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

FORM S-1
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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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 is not an offer to sell these 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.

**SUBJECT TO COMPLETION, DATED DECEMBER 11, 2023
Preliminary Prospectus**

**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 , 2023 (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 , 2023 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. 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.

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 36 of this prospectus for more information regarding these arrangements.

Our common stock is listed on the Nasdaq Capital Market under the symbol “AGRX.” On , 2023, 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 10 of this prospectus and the section entitled “Risk Factors” included in our most recent Annual Report on Form 10-K, as revised or supplemented by our subsequent Quarterly Reports on Form 10-Q, which are or will be incorporated herein by reference, for a discussion of information that you should consider before investing in our securities.

| | 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 36 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 36 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 , 2023, 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 , 2023

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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, and the documents incorporated by reference herein before making your investment decision. You should rely only on the information provided in this prospectus and the documents incorporated by reference herein 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, will be filed or will be incorporated by reference 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, the documents incorporated by reference herein 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, the documents incorporated by reference 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 prospectus or the documents incorporated by reference herein 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, including the information incorporated by reference into 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 clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, including expense reduction strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this 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 or in the documents incorporated by reference 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 our prospectus and in our most recent Annual Report on Form 10-K, as revised or supplemented by our subsequent Quarterly Reports on Form 10-Q or our Current Reports on Form 8-K, as well as any amendments thereto, as filed with the SEC and which are incorporated herein by reference. 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 or in any document incorporated herein by reference 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 or the date of the document incorporated by reference in 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 and the documents incorporated by reference herein and therein. You should read all such documents carefully, especially the risk factors and our financial statements and the related notes included or incorporated by reference herein or therein, 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 2023, 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).

Nasdaq Listing Compliance

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”). 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, the Company received a notice from the Staff advising the Company that the Staff had determined that the Company did not meet the terms of the extension and that unless the Company requests an appeal, the Staff would proceed with delisting. The Company 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 the Company presented a multi-step plan to regain compliance with the Stockholders’ Equity Requirement. The Company’s 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.

We intend to monitor our stockholders’ equity and, if appropriate, consider further available options to regain compliance with the Stockholders’ Equity Requirement. There can be no assurance that we will regain compliance or otherwise maintain compliance with any of the other listing requirements.

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.

Risks Associated with this Offering

This offering is subject to numerous risks and uncertainties, including those highlighted in the section entitled “Risk Factors” immediately following this prospectus summary and the section entitled “Risk Factors” included in our [Annual Report on Form 10-K for the fiscal year ended December 31, 2022](#) as revised or supplemented by our Quarterly Reports on Form 10-Q for the quarters ended [March 31, 2023](#), [June 30, 2023](#) and [September 30, 2023](#), which are incorporated herein by reference. 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 , 2023. |
| 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 17 of this prospectus. |
| Risk factors | See "Risk Factors" beginning on page 10 of this prospectus and the section entitled "Risk Factors" included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 as revised or supplemented by our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2023 , June 30, 2023 , and September 30, 2023 which are incorporated herein by reference, and the other information included or incorporated by reference 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 2,511,657 shares of our common stock outstanding as of November 30, 2023, and excludes:

- 43,043 shares of common stock issuable upon the exercise of outstanding options to purchase common stock as of November 30, 2023 at a weighted average exercise price of \$548.70 per share;
- 153,517 shares of common stock issuable upon the vesting of outstanding restricted stock units as of November 30, 2023;
- 6,200 shares of common stock reserved for future issuance under our 2023 Equity Incentive Plan as of November 30, 2023; and
- 452,000 shares of common stock issuable upon the exercise of outstanding pre-funded warrants as of November 30, 2023; and
- 4,484,077 shares of common stock issuable upon the exercise of outstanding warrants as of November 30, 2023 at a weighted average exercise price of \$10.10 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 under the Section captioned “Risk Factors” contained in our [Annual Report on Form 10-K for the year ended December 31, 2022](#), our [Quarterly Report on Form 10-Q for the quarter ended March 31, 2023](#), our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2023](#), our [Quarterly Report on Form 10-Q for the quarter ended September 30, 2023](#), or our current reports on Form 8-K, each as filed with the SEC and which are incorporated by reference in this prospectus, together with other information in this prospectus, the information and documents incorporated by reference herein and therein, 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. Our cash and cash equivalents will not be sufficient to fund our current and planned operations through the 12 months following the date on which our Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 was filed, which raises substantial doubt about our ability to continue as a going concern. Substantial doubt about our ability to continue as a going concern may create negative reactions to the price of our common stock and we may have a more difficult time obtaining financing in the future.

