

Prospectus



Agile Therapeutics, Inc.
\$7,500,000

**1,896,286 Shares of Common Stock and
Accompanying Series C-1 Warrants to Purchase 1,896,286 Shares of Common Stock and Series C-2
Warrants to Purchase 1,896,286 Shares of Common Stock**

or

**1,896,286 Series D Pre-funded Warrants to Purchase 1,896,286 Shares of Common Stock and
Accompanying Series C-1 Warrants to Purchase 1,896,286 Shares of Common Stock and Series C-2
Warrants to Purchase 1,896,286 Shares of Common Stock**

Placement Agent Warrants to Purchase 94,814 Shares of Common Stock

We are offering 1,896,286 shares of common stock, together with Series C-1 warrants to purchase 1,896,286 shares of common stock (the "Series C-1 warrants") and Series C-2 warrants to purchase 1,896,286 shares of common stock (the "Series C-2 warrants", and together with the Series C-1 warrants, the "Series C warrants") at a combined public offering price of \$3.9551 per share and Series C warrants (and the shares issuable from time to time upon exercise of the Series C warrants) pursuant to this prospectus. The shares of common stock and Series C warrants will be separately issued, but the shares of common stock and Series C warrants will be issued to purchasers in the ratio of one to one. Each Series C-1 warrant will have an exercise price of \$3.69 per share, will be exercisable upon issuance and will expire five years from the date of issuance. Each Series C-2 warrant will have an exercise price of \$3.69 per share, will be exercisable upon issuance and will expire eighteen months from the date of issuance.

We are also offering 1,896,286 pre-funded warrants (the "Series D pre-funded warrants" and collectively with the Series C 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 D pre-funded warrant will be exercisable for one share of common stock at an exercise price of \$0.0001 per share. Each Series D pre-funded warrant is being issued together with the same Series C warrants described above being issued with each share of common stock. The combined public offering price for each such Series D pre-funded warrant, together with the Series C warrant, is \$3.9551, public offering price per share of common stock less the \$0.0001 per share exercise price of each such Series D pre-funded warrant. Each Series D 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 D pre-funded warrants and Series C 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 D pre-funded warrants. For each Series D pre-funded warrant and the accompanying Series C warrants we sell, the number of shares of common stock and the accompanying Series C 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.

We have engaged H.C. Wainwright & Co., LLC, 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 May 22, 2023, the last reported sale price of our common stock on the Nasdaq Capital Market was \$3.9551 per share.

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 C Warrants	Per Series D Pre-Funded Warrant and Series C Warrants	Total
Public offering price	\$ 3.9551	\$ 3.9550	\$ 7,500,000
Placement Agent’s fees ⁽¹⁾	\$ 0.2769	\$ 0.2769	\$ 525,000
Proceeds, before expenses, to us ⁽²⁾	\$ 3.6782	\$ 3.6781	\$ 6,975,000

(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 D 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 C 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 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 May 25, 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.

H.C. Wainwright & Co.

Prospectus dated May 22, 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 Annual Report on Form 10-K and include statements regarding our current intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned manufacturing and commercialization of Twirla®, the potential market acceptance and uptake of Twirla®, the development of our other potential product candidates, the attractiveness of our business to potential investors or business partners, the strength and breadth of our intellectual property, our ongoing and planned clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our potential product candidates, the legal and regulatory landscape impacting our business, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, including expense reduction strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.

