-2 Warrants to Purchase up to Shares of Common Stock
or
Series F Pre-funded Warrants to Purchase up to Shares of Common Stock and
Accompanying Series E-1 Warrants to Purchase up to Shares of Common Stock and
Series E-2 Warrants to Purchase up to Shares of Common Stock
Placement Agent Warrants to Purchase up to Shares of Common Stock

Preliminary Prospectus

, 2024

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the fees and expenses in connection with the issuance and distribution of the securities being registered (excluding the underwriting discount). Except for the Securities and Exchange Commission registration fee and the FINRA filing fee, all amounts are estimates.

	Amount Paid or to be Paid
SEC registration fee	\$ 2,214.00
FINRA filing fee	\$ 2,750.00
Legal fees and expenses	*
Accounting fees and expenses	*
Printing expenses	*
Transfer agent fees and expenses	*
Miscellaneous	*
Total	*

* To be completed by amendment

Each of the amounts set forth above, other than the SEC registration fee and FINRA filing fee, is an estimate.

Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law authorizes a corporation's board of directors to grant, and authorizes a court to award, indemnity to officers, directors, and other corporate agents.

As permitted by Delaware law, our Amended and Restated Certificate of Incorporation, as amended, provides that, to the fullest extent permitted by Delaware law, no director will be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director. Pursuant to Delaware law such protection would be not available for liability:

- for any breach of a duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- for any transaction from which the director derived an improper benefit; or
- for an act or omission for which the liability of a director is expressly provided by an applicable statute, including unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law.

Our Amended and Restated Certificate of Incorporation, as amended, also provides that if Delaware law is amended after the approval by our stockholders of the amended and restated certificate of incorporation to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law.

Our amended and restated bylaws, as amended, further provide that we must indemnify our directors and officers to the fullest extent permitted by Delaware law. The amended and restated bylaws also authorize us to indemnify any of our employees or agents and permit us to secure insurance on behalf of any officer, director, employee or agent for any liability arising out of his or her action in that capacity, whether or not Delaware law would otherwise permit indemnification.

In addition, our amended and restated bylaws provide that we are required to advance expenses to our directors and officers as incurred in connection with legal proceedings against them for which they may be indemnified and that the rights conferred in the amended and restated bylaws are not exclusive.

At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought, and we are not aware of any threatened litigation that may result in claims for indemnification.

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us to indemnify each director and officer to the fullest extent permitted by Delaware law, the amended and restated certificate of incorporation and amended and restated bylaws, for expenses such as, among other things, attorneys' fees, judgments, fines, and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action by or in our right, arising out of the person's services as our director or executive officer or as the director or executive officer of any subsidiary of ours or any other company or enterprise to which the person provides services at our request. We also maintain directors' and officers' liability insurance.

The SEC has taken the position that personal liability of directors for violation of the federal securities laws cannot be limited and that indemnification by us for any such violation is unenforceable. The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Item 15. Recent Sales of Unregistered Securities

Set forth below is information regarding securities we have issued within the past three years that were not registered under the Securities Act:

On February 10, 2020, in connection with the Perceptive Credit Agreement, we issued to Perceptive two warrants to purchase an aggregate of 700 shares of our common stock (together, the "2020 Perceptive Warrants"). The first warrant is exercisable for 350 shares of common stock at an exercise price of \$7,480.00 per share. The second warrant is exercisable for 350 shares of common stock at an exercise price of \$9,340.00 per share. The 2020 Perceptive Warrants expire on February 10, 2027. In connection with the Amended Perceptive Credit Agreement, we issued to Perceptive a warrant to purchase 225 shares of our common stock (the "2021 Perceptive Warrant" and, together with the 2020 Perceptive Warrants, the "Perceptive Warrants") at an exercise price of \$5,740.00 per share. The 2021 Perceptive Warrant expires on February 26, 2028. The Perceptive Warrants contain anti-dilution provisions that expired on December 31, 2022 and other warrant holder protections and are not exercisable to the extent that Perceptive would beneficially own more than 19.99% of our common stock as a result of the exercise. In connection with the Sixth Amendment, we amended and restated the Perceptive Warrants to reset the strike price of the Perceptive Warrants.