Specialty pharmaceutical product development is a speculative undertaking, involves a substantial degree of risk and is a capital-intensive business. We 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 December 2023, including among other items, the commercialization of Twirla and advancing the development of our other potential product candidates. We may not be able to obtain sufficient additional funding to continue our operations at planned levels and be forced to reduce, or even terminate, our operations. To date, we have financed our operations primarily through sales of common stock, convertible preferred stock and convertible promissory notes and to a lesser extent, through term loans and government grants.

We expect that our expenses will increase as we continue to commercialize Twirla. As a result, we 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 and Part I, Item 1A “Risk Factors” of our Annual Report on Form 10-K filed with the SEC on March 23, 2023, as revised or supplemented by our quarterly reports on Form 10-Q and current reports on Form 8-K, each as filed with the SEC. 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, the Company received a notice from the Staff advising the Company that the Staff had determined that the Company did not meet the terms of the extension and that unless the Company requests an appeal, the Staff would proceed with delisting. The Company 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, the Company 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. The Company's 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.

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.

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 5 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 September 30, 2023, we had outstanding warrants to acquire 4,484,077 shares of our common stock, and stock options to purchase 43,510 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 , 2023), 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.

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 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 10 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 _____, 2023, 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 incorporated by reference in this prospectus supplement and the sections entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, each as incorporated by reference herein.

| | 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 2023, 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 _____, 2023, 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 _____, 2023, 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.

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 39 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 November 30, 2023, there were 2,511,657 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-8ECL, 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 and Series F pre-funded warrant 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 , 2023, 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. appearing in Agile Therapeutics, Inc.'s [Annual Report \(Form 10-K\) for the year ended December 31, 2022](#), have been audited by Ernst & Young LLP, our independent registered public accounting firm, as set forth in their report thereon included therein, and incorporated herein by reference 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. Such financial statements are, and audited financial statements to be included in subsequently filed documents will be, incorporated herein in reliance upon the report of Ernst & Young LLP pertaining to such financial statements (to the extent covered by consents filed with the Securities and Exchange Commission) 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 or the documents incorporated by reference herein and therein. 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 and the documents incorporated by reference herein and therein. You should rely only on the information contained in this prospectus or incorporated by reference herein or therein. 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.

INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to “incorporate by reference” information into this prospectus, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The SEC file number for the documents incorporated by reference in this prospectus is 001-36464. The documents incorporated by reference into this prospectus contain important information that you should read about us.

The following documents are incorporated by reference into this document:

1. [our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 filed with the SEC on March 23, 2023 \(the “Form 10-K”\);](#)
2. [the information contained in our Definitive Proxy Statement on Schedule 14A filed with the SEC on April 28, 2023, to the extent incorporated by reference in Part III of the Form 10-K;](#)
3. [our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 filed with the SEC on May 11, 2023;](#)
4. [our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 filed with the SEC on August 9, 2023;](#)
5. [our Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 filed with the SEC on November 9, 2023;](#)
6. our Current Reports on Form 8-K or 8-K/A filed with the SEC on [January 26, 2023](#); [February 27, 2023](#); [March 14, 2023](#); [March 30, 2023](#); [April 10, 2023](#); [April 26, 2023](#); [May 17, 2023](#); [May 25, 2023](#); [June 5, 2023](#); [June 8, 2023](#); [June 14, 2023](#); [June 27, 2023](#); [June 30, 2023](#); [August 22, 2023](#); [September 28, 2023](#); [October 2, 2023](#); [December 4, 2023](#); and [December 6, 2023](#); and
7. our description of our common stock contained in the [registration statement on Form 8-A, filed on May 20, 2014](#), as updated by [Exhibit 4.1 to the Form 10-K](#), and including any amendments or reports filed for the purpose of updating such description.

We also incorporate by reference into this prospectus all documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items) that are filed by us with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus but prior to the termination of the offering. These documents include periodic reports, such as Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as proxy statements.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, without charge upon written or oral request, a copy of any or all of the documents that are incorporated by reference into this prospectus but not delivered with the prospectus, including exhibits which are specifically incorporated by reference into such documents. Requests should be directed to: Agile Therapeutics, Inc., Attn: Investor Relations, 500 College Road East, Suite 310, Princeton, New Jersey 08540. Our telephone number is (609) 683-1880.