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

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

- our 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;
- our available cash and our ability to obtain additional funding to fund our business plan without delay and to continue as a going concern;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the growth in demand for Twirla and our ability to manage the levels of Twirla inventory, which could result in our having to write off inventory and our inability to meet the minimum requirements under our supply agreement with Corium Pharma Solutions (“Corium”);

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

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

We are focused on our advancement as a commercial company. Over the course of 2022, we continued to implement our commercialization plan for Twirla, with the goal of establishing a growing position in the hormonal contraceptive market. We believe we can achieve this goal by focusing our growth strategy in the states with the highest Twirla reimbursement potential, which we estimate will allow us to reach approximately 45% of U.S. women between the ages of 18-24. We also believe we can grow Twirla by leveraging our partnerships in the retail and non-retail channels. For example, we initiated a relationship with Nurx®, which we believe can make Twirla nationally available on Nurx.com, part of the Thirty Madison telehealth platform focused on sexual and reproductive health. Nurx has provided contraception to over 1 million patients. In addition to growing Twirla, we also plan to continue pursuing opportunities to broaden our portfolio to address areas of unmet medical need in women’s health.

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

Recent Developments

Amendment to Amended and Restated Certificate of Incorporation — Reverse Stock Split

At a special meeting of stockholders held on March 9, 2023, our stockholders approved an amendment to our Amended and Restated Certificate of Incorporation to effect a reverse stock split of our outstanding shares of common stock by a ratio of any whole number between 1-for-20 and 1-for-50, at any time prior to June 30, 2023, with the exact ratio to be set within that range at the discretion of our board of directors, without further approval or authorization of our stockholders. Following the meeting, our board of directors determined the appropriate ratio for the reverse stock split to be 1-for-50. The amendment became effective at 4:00 p.m. Eastern Time upon filing with the Secretary of State of the State of Delaware on April 10, 2023. Our common stock opened for trading on the Nasdaq Capital Market on Tuesday, April 11, 2023 on a split-adjusted basis under the current trading symbol “AGRX.”

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

The table below details the pre- and post-split share and per share amounts for certain key amounts presented in our Annual Report on Form 10-K for the year ended December 31, 2022, assuming a reverse stock split using the maximum ratio approved by our stockholders, 1-for-50. Post-split share amounts and per share amounts for all other share-related items in our Annual Report on Form 10-K are not reflected in the table below. The number of authorized shares of common stock and the par value per share remains unchanged.

Item	Pre-Split Amount	Post-Split Amount
Shares outstanding, 12/31/20	2,189,100	43,782
Shares outstanding, 12/31/21	3,034,901	60,698
Shares outstanding, 12/31/22	42,970,134	859,402
Net loss per share (basic and diluted), year ended 12/31/20	\$ (24.40)	\$ (1,220.00)
Net loss per share (basic and diluted), year ended 12/31/21	\$ (29.28)	\$ (1,464.00)
Net loss per share (basic and diluted), year ended 12/31/22	\$ (1.18)	\$ (59.00)
Common stock warrants outstanding, 12/31/20	35,000	700
Common stock warrants outstanding, 12/31/21	379,583	7,591
Common stock warrants outstanding, 12/31/22	56,501,249	1,130,024
Unvested restricted stock units outstanding, 12/31/20	3,988	79
Unvested restricted stock units outstanding, 12/31/21	8,325	166
Unvested restricted stock units outstanding, 12/31/22	6,461	129
Common stock options outstanding, 12/31/20	212,946	4,258
Common stock options outstanding, 12/31/21	259,145	5,182
Common stock options outstanding, 12/31/22	397,818	7,956

August 2022 ATM Program with H.C. Wainwright & Co.

On April 27, 2022, we terminated our previous at-the-market (“ATM”) offering program and entered into a new ATM program with H.C. Wainwright & Co., which we increased in August 2022, and which we refer to as the August 2022 ATM, under which we may, from time to time in our sole discretion, issue and sell through H.C. Wainwright & Co., acting as our agent, up to \$75.0 million of shares of our common stock. We pay H.C. Wainwright & Co. a commission of up to 3.0% of the gross sales proceeds of shares sold under the August 2022 ATM. In the second quarter of 2023, through May 18, 2023, we sold 105,342 shares of common stock for \$0.7 million gross proceeds under our August 2022 ATM program.