On December 3, 2023, we entered into a Warrant Amendment and Additional Issuance Agreement ("Warrant Amendment and Additional Issuance Agreement") relating to the amendment of warrants to purchase shares of our common stock that were issued in transactions on March 14, 2022, April 25, 2022, and May 25, 2023 (collectively, the "Warrants"). Collectively, the Warrants represent the right to purchase approximately 3.8 million shares of our common stock. Under the terms of the Warrant Amendment and Additional Issuance Agreement, the holder agreed to revise provisions related to the use of a Black-Scholes model to value the Warrants in the event of a change of control transaction. The holder also agreed to revise provisions related to the cashless exercise of the Warrants. In exchange for the holder's agreement to amend the Warrants, we agreed to issue an additional new warrant (the "New Warrant") to purchase 1,005,560 shares of our common stock. The New Warrant has an exercise price of \$2.09 per share. The New Warrant is exercisable six months after issuance and will expire five years from the date that the New Warrant is initially exercisable. The exercise price of the New Warrant is subject to adjustment for stock splits, reverse splits, and similar capital transactions as described in the New Warrant.

Our issuances of the warrants were deemed to be exempt from registration under the Securities Act pursuant to Section 4(a)(2) of the Securities Act in that such issuances did not involve a public offering. The recipient of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. The recipient of securities in these transactions was an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act and had adequate access, through employment, business or other relationships, to information about us. No underwriters were involved in these transactions.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits

**Exhibit
Number**

- 3.1 [Amended and Restated Certificate of Incorporation of the Registrant. \(Incorporated by reference, Exhibit 3.1 to Company's Current Report on Form 8-K, file number 001-36464, filed May on 30, 2014.\)](#)
- 3.2 [Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Secretary of State of the State of Delaware on January 7, 2022 \(Incorporated by reference, Exhibit 3.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on January 10, 2022.\)](#)
- 3.3 [Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Secretary of State of Delaware on April 26, 2022 \(Incorporated by reference, Exhibit 3.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on April 27, 2022.\)](#)
- 3.4 [Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Secretary of State of Delaware on April 10, 2023 \(Incorporated by reference, Exhibit 3.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on April 10, 2023.\)](#)
- 3.5 [Amended and Restated Bylaws of the Registrant \(Incorporated by reference, Exhibit 3.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on January 26, 2023.\)](#)
- 3.6 [Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock filed with the Secretary of State of the State of Delaware on March 14, 2022 \(Incorporated by reference, Exhibit 3.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on March 15, 2022.\)](#)
- 3.7 [Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock filed with the Secretary of State of the State of Delaware on March 14, 2022 \(Incorporated by reference, Exhibit 3.2 to Company's Current Report on Form 8-K, file number 001-36464, filed on March 15, 2022.\)](#)
- 3.8 [Certificate of Designation of Preferences, Rights, and Limitations of Series C Preferred Stock filed with the Secretary of State of the State of Delaware on January 26, 2023 \(Incorporated by reference, Exhibit 3.2 to Company's Current Report on Form 8-K, file number 001-36464, filed on January 26, 2023.\)](#)
- 4.1 [Specimen Certificate evidencing shares of Registrant's common stock \(Incorporated by reference, Exhibit 4.1 to Company's Third Amendment of Registration Statement on Form S-1, file number 333-194621, filed on May 9, 2014.\)](#)
- 4.2 [Amended and Restated Common Stock Purchase Warrant between Agile Therapeutics, Inc. and Perceptive Credit Holdings III, LP, dated as of March 21, 2023 \(Incorporated by reference, Exhibit 4.2 to Company's Annual Report on Form 10-K, file number 001-36464, filed on March 23, 2023.\)](#)
- 4.3 [Amended and Restated Common Stock Purchase Warrant between Agile Therapeutics, Inc. and Perceptive Credit Holdings III, LP, dated as of March 21, 2023 \(Incorporated by reference, Exhibit 4.3 to Company's Annual Report on Form 10-K, file number 001-36464, filed on March 23, 2023.\)](#)
- 4.4 [Amended and Restated Common Stock Purchase Warrant between Agile Therapeutics, Inc. and Perceptive Credit Holdings III, LP, dated as of March 21, 2023 \(Incorporated by reference, Exhibit 4.4 to Company's Annual Report on Form 10-K, file number 001-36464, filed on March 23, 2023.\)](#)
- 4.5 [Form of Warrant \(Incorporated by reference, Exhibit 4.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on October 8, 2021.\)](#)