Any statement contained herein or in a document incorporated or deemed to be incorporated by reference into this document will be deemed to be modified or superseded for purposes of the document to the extent that a statement contained in this document or any other subsequently filed document that is deemed to be incorporated by reference into this document modifies or supersedes the statement.



\$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

, 2023

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.)
- [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 \(Incorporated by reference, Exhibit 4.9 to Company's Current Report on Form 8-K, file number 001-36464, filed on May 25, 2023.\)](#)
 - [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.](#)
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- 4.26++ Form of Series E Warrant
- 4.27++ Form of Series F Pre-Funded Warrant
- 4.28++ 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 \(Incorporated by reference, Exhibit 10.32 to Company's Amendment No. 1 to Registration Statement on Form S-1/A, file number 333-264960, filed on June 29, 2022.\)](#)
- [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 \(Incorporated by reference, Exhibit 10.11 to Company's Annual Report on Form 10-K, file number 001-36464, filed on March 1, 2021.\)](#)
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- [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 \(Incorporated by reference, Exhibit 10.1 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on August 11, 2020.\)](#)
- [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 \(Incorporated by reference, Exhibit 10.5 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on May 12, 2022.\)](#)
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- [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 \(Incorporated by reference, Exhibit 10.34 to the Company's Annual Report on Form 10-K, file number 001-36464, filed on March 23, 2023.\)](#)
- [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. \(Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on December 4, 2023.\)](#)
- [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 \(contained on the signature page to the Registration Statement\).](#)
- [107](#) [Filing Fee Table](#)
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- + 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).

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.
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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 December 11, 2023.

AGILE THERAPEUTICS, INC.

By:

/s/ Alfred Altomari

Alfred Altomari

Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Alfred Altomari and Geoff Gilmore, and each of them, as his or her true and lawful agent, proxy and attorney-in-fact, each acting alone, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to (i) act on, sign, and file with the SEC any and all amendments (including post-effective amendments) to this registration statement together with all schedules and exhibits thereto, (ii) act on, sign and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, (iii) act on and file any supplement to any prospectus included in this registration statement or any such amendment or any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act, and (iv) take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his substitutes may lawfully do or cause to be done by virtue thereof. This Power of Attorney may be executed in several counterparts.

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>) | December 11, 2023 |
| <u>/s/ Scott Coiante</u> Scott Coiante | Chief Financial Officer (<i>Principal Financial and Accounting Officer</i>) | December 11, 2023 |
| <u>/s/ Sharon Barbari</u> Sharon Barbari | Director | December 11, 2023 |
| <u>/s/ Sandra Carson, M.D., FACOG</u> Sandra Carson, M.D., FACOG | Director | December 11, 2023 |
| <u>/s/ Seth H.Z. Fischer</u> Seth H.Z. Fischer | Director | December 11, 2023 |
| <u>/s/ John Hubbard, Ph.D.</u> John Hubbard, Ph.D. | Director | December 11, 2023 |
| <u>/s/ Josephine Torrente</u> Josephine Torrente | Director | December 11, 2023 |

AMENDMENT TO WARRANTS AND CERTIFICATE OF ADJUSTMENT

This AMENDMENT TO WARRANTS AND CERTIFICATE OF ADJUSTMENT (this "Amendment") is hereby entered into as of October 30, 2023 by and between Agile Therapeutics, Inc., a Delaware corporation (the "Company"), and Perceptive Credit Holdings III, LP, a Delaware limited partnership (the "Holder"). Capitalized terms used herein and not defined herein shall have the meanings ascribed to such terms in the Warrants (as defined below).