Perceptive Credit Agreement Amendment

On March 21, 2023, we entered into a waiver and sixth amendment to that certain Credit Agreement and Guaranty (the “Perceptive Credit Agreement”), dated February 10, 2020, as amended, with Perceptive Credit Holdings III, LP (“Perceptive”), pursuant to which we have received a waiver of certain financial covenants through the second quarter of 2023 (the “Sixth Amendment”). In the event we do not pay off the remainder of the outstanding principal under the facility, we will need to negotiate for a waiver of our obligations to comply with the covenants relating to revenue for Twirla in the second quarter of 2023.

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 have been 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”). If the Compliance Plan is acceptable to Nasdaq, they may grant an extension of 180 calendar days from the date of the Nasdaq notification to regain compliance with the Stockholders’ Equity Requirement.

If Nasdaq does not accept the Compliance Plan, Nasdaq will provide us with written notification that the Compliance Plan has been rejected. At that time, we may appeal the Staff’s determination to a Nasdaq Hearings Panel.

We submitted the Compliance Plan on May 11, 2023, and will 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.

Warrant Amendment Agreement

In connection with this offering, the Company also entered into a warrant amendment agreement, or the Warrant Amendment Agreement, with the investor in this offering. Under the Warrant Amendment Agreement, the Company agreed to amend certain existing warrants to purchase up to 229,669 shares of common stock that were previously issued in October 2021 through July 2022 to such investor, with exercise prices ranging from \$45.00 to \$1,700.00 per share, or the Existing Warrants, in consideration for their purchase of the securities in this offering, as follows: (i) lower the exercise price of the Existing Warrants to \$3.69 per share and (ii) amend the original expiration date to five (5) years from the closing date of this offering.

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, which is 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 ongoing outbreak of coronavirus, or COVID-19, or other similar public health crises, could have a material adverse impact on our business, financial condition and results of operations, including our ability to successfully produce, market and distribute Twirla®;*
- *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;*
- *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;*
- *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	1,896,286 shares of our common stock, Series C-1 warrants to purchase 1,896,286 shares of common stock, and Series C-2 warrants to purchase 1,896,286 shares of common stock or 1,896,286 Series D pre-funded warrants to purchase shares of common stock, Series C-1 warrants to purchase 1,896,286 shares of common stock, and Series C-2 warrants to purchase 1,896,286 shares of common stock in each case, at a combined public offering price of \$3.9551 per share (or Series D pre-funded warrant in lieu thereof) and Series C warrants. The shares, or Series D pre-funded warrants, and Series C warrants will be separately transferable immediately upon issuance, but the shares, or Series D pre-funded warrants, and Series C warrants will be issued to purchasers in the ratio of one to one.
Description of Series C warrants	Each Series C-1 warrant will have an exercise price of \$3.69 per share, will be exercisable upon issuance and will expire five years from the date of issuance. Each Series C-2 warrant will have an exercise price of \$3.69 per share, will be exercisable upon issuance and will expire eighteen months from the date of issuance. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of these Series C warrants.
Description of Series D 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 D pre-funded warrant to purchase shares of our common stock for a purchase price per share of common stock subject to such Series D pre-funded warrant equal to the per share public offering price for the common stock in this offering less \$0.0001. Each Series D 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 D pre-funded warrants will also receive Series C 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 D pre-funded warrants.</p> <p>For each Series D pre-funded warrant and the accompanying Series C warrants we sell, the number of shares of common stock and the accompanying Series C warrants we are offering will be decreased on a one-for-one basis.</p>
Common stock outstanding before offering:	1,032,033 shares of common stock.
Common stock outstanding after this offering	2,928,319 shares of common stock, assuming no sale of Series D pre-funded warrants in this offering and no exercise of the Series C warrants being issued in this offering.
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 Report on Form 10-Q for the quarter ended March 31, 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 C warrants or the Series D pre-funded warrants, and we do not expect a trading market to develop. We do not intend to list the Series C warrants or the Series D pre-funded warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the Series C warrants or Series D pre-funded warrants will be extremely limited.