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- 4.6 [Form of Series A Warrant \(Incorporated by reference, Exhibit 4.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on March 15, 2022.\)](#)
- 4.7 [Form of Series B Warrant \(Incorporated by reference, Exhibit 4.2 to Company's Current Report on Form 8-K, file number 001-36464, filed on March 15, 2022.\)](#)
- 4.8 [Form of Placement Agent Warrant \(Incorporated by reference, Exhibit 4.3 to Company's Current Report on Form 8-K, file number 001-36464, filed on March 15, 2022.\)](#)
- 4.9 [Form of Series A-1 Warrant \(Incorporated by reference, Exhibit 4.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on July 8, 2022.\)](#)
- 4.10 [Form of Series A-2 Warrant \(Incorporated by reference, Exhibit 4.2 to Company's Current Report on Form 8-K, file number 001-36464, filed on July 8, 2022.\)](#)
- 4.11 [Form of Series B Pre-Funded Warrant \(Incorporated by reference, Exhibit 4.3 to Company's Current Report on Form 8-K, file number 001-36464, filed on July 8, 2022.\)](#)
- 4.12 [Form of Placement Agent Warrant \(Incorporated by reference, Exhibit 4.4 to Company's Current Report on Form 8-K, file number 001-36464, filed on July 8, 2022.\)](#)
- 4.13 [Description of Capital Stock \(Incorporated by reference, Exhibit 4.4 to Company's Annual Report on Form 10-K, file number 001-36464, filed on February 20, 2020.\)](#)
- 4.14 [Form of Series C-1 Warrant \(Incorporated by reference, Exhibit 4.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.\)](#)
- 4.15 [Form of Series C-2 Warrant \(Incorporated by reference, Exhibit 4.2 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.\)](#)
- 4.16 [Form of Series D Pre-funded Warrant \(Incorporated by reference, Exhibit 4.3 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.\)](#)
- 4.17 [Form of Placement Agent Warrant \(Incorporated by reference, Exhibit 4.4 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.\)](#)
- 4.18 [Form of Amended and Restated Common Stock Purchase Warrant between Agile Therapeutics, Inc. and an institutional investor, dated October 8, 2021 \(Incorporated by reference, Exhibit 4.5 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.\)](#)
- 4.19 [Form of Amended and Restated Series A Common Stock Purchase Warrant between Agile Therapeutics, Inc. and an institutional investor, dated March 14, 2022 \(Incorporated by reference, Exhibit 4.6 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.\)](#)
- 4.20 [Form of Amended and Restated Series A Common Stock Purchase Warrant between Agile Therapeutics, Inc. and an institutional investor, dated April 25, 2022 \(Incorporated by reference, Exhibit 4.7 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.\)](#)
- 4.21 [Form of Amended and Restated Series A-1 Common Stock Purchase Warrant between Agile Therapeutics, Inc. and an institutional investor, dated July 6, 2022 \(Incorporated by reference, Exhibit 4.8 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.\)](#)
- 4.22 [Form of Amended and Restated Series A-2 Common Stock Purchase Warrant between Agile Therapeutics, Inc. and an institutional investor, dated July 6, 2022 \(Incorporated by reference, Exhibit 4.9 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.\)](#)