WHEREAS, the Company issued that certain Common Stock Purchase Warrant dated February 10, 2020, to Perceptive Credit Holdings III, LP for 350 shares with an Exercise Price of \$10.50 per share (the "First Warrant");

WHEREAS, the Company issued that certain Common Stock Purchase Warrant dated February 10, 2020, to Perceptive Credit Holdings III, LP for 350 shares with an Exercise Price of \$10.50 per share (the "Second Warrant");

WHEREAS, the Company issued that certain First Amendment to Common Stock Purchase Warrant dated February 26, 2021, to Perceptive Credit Holdings III, LP for 225 shares with an Exercise Price of \$10.50 per share (the "Third Warrant" and collectively with the First Warrant and the Second Warrant, the "Warrants");

WHEREAS, the Company previously issued a Certificate of Adjustment with respect to the Warrants dated July 25, 2022 (the "Certificate of Adjustment");

WHEREAS, following the effective date of the Certificate of Adjustment, the Company effected a stock combination in April 2023, whereby each set of fifty (50) shares of the Company's equity securities were exchanged by the shareholders of the Company for one (1) share of the Company's equity securities (the "Stock Combination");

WHEREAS, the Company previously effected a stock offering in May 2023 where the lowest price of the equity securities issued in such offering was \$3.69 per equity security (the "Stock Offering");

WHEREAS, in accordance with Section 3(h) of the Warrants, the Company is required to provide a certificate of adjustment in favor of the Holder promptly following the occurrence of any event that has the effect of adjusting the Exercise Price of the Warrants or the number of Warrant Shares;

WHEREAS, in lieu of delivering a certificate of adjustment pursuant to Section 3(h) of the Warrants, this Amendment reflects the adjustments caused by the Stock Combination and Stock Offering such that, immediately prior to the effective date of this Amendment, the First Warrant was exercisable for 350 shares at \$3.69 per share, the Second Warrant was exercisable for 350 shares at \$3.69 per share, and the Third Warrant was exercisable for 225 shares at \$3.69 per share; and

WHEREAS, in connection with that certain Seventh Amendment to Credit Agreement and Guaranty dated as of October 30, 2023, by and among the Company and the Holder (the "Seventh Amendment") and the transactions contemplated by the Seventh Amendment as set forth therein, the Company desires to adjust the Exercise Price of the Warrants to \$1.82.

NOW, THEREFORE, the parties hereto agree as follows:

1. *Amendments to Warrants.* Upon satisfaction of the conditions set forth in Section 3 below, the Warrants are hereby amended as follows:
 - (A) The First Warrant which was previously exercisable for 350 shares at \$3.69 per share, is now exercisable for 350 shares at \$1.82 per share.
 - (B) The Second Warrant which was previously exercisable for 350 shares at \$3.69 per share, is now exercisable for 350 shares at \$1.82 per share.
 - (C) The Third Warrant which was previously exercisable for 225 shares at \$3.69 per share, is now exercisable for 225 shares at \$1.82 per share.

2. *Representations And Warranties.* In order to induce the Holder to enter into this Amendment, the Company hereby represents and warrants to the Holder as follows:

(A) The calculations set forth on Exhibit A attached hereto accurately reflect the facts underlying the Stock Combination and the Stock Offering which, by the terms of the Warrants, triggered an adjustment to the Exercise Price and/or the number of Warrant Shares for which the Warrants are exercisable and which are reflected in the amendments set forth above.

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

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

- (A) The Holder shall have received executed counterparts of this Amendment duly executed and delivered by the Company.
- (B) The Holder shall have received a duly executed copy of the Seventh Amendment.

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

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

6. *Captions.* The captions and section headings appearing herein are included solely for convenience of reference and are not intended to affect the interpretation of any provision of this Amendment.

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

IN WITNESS WHEREOF, the undersigned has caused this certificate to be executed as of the date hereof.

COMPANY:

AGILE THERAPEUTICS, INC.

By: /s/ Al Altomari

Name: Alfred Altomari

Title: President and Chief Executive Officer

[Signature Page to Amendment to Warrants and Certificate of Adjustment]

HOLDER:

Perceptive Credit Holdings III, LP

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

By: /s/ Sandeep Dixit

Name: Sandeep Dixit

Title: Chief Credit Officer

By: /s/ Sam Chawla

Name: Sam Chawla

Title: Portfolio Manager

[Signature Page to Amendment to Warrants and Certificate of Adjustment]

EXHIBIT A

See attached.

Ex. A

SEVENTH AMENDMENT TO CREDIT AGREEMENT AND GUARANTY

This Seventh Amendment to Credit Agreement and Guaranty (herein, this “*Agreement*”) is entered into as of October 30, 2023 (the “*Seventh Amendment Effective Date*”), by and among Agile Therapeutics, Inc., a Delaware corporation (the “*Borrower*”), the Lenders party hereto (each a “*Lender*” and collectively, the “*Lenders*”) and Perceptive Credit Holdings III, LP, a Delaware limited partnership, as a lender and as administrative agent for the Lenders (in such capacity, together with its successors and assigns, the “*Administrative Agent*”).