The number of shares of our common stock to be outstanding after this offering is based on 1,032,033 shares of our common stock outstanding as of May 18, 2023, and excludes:

- 7,831 shares of common stock issuable upon the exercise of outstanding options to purchase common stock as of May 18, 2023 at a weighted average exercise price of \$3,187.22 per share;
- 129 shares of common stock issuable upon the vesting of outstanding restricted stock units as of May 18, 2023;
- 6,287 shares of common stock reserved for future issuance under our 2014 Amended and Restated Incentive Compensation Plan as of May 18, 2023; and
- 1,129,991 shares of common stock issuable upon the exercise of outstanding warrants as of May 18, 2023 at a weighted average exercise price of \$66.97 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 C warrants or the placement agent warrants issued in this offering; and
- no sale of Series D pre-funded warrants in this offering.

All information included in this prospectus 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 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 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 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 have been 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”). If the Compliance Plan is acceptable to Nasdaq, they may grant an extension of 180 calendar days from the date of the Nasdaq notification to regain compliance with the Stockholders’ Equity Requirement.

If Nasdaq does not accept the Compliance Plan, Nasdaq will provide us with written notification that the Compliance Plan has been rejected. At that time, we may appeal the Staff’s determination to a Nasdaq Hearings Panel.

We submitted the Compliance Plan on May 11, 2023, and will 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.

The ongoing outbreak of the novel strain of coronavirus, or COVID-19, or other similar public health crises, could have a material adverse impact on our business, financial condition and results of operations, including our ability to successfully produce, market, and distribute Twirla®.

The ongoing impact of the COVID-19 pandemic has been and may continue to be extensive, affecting many aspects of society, and it has resulted in and may continue to result in significant disruptions to global business activities and capital markets around the world. As a result of the COVID-19 pandemic, or similar pandemics, we may experience disruptions that could severely affect our business, including our plans to clinically develop and commercialize our products. We may not be able to meet expectations with respect to the commercialization and post-market study of Twirla. In addition, global business interruptions resulting from COVID-19 continue to persist, including ongoing global supply chain issues, and may adversely impact our third-party manufacturer, Corium, whom we rely upon for the manufacture of Twirla, as well as its suppliers of raw materials. If Corium or any of its suppliers of raw materials are adversely impacted by the COVID-19 pandemic or the restrictions resulting from the pandemic, if they cannot obtain the necessary supplies, or if such third parties need to prioritize other products or customers over us, including under the Defense Production Act of 1950, or the Defense Production Act, we may experience delays or disruptions in our supply chain, which could have a material and adverse impact on our business. Third party manufacturers may also need to implement measures and changes, or deviate from typical requirements because of the COVID-19 pandemic that may otherwise adversely impact our supply chains or the quality of the resulting products or supplies. Depending on the change, we may need to obtain FDA pre-approval or otherwise provide FDA with a notification of the change. As a result, we may not be able to obtain sufficient quantities of Twirla, which could impair our ability to commercialize Twirla and conduct the PMR. In addition, if there are continued or future disruptions, our third-party manufacturers may not be able to supply our other potential product candidates, which would adversely affect our research and development activities.

Further, the pandemic has led and may in the future lead to travel restrictions, flight cancellations and social distancing requirements in many areas of the world, any of which may have a material adverse impact on the third-party consultants and agents who assist us with our sales and marketing functions, as well as on our ability to develop our own sales and marketing infrastructure. For example, reimplementation of such social distancing orders could limit the ability of sales representatives to interact with healthcare providers and also restrict the ability of patients to interact with their healthcare providers and obtain prescriptions for our products. Patients may also be more reticent to visit their providers to obtain Twirla prescriptions in the wake of the COVID-19 pandemic. This could negatively affect our ability to commercialize Twirla, which would require us to negotiate a waiver of our obligations to comply with the Perceptive Credit Agreement covenants relating to revenue for Twirla in the second quarter of 2023, as further described above in “Recent Developments.”