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- 4.23 [Form of Amended and Restated Series B Common Stock Purchase Warrant between Agile Therapeutics, Inc. and an institutional investor, dated March 14, 2022 \(Incorporated by reference, Exhibit 4.10 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.\)](#)
- 4.24 [Form of New Warrant. \(Incorporated by reference, Exhibit 4.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on December 4, 2023.\)](#)
- 4.25** [Amendment to Warrants and Certificate of Adjustment between Agile Therapeutics, Inc. and Perceptive Credit Holdings III, LP, dated as of October 30, 2023.](#)
- 4.26** [Form of Series E-1 Warrant](#)
- 4.27** [Form of Series E-2 Warrant](#)
- 4.28** [Form of Series F Pre-Funded Warrant](#)
- 4.29** [Form of Placement Agent Warrant](#)
- 5.1++ Opinion of Morgan, Lewis & Bockius LLP
- 10.1+ [Form of Indemnification Agreement. \(Incorporated by reference, Exhibit 10.1 to Company's Second Amendment of Registration Statement on Form S-1, file number 333-194621, filed on May 5, 2014.\)](#)
- 10.2+ [Agile Therapeutics, Inc. Amended and Restated 1997 Equity Incentive Plan, as amended, and form of Stock Option Agreement thereunder. \(Incorporated by reference, Exhibit 10.2 to Company's Registration Statement on Form S-1, file number 333-194621, filed on March 17, 2014.\)](#)
- 10.3+ [Agile Therapeutics, Inc. Amended and Restated 2008 Equity Incentive Plan and form of Nonqualified Stock Option Agreement and form of Incentive Stock Option Agreement thereunder. \(Incorporated by reference, Exhibit 10.3 to Company's Registration Statement on Form S-1, file number 333-194621, filed on March 17, 2014.\)](#)
- 10.4+ [Form of Performance Unit Issuance Agreement \(Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on January 26, 2018.\)](#)
- 10.5 [Lease Agreement, dated August 6, 2021 by and between Agile Therapeutics, Inc. and 500 College Road Venture, LLC \(Incorporated by reference, Exhibit 10.1 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on November 2, 2021.\)](#)
- 10.6 [Common Stock Sales Agreement dated November 8, 2019 by and between the Registrant and H.C. Wainwright & Co., LLC \(Incorporated by reference, Exhibit 1.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on November 8, 2019.\)](#)
- 10.7 [Common Stock Sales Agreement dated March 18, 2021, by and between Agile Therapeutics, Inc. and H.C. Wainwright & Co., LLC \(Incorporated by reference, Exhibit 1.1 to the Company's Current Report on Form 8-K, file number 001-036464, filed on March 18, 2021.\)](#)
- 10.8 [Common Stock Sales Agreement dated April 27, 2022 by and between Agile Therapeutics, Inc. and H.C. Wainwright & Co., LLC \(Incorporated by reference, Exhibit 1.1 to Company's Current Report on Form 8-K, file number 001-036464, filed on April 27, 2022.\)](#)
- 10.9 [Controlled Equity OfferingSM Sales Agreement dated January 10, 2022 by and among Agile Therapeutics, Inc. and Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC \(Incorporated by reference, Exhibit 1.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on January 10, 2022.\)](#)
- 10.10 [Engagement Agreement, by and between Agile Therapeutics, Inc. and H.C. Wainwright & Co., LLC \(Incorporated by reference, Exhibit 10.32 to Company's Amendment No. 1 to Registration Statement on Form S-1/A, file number 333-264960, filed on June 29, 2022.\)](#)

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- 10.11 [Amendment to Engagement Agreement, by and between Agile Therapeutics, Inc. and H.C. Wainwright & Co., LLC \(Incorporated by reference, Exhibit 10.33 to Company's Amendment No. 1 to Registration Statement on Form S-1/A, file number 333-264960, filed on June 29, 2022.\)](#)
- 10.12 [Credit Agreement and Guaranty among Agile Therapeutics, Inc., the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, dated as of February 10, 2020 \(Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on February 12, 2020.\)](#)
- 10.13 [Waiver and First Amendment to Credit Agreement and Guaranty among Agile Therapeutics, Inc., the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, dated as of February 26, 2021 \(Incorporated by reference, Exhibit 10.11 to Company's Annual Report on Form 10-K, file number 001-36464, filed on March 1, 2021.\)](#)
- 10.14 [Waiver and Second Amendment to Credit Agreement and Guaranty among Agile Therapeutics, Inc., the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, dated as of January 7, 2022 \(Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on January 10, 2022.\)](#)
- 10.15 [Waiver and Third Amendment to Credit Agreement and Guaranty among Agile Therapeutics, Inc., the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, dated as of March 10, 2022 \(Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on March 11, 2022.\)](#)
- 10.16 [Waiver and Fourth Amendment to Credit Agreement and Guaranty among Agile Therapeutics, Inc., the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, dated as of May 11, 2022 \(Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 12, 2022.\)](#)
- 10.17 [Fifth Amendment to Credit Agreement and Guaranty among Agile Therapeutics, Inc., the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, L.P. dated as of July 25, 2022 \(Incorporated by reference, Exhibit 10.1 to Company's Quarterly Report on form 10-Q, file number 001-36464, filed on November 7, 2022.\)](#)
- 10.18 [Waiver and Sixth Amendment to Credit Agreement and Guaranty among Agile Therapeutics, Inc., the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, dated as of March 21, 2023 \(Incorporated by reference, Exhibit 10.18 to Company's Registration Statement on Form S-1, file number 333-271249, filed on April 14, 2023.\)](#)
- 10.19 [Seventh Amendment to Credit Agreement and Guaranty among Agile Therapeutics, Inc., the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, L.P., dated as of October 30, 2023.](#)
- 10.20 [Form of Securities Purchase Agreement, dated March 13, 2022, by and between Agile Therapeutics, Inc. and the purchaser signatory thereto \(Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on March 15, 2022.\)](#)
- 10.21 [Form of Securities Purchase Agreement by and between Agile Therapeutics, Inc. and the purchasers signatory thereto \(Incorporated by reference, Exhibit 10.31 to Company's Amendment No. 1 to Registration Statement on Form S-1/A, file number 333-264960, filed on June 29, 2022.\)](#)
- 10.22 [Form of Securities Purchase Agreement, by and between Agile Therapeutics, Inc., and certain purchasers \(Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on July 8, 2022.\)](#)
- 10.23* [Project Agreement, dated April 30, 2020, by and between Agile Therapeutics, Inc. and inVentiv Commercial Services, LLC \(Incorporated by reference, Exhibit 10.1 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on August 11, 2020.\)](#)