RECITALS:

A. The Lenders have extended credit to the Borrower on the terms and conditions set forth in that certain Credit Agreement and Guaranty, dated as of February 10, 2020 (as amended by that certain Waiver and First Amendment to Credit Agreement and Guaranty dated as of February 26, 2021, that certain Waiver and Second Amendment to Credit Agreement and Guaranty dated as of January 7, 2022, that certain Waiver and Third Amendment to Credit Agreement and Guaranty dated as of March 10, 2022, that certain Fourth Amendment to Credit Agreement dated as of May 11, 2022, that certain Fifth Amendment to Credit Agreement and Guaranty dated July 25, 2022 and that certain Waiver and Sixth Amendment to Credit Agreement and Guaranty dated March 21, 2023, the “*Existing Credit Agreement*”; the Existing Credit Agreement as amended by this Agreement, the “*Credit Agreement*”).

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

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

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

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

2. *Seventh Amendment to Existing Credit Agreement.* Upon satisfaction of the conditions set forth in Section 5 hereof, the Borrower, the Lenders and the Administrative Agent hereby agree that the Existing Credit Agreement is hereby amended by incorporating the changes shown on the marked copy of the Existing Credit Agreement attached hereto as Annex A. Deletions of text in the Existing Credit Agreement as amended hereby are indicated by struck-through red text, and insertions of text as amended hereby are indicated by underlined blue text. Attached hereto as Annex B is a clean copy of the Credit Agreement conformed through the Seventh Amendment.

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

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

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

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

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

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

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

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

(C) The Administrative Agent and the Lenders shall have received (i) certified copies of the Organizational Documents of the Borrower (or to the extent that such Organizational Documents have not been amended, restated or otherwise modified since the Third Amendment Effective Date, a certification by a Responsible Officer of the Borrower to that effect), (ii) resolutions of the board of directors of the Borrower approving and authorizing the execution, delivery and performance of the Seventh Amendment and the Warrant Amendment, certified as of the Seventh Amendment Effective Date by the secretary or a Responsible Officer of the Borrower as being in full force and effect without modification or amendment, (c) a good standing certificate and/or compliance certificate from the applicable Governmental Authority of the Borrower’s jurisdiction of incorporation and in each jurisdiction in which it is qualified as a foreign corporation or other entity to do business, each dated a recent date prior to the Seventh Amendment Effective Date and (e) a certificate of the Borrower as to the authority, incumbency and specimen signatures of the persons who have executed the Seventh Amendment and any other documents in connection herewith on behalf of the Borrower.

(D) The Administrative Agent and the Lenders shall have received an executed copy of that certain Amendment to Warrants and Certificate of Adjustment, dated as of the date hereof, by and between the Borrower and the Administrative Agent (the “*Warrant Amendment*”).

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

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

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

(C) Except as expressly set forth in this Agreement, the Loan Documents and all of the obligations of the Loan Parties thereunder and the rights and benefits of the Administrative Agent and the Lenders thereunder remain in full force and effect. This Agreement is not a novation nor is it to be construed as a release, waiver or modification of any of the terms, conditions, representations, warranties, covenants, rights or remedies set forth in the Loan Documents, except as specifically set forth herein. Without limiting the foregoing, the Loan Parties agree to comply with all of the terms, conditions, and provisions of the Loan Documents except to the extent such compliance is irreconcilably inconsistent with the express provisions of this Agreement. This Agreement may not be amended, supplemented, or otherwise modified except by a written agreement entered into in accordance with Section 13.04 of the Credit Agreement. THIS AGREEMENT REPRESENTS THE FINAL AGREEMENT BETWEEN THE PARTIES AND MAY NOT BE CONTRADICTED BY EVIDENCE OF PRIOR, CONTEMPORANEOUS OR SUBSEQUENT ORAL AGREEMENTS OF THE PARTIES. THERE ARE NO UNWRITTEN ORAL AGREEMENTS BETWEEN THE PARTIES.