If the COVID-19 pandemic or other factors impact our current business plan or our ability to generate revenue from the launch of Twirla, we believe we have the ability to revise our commercial plans, including curtailing sales and marketing spending, to allow us to continue to fund our operations. However, significant delays in the timelines to manufacture commercial supply of Twirla, and/or the ability of a salesforce to engage with healthcare providers could delay, or even prevent, our ability to generate revenue, which in turn could require us to raise additional capital if the revisions to our commercial plans are inadequate or management determines that it is necessary.

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.

Holder 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 five years or eighteen months, as applicable, 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.

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

As of May 18, 2023, we had 925 common stock purchase warrants outstanding that were issued in connection with the Perceptive Credit Agreement that contain price protection provisions in the event that we sell securities at a price per share below their respective exercise prices on or before June 30, 2023 (collectively "Price Protection Warrants"). On March 22, 2023, in connection with the Waiver and Sixth Amendment to the Perceptive Credit Agreement, the current exercise price of the Price Protection Warrants was reset to \$10.50 per share. In the event that we sell securities at a price per share lower than the current exercise price of the Price Protection Warrants on or before June 30, 2023, their exercise prices will be reduced to match that lower price. Any future adjustments to the exercise prices of the Price Protection Warrants may have a negative impact on the trading price of our common stock. Additionally, raising additional capital with new investors may be difficult as a result of the adjustment feature.

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

In February 2020, we entered into the Perceptive Credit Agreement, the terms of which are described in more detail in 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). We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. We have received a waiver of certain financial covenants through the second quarter of 2023, see "Recent Developments" on page 5 of this prospectus.

In the event we do not pay off our indebtedness to Perceptive, we will need to negotiate for a waiver of our obligations to comply with the covenants relating to revenue for Twirla in the second quarter of 2023. If we cannot repay our indebtedness and do not receive a waiver, we may be required to delay, limit, reduce or terminate our pipeline development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Perceptive could also exercise its rights as collateral agent to take possession and dispose of the collateral securing the loan for its benefit, which collateral includes substantially all of our property. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

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.

We have incurred operating losses in each year since our inception and expect to continue to incur substantial losses for the foreseeable future. Management has concluded that these factors raise substantial doubt about our ability to continue as a going concern.

We have incurred losses in each year since our inception in December 1997. Our net loss was \$5.4 million and \$10.4 million for the three months ended March 31, 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 March 31, 2023, we had an accumulated deficit of approximately \$414 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 March 31, 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 expect to incur expenses without corresponding revenues until we are able to sell Twirla in significant quantities, which may not happen. We have devoted most of our financial resources to research and development, including our non-clinical development activities and clinical trials. We will require additional capital to fund our operating needs into the second quarter of 2023, including among other items, the commercialization of Twirla and advancing the development of our other potential product candidates. We may not be able to obtain sufficient additional funding to continue our operations at planned levels and be forced to reduce, or even terminate, our operations. To date, we have financed our operations primarily through sales of common stock, convertible preferred stock and convertible promissory notes and to a lesser extent, through term loans and government grants.

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

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.

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 May 18, 2023, we had outstanding warrants to acquire 1,129,991 shares of our common stock, and stock options to purchase 7,831 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 \$7.5 million at \$3.9551 per share and Series C warrants, and after deducting estimated offering commissions and expenses payable by us, you would suffer immediate dilution of \$4.70 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 \$6.6 million based on the sale of 1,896,286 shares of common stock, Series C-1 warrants to purchase 1,896,286 shares of common stock and Series C-2 warrants to purchase 1,896,286 shares of common stock at a combined public offering price of \$3.9551 per share of common stock and Series C warrants, after deducting the placement agent fees and estimated offering expenses payable by us, and assuming no sale of Series D pre-funded warrants in this offering and no exercise of the Series C 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.