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- 10.24* [First Amendment to Project Agreement, dated June 1, 2020, by and between Agile Therapeutics, Inc. and inVentiv Commercial Services, LLC \(Incorporated by reference, Exhibit 10.13 to Company's Annual Report on Form 10-K, file number 001-36464, filed on March 1, 2021.\)](#)
- 10.25* [Second Amendment to Project Agreement, dated January 1, 2021, by and between Agile Therapeutics, Inc. and inVentiv Commercial Services, LLC \(Incorporated by reference, Exhibit 10.2 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on November 2, 2021.\)](#)
- 10.26* [Third Amendment to Project Agreement, dated July 1, 2021, by and between Agile Therapeutics, Inc. and inVentiv Commercial Services, LLC. \(Incorporated by reference, Exhibit 10.3 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on November 2, 2021.\)](#)
- 10.27* [Fourth Amendment to Project Agreement, dated September 1, 2021, by and between Agile Therapeutics, Inc. and inVentiv Commercial Services, LLC. \(Incorporated by reference, Exhibit 10.24 to Company's Annual Report on Form 10-K, file number 001-36464, filed on March 30, 2022.\)](#)
- 10.28* [Fifth Amendment to Project Agreement, dated February 1, 2022, by and between Agile Therapeutics, Inc. and inVentiv Commercial Services LLC \(Incorporated by reference, Exhibit 10.5 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on May 12, 2022.\)](#)
- 10.29* [Sixth Amendment to Project Agreement, dated January 3, 2023, by and between Agile Therapeutics, Inc. and inVentiv Commercial Services, LLC \(Incorporated by reference, Exhibit 10.27 to the Company's Annual Report on Form 10-K, file number 001-36464, filed on March 23, 2023.\)](#)
- 10.30* [Seventh Amendment to Project Agreement, dated September 28, 2023, by and between Agile Therapeutics, Inc. and Syneos Health Commercial Services, LLC \(Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on September 28, 2023.\)](#)
- 10.31* [Master Service Agreement, dated October 11, 2017, by and between Agile Therapeutics, Inc. and inVentiv Commercial Services, LLC \(Incorporated by reference, Exhibit 10.2 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on August 11, 2020.\)](#)
- 10.32* [First Amendment to Master Service Agreement, dated April 30, 2020, by and between Agile Therapeutics, Inc. and inVentiv Commercial Services, LLC \(Incorporated by reference, Exhibit 10.3 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on August 11, 2020.\)](#)
- 10.33* [Manufacturing and Commercialization Agreement, dated April 30, 2020, by and between Agile Therapeutics, Inc. and Corium, Inc. \(Incorporated by reference, Exhibit 10.4 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on August 11, 2020.\)](#)
- 10.34 [Amendment No. 1 to Manufacturing and Commercialization Agreement, by and between Corium, Inc. and Agile Therapeutics, Inc., dated as of July 25, 2022, and Bill of Sale by Agile Therapeutics, Inc. to Corium Inc., dated as of July 25, 2022 \(Incorporated by reference, Exhibit 10.2 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on November 7, 2022.\)](#)
- 10.35+ [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.\)](#)
- 10.36+ [Amended and Restated Employment Agreement, dated November 22, 2022 by and between Agile Therapeutics, Inc. and Alfred Altomari \(Incorporated by reference, Exhibit 10.33 to the Company's Annual Report on Form 10-K, file number 001-36464, filed on March 23, 2023.\)](#)
- 10.37+ [Amended and Restated Employment Agreement, dated November 1, 2022 by and between Agile Therapeutics, Inc. and Geoffrey P. Gilmore \(Incorporated by reference, Exhibit 10.34 to the Company's Annual Report on Form 10-K, file number 001-36464, filed on March 23, 2023.\)](#)