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

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

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

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

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

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

[SIGNATURE PAGES TO FOLLOW]

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

AGILE THERAPEUTICS, INC., as Borrower

By: /s/ Al Altomari

Name: Alfred Altomari

Title: Chairperson and CEO

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

PERCEPTIVE CREDIT HOLDINGS III, LP,
as Agent and Lender

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

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

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

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

ANNEX A
Marked Credit Agreement

ANNEX B

Conformed Credit Agreement

(Seventh Amendment)

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption “Experts” in 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, and to the incorporation by reference therein of our report dated March 22, 2023, with respect to the financial statements of Agile Therapeutics, Inc., included in its Annual Report (Form 10-K) for the year ended December 31, 2022, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

Iselin, New Jersey
December 11, 2023

Calculation of Filing Fee Tables

Form S-1

(Form Type)

Agile Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered Securities and Carry Forward Securities

| | <u>Security type</u> | <u>Security class title</u> | <u>Fee calculation or carry forward rule</u> | <u>Amount registered</u> | <u>Proposed maximum offering price per unit</u> | <u>Maximum aggregate offering price⁽¹⁾⁽²⁾</u> | <u>Fee rate</u> | <u>Amount of registration fee⁽¹⁾</u> |
|--------------------------|----------------------|--|--|--------------------------|---|--|-----------------|---|
| Fees to Be Paid | Equity | Common Stock, par value \$0.0001 per share ⁽³⁾ | 457(o) | — | — | \$ | 0.00014760 | \$ |
| Fees to Be Paid | Equity | Series F pre-funded warrants ⁽³⁾⁽⁴⁾ | Other | — | — | — | — | — |
| Fees to Be Paid | Equity | Shares of Common Stock issuable upon exercise of Series F pre-funded warrants ⁽³⁾ | 457(o) | — | — | \$ | 0.00014760 | \$ |
| Fees to Be Paid | Equity | Series E-1 warrants ⁽⁴⁾ | Other | — | — | — | — | — |
| Fees to Be Paid | Equity | Shares of Common Stock issuable upon exercise of Series E-1 warrants | 457(o) | — | — | \$ | 0.00014760 | \$ |
| Fees to Be Paid | Equity | Series E-2 warrants ⁽⁴⁾ | Other | — | — | — | — | — |
| Fees to Be Paid | Equity | Shares of Common Stock issuable upon exercise of Series E-2 warrants | 457(o) | — | — | \$ | 0.00014760 | \$ |
| Fees to Be Paid | Equity | Placement agent warrants ⁽⁴⁾⁽⁵⁾ | Other | — | — | — | — | — |
| Fees to Be Paid | Equity | Shares of Common Stock issuable upon exercise of Placement agent warrants ⁽⁴⁾ | 457(o) | — | — | \$ | 0.00014760 | \$ |
| Fees Previously Paid | — | — | — | — | — | — | — | — |
| Carry Forward Securities | — | — | — | — | — | — | — | — |
| | | Total Offering Amounts | | | | \$ 15,000,000 | | \$ 2,214.00 |
| | | Total Fees Previously Paid | | | | | | — |
| | | Total Fee Offsets | | | | | | — |
| | | Net Fee Due | | | | | | \$ 2,214.00 |

(1) Estimated solely for the purpose of calculating the registration fee pursuant Rule 457(o) under the Securities Act of 1933, as amended (the "Securities Act").

(2) Pursuant to Rule 416(a) under the Securities Act, this registration statement shall also cover an indeterminate number of shares that may be issued and resold resulting from stock splits, stock dividends or similar transactions.

(3) The proposed maximum aggregate offering price of the common stock will be reduced on a dollar-for-dollar basis based on the offering price of any Series F pre-funded warrants issued in the offering, and the proposed maximum aggregate offering price of the Series F pre-funded warrants to be issued in the offering will be reduced on a dollar-for-dollar basis based on the offering price of any common stock issued in the offering. Accordingly, the proposed maximum aggregate offering price of the common stock, Series F pre-funded warrants and Series E warrants (including the common stock issuable upon exercise of the Series F pre-funded warrants), if any, is \$15,000,000.

(4) No fee pursuant to Rule 457(g) of the Securities Act.

(5) Represents warrants issuable to or its designees, to purchase a number of shares of common stock equal to 5.0% of the aggregate number of shares of common stock and shares of common stock issuable upon exercise of the 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.