These estimates exclude the proceeds, if any, from the exercise of Series C warrants issued in this offering. If all of the Series C warrants issued in this offering were to be exercised in cash at the exercise price of \$3.69 per share of common stock, we would receive additional proceeds of approximately \$14 million. We cannot predict when or if these Series C warrants will be exercised. It is possible that these Series C warrants may expire and may never be exercised. Additionally, the Series C warrants contain a cashless exercise provision that permit exercise of Series C 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 London Interbank Offered Rate for one-month deposits, or LIBOR, plus 10.25%, provided that LIBOR shall not be less than 1.5%. The Perceptive Credit Agreement provides that beginning on August 31, 2022, we must make monthly principal payments in an amount equal to \$75,000 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 March 31, 2023:

- on an actual basis;
- on a pro forma basis to give effect to the sale of 105,342 shares of common stock for \$0.7 million gross proceeds under our August 2022 ATM program from April 1, 2023 through May 18, 2023 (the “August 2022 ATM Sales”); and
- On a pro forma as adjusted basis to give further effect to the sale of 1,896,286 shares of common stock and accompanying Series C warrants in this offering at a public offering price of \$3.9551 per share and accompanying Series C warrants, assuming no sale of any Series D 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 March 31, 2023		
	Actual	Pro- Forma	Pro- Forma As Adjusted ⁽¹⁾
	(in thousands, except share and per share data) (unaudited)		
Cash and cash equivalents	\$ 4,429	\$ 5,081	11,681
Stockholders’ equity:			
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized, 4,850 shares issued, no shares outstanding actual, 2,425 shares issued, no shares outstanding, pro-forma and pro-forma as adjusted.	--	--	-
Common stock, \$0.0001 par value; 300,000,000 shares authorized, 932,101 shares issued and outstanding, actual, 1,032,033 shares issued and outstanding, proforma, 2,928,319 shares issued and outstanding pro-forma adjusted	-	-	-
Additional paid-in capital	404,658	405,310	411,910
Accumulated other comprehensive income	-	-	-
Accumulated deficit	(414,092)	(414,092)	(414,092)
Total stockholders’ equity (deficit)	\$ (9,434)	\$ (8,782)	\$ (2,182)
Total capitalization	\$ (9,434)	\$ (8,782)	\$ (2,182)

- (1) The as adjusted balance sheet data reflects the sale of 1,896,286 shares of common stock and Series C Warrants to purchase 3,792,572 shares of common stock offered by us in this offering at the public offering price of \$3.9551 per share and accompanying Series C 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 932,101 shares of our common stock outstanding as of March 31, 2023, and excludes:

- 7,956 shares of common stock issuable upon the exercise of outstanding options to purchase common stock as of March 31, 2023 at a weighted average exercise price of \$3,187.50 per share;
- 129 shares of common stock issuable upon the vesting of outstanding restricted stock units as of March 31, 2023;

- 6,287 shares of common stock reserved for future issuance under our 2014 Amended and Restated Incentive Compensation Plan as of March 31, 2023; and
- 1,129,991 shares of common stock issuable upon the exercise of outstanding warrants as of March 31, 2023 at a weighted average exercise price of \$66.97 per share.

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 C warrants or issuable upon the exercise of the Series D pre-funded warrants and the pro forma as adjusted net tangible book value per share of common stock after this offering. As of March 31, 2023, our historical net tangible book value was \$(9.4) million, or \$(10.12) per share, based on 932,101 shares of common stock outstanding as of March 31, 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 March 31, 2023.

On a pro forma basis, after giving effect to the August 2022 ATM Sales, our net tangible book value at March 31, 2023 would have been \$(8.8) million, or \$(8.47) per share.