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10.38+	Amended and Restated Employment Agreement, dated November 1, 2022 by and between Agile Therapeutics, Inc. and Paul Korner, M.D. (Incorporated by reference, Exhibit 10.35 to the Company's Annual Report on Form 10-K, file number 001-36464, filed on March 23, 2023.)
10.39	Form of Securities Purchase Agreement, dated May 22, 2023, by and between Agile Therapeutics, Inc. and certain purchasers (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.)
10.40	Form of Warrant Amendment Agreement, dated May 22, 2023, by and between Agile Therapeutics, Inc. and certain holders (Incorporated by reference, Exhibit 10.2 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.)
10.41	Agile Therapeutics, Inc. 2023 Equity Incentive Plan effective June 8, 2023 (Incorporated by reference, Exhibit 99.1 to the Company's Registration Statement on Form S-8, file number 333-272576, filed on June 9, 2023.)
10.42+	Employment Agreement, dated August 16, 2023, by and between Agile Therapeutics, Inc. and Scott Coiante (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K/A, file number 001-36464, filed August 22, 2023.)
10.43	Form of Warrant Amendment and Additional Issuance Agreement. (Incorporated by reference, Exhibit 10.1 to the Company's Current Report on Form 8-K, file number 001-36464, filed on December 4, 2023.)
10.44**	Form of Securities Purchase Agreement, by and among Agile Therapeutics, Inc. and the purchasers signatory thereto.
23.1	Consent of Independent Registered Public Accounting Firm.
23.2++	Consent of Morgan, Lewis & Bockius LLP (included in Exhibit 5.1)
24.1**	Power of Attorney (contained on the signature page to the Registration Statement).
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
107**	Filing Fee Table

+ Indicates management contract or compensatory plan or arrangement.

++ To be filed by amendment.

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

** Previously filed.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

- (a) (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
- (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933, as amended (the “Securities Act”);
 - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the “Calculation of Registration Fee” table in the effective registration statement; and
 - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

- (2) That, for the purposes of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at the time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
 - (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
 - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
 - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
 - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

- (5) That, for purposes of determining any liability under the Securities Act:
- (i) the information omitted from the form of prospectus filed as part of the registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of the registration statement as of the time it was declared effective; and
 - (ii) each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (c) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the indemnification provisions described herein, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Princeton, State of New Jersey on February 7, 2024.

AGILE THERAPEUTICS, INC.

By:

/s/ Alfred Altomari
Alfred Altomari
Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Alfred Altomari</u> Alfred Altomari	Chief Executive Officer and Director (<i>Principal Executive Officer</i>)	February 7, 2024
<u>/s/ Scott Coiante</u> Scott Coiante	Chief Financial Officer (<i>Principal Financial and Accounting Officer</i>)	February 7, 2024
<u>*</u> Sharon Barbari	Director	February 7, 2024
<u>*</u> Sandra Carson, M.D., FACOG	Director	February 7, 2024
<u>*</u> Seth H.Z. Fischer	Director	February 7, 2024
<u>*</u> John Hubbard, Ph.D.	Director	February 7, 2024
<u>*</u> Josephine Torrente	Director	February 7, 2024

* By: /s/ Alfred Altomari
Alfred Altomari
Attorney-In-Fact

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption “Experts” and to the use of our report dated March 22, 2023, in Amendment No. 4 to the Registration Statement (Form S-1) and related Prospectus of Agile Therapeutics, Inc. for the registration of \$15,000,000 of its common stock, Series E warrants, Series F pre-funded warrants and placement agent warrants.

/s/ Ernst & Young LLP

Iselin, New Jersey
February 7, 2024