After giving further effect to our sale in this offering of shares of 1,896,286 common stock and accompanying Series C warrants at a public offering price per share of common stock and accompanying Series C warrants of \$3.9551, assuming no sale of any Series D 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 pro forma as adjusted net tangible book value as of March 31, 2023 would have been \$(2.2) million, or \$(0.74) per share. This represents an immediate increase of pro forma net tangible book value of \$7.73 per share to our existing stockholders and an immediate dilution of pro forma net tangible book value of \$4.70 per share to investors purchasing shares of common stock and accompanying Series C warrants in this offering. The following table illustrates this per share dilution:

Public offering price per share of common stock and accompanying Series C warrants		\$	3.9551
Historical net tangible book value (deficit) per share as of March 31, 2023	\$	(10.12)	
Pro forma increase in net tangible book value per share attributable to the August 2022 ATM Sales	\$	1.65	
Pro forma net tangible book value per share as of March 31, 2023	\$	(8.47)	
Increase in pro forma net tangible book value per share attributable to investors purchasing in this offering	\$	7.73	
Pro forma as adjusted net tangible book value per share as of March 31, 2023 after this offering	\$	(0.74)	
Dilution per share to investors purchasing in this offering	\$	4.70	

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

The foregoing table and calculations are based on 932,101 shares of our common stock outstanding as of March 31, 2023, and exclude:

- 7,956 shares of common stock issuable upon the exercise of outstanding options to purchase common stock as of March 31, 2023 at a weighted average exercise price of \$3,187.50 per share;
- 129 shares of common stock issuable upon the vesting of outstanding restricted stock units as of March 31, 2023;
- 6,287 shares of common stock reserved for future issuance under our 2014 Amended and Restated Incentive Compensation Plan as of March 31, 2023; and

- 1,129,991 shares of common stock issuable upon the exercise of outstanding warrants as of March 31, 2023 at a weighted average exercise price of \$66.97 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 May 18, 2023, there were 1,032,033 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 1,896,286 shares of common stock, together with Series C-1 warrants to purchase 1,896,286 shares of common stock (the “Series C-1 warrants”) and Series C-2 warrants to purchase 1,896,286 shares of common stock (the “Series C-2 warrants”, and together with the Series C-1 warrants, the “Series C warrants”). We are also offering 1,896,286 pre-funded warrants (the “Series D pre-funded warrants”) and collectively with the Series C 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 D pre-funded warrant will be exercisable for one share of common stock. Each Series D pre-funded warrant is being issued together with the same Series C warrants described above being issued with each share common stock. The shares of common stock or Series D pre-funded warrants, as the case may be, and the Series C warrants, can only be purchased together in this offering, but the Series D pre-funded warrants and Series C 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 D pre-funded warrants and Series C 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 D Pre-Funded Warrants

The following summary of certain terms and provisions of the Series D 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 D 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 D pre-funded warrant for a complete description of the terms and conditions of the Series D pre-funded warrants.

Duration and Exercise Price

Each Series D pre-funded warrant offered hereby will have an initial exercise price per share equal to \$0.0001. The Series D 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 D pre-funded warrants will be issued separately from the accompanying Series C warrants with Series D pre-funded warrants.

Exercisability

The Series D 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 D 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 D 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 D pre-funded warrants and in accordance with the rules and regulations of the SEC. Purchasers of Series D pre-funded warrants in this offering may also elect prior to the issuance of the Series D 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 D pre-funded warrants.

Transferability

Subject to applicable laws, a Series D pre-funded warrant may be transferred at the option of the holder upon surrender of the Series D 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 D 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 D 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 D pre-funded warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the Series D pre-funded warrants will be extremely limited. The common stock issuable upon exercise of the Series D pre-funded warrants is currently listed on the Nasdaq Capital Market.

Right as a Stockholder

Except as otherwise provided in the Series D pre-funded warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the Series D 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 D pre-funded warrants. The Series D 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 D 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 50% of the voting power represented by our outstanding common stock, the holders of the Series D pre-funded warrants will be entitled to receive upon exercise of the Series D pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Series D pre-funded warrants immediately prior to such fundamental transaction.

Series C Warrants

The following summary of certain terms and provisions of the Series C warrants included with the shares of common stock and the Series D 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 C 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 C warrants for a complete description of the terms and conditions of the Series C warrants. The Series C-1 warrants and Series C-2 warrants have the same terms and provisions, other than the exercise period of each, as described below.

Duration and Exercise Price

Each Series C warrant offered hereby will have an initial exercise price equal to \$3.69 per share of common stock. The Series C-1 warrants will be immediately exercisable and will expire five years from the date of issuance. The Series C-2 warrants will be immediately exercisable and will expire eighteen months from the date of issuance. 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 C warrants will be issued separately from the common stock, or the Series D pre-funded warrants, as the case may be.

Exercisability

The Series C 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 C 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 C 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 C warrants and in accordance with the rules and regulations of the SEC.

Cashless Exercise

If, at the time a holder exercises its Series C warrants, a registration statement registering the issuance of the shares of common stock underlying the Series C 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 C warrants.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the Series C 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 C warrant may be transferred at the option of the holder upon surrender of the Series C warrant to us together with the appropriate instruments of transfer.

Trading Market

There is no trading market available for the Series C 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 C warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the Series C warrants will be extremely limited. The common stock issuable upon exercise of the Series C warrants is currently listed on the Nasdaq Capital Market.

Right as a Stockholder

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

Fundamental Transaction

In the event of a fundamental transaction, as described in the Series C 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 50% of the voting power represented by our outstanding common stock, the holders of the Series C warrants will be entitled to receive upon exercise of the Series C warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Series C 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 C warrants have the right to require us or a successor entity to redeem the Series C warrant for cash in the amount of the Black-Scholes value of the unexercised portion of the Series C 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 C warrants have the right to require us or a successor entity to redeem the Series C warrant for the consideration paid in the fundamental transaction in the amount of the Black Scholes value of the unexercised portion of the Series C 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 \$4.9439 per share of common stock (125% of the combined public offering price per share of common stock and Series C warrants). The Placement Agent Warrants will be immediately exercisable 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 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 D PRE-FUNDED WARRANTS AND SERIES C WARRANTS

The following discussion describes certain material U.S. federal income tax consequences of the acquisition, ownership and disposition of our common stock, Series D pre-funded warrants and Series C 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 D pre-funded warrants or Series C 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 D pre-funded warrants and Series C 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 D pre-funded warrants, or Series C warrants that is liable for the alternative minimum tax;
- a holder of our common stock, Series D pre-funded warrants, or Series C 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 D pre-funded warrants, or Series C 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 D pre-funded warrants, or Series C warrants that has a functional currency other than the U.S. dollar;
- a holder of our common stock, Series D pre-funded warrants, or Series C 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 D pre-funded warrants, or Series C 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 D pre-funded warrants, or Series C 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 D pre-funded warrants, or Series C 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 D pre-funded warrants, or Series C 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 D pre-funded warrants, or Series C 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 D pre-funded warrants or Series C 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 D pre-funded warrants or Series C warrants should consult his, her or its own tax advisor regarding the tax consequences of the ownership and disposition of our common stock, Series D pre-funded warrants or Series C 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 D pre-funded warrants and Series C warrants.

For the purposes of this discussion, a “U.S. Holder” means a beneficial owner of our common stock, Series D pre-funded warrants or Series C 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 D pre-funded warrants or Series C 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 D Pre-Funded Warrants

Although it is not entirely free from doubt, we believe a Series D 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 D 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 D pre-funded warrant, and upon exercise, the holding period of the share of common stock received should include the holding period of the Series D pre-funded warrant. Similarly, the tax basis of a share of common stock received upon exercise of a Series D pre-funded warrant should include the tax basis of the Series D 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 D Pre-Funded Warrants and Series C Warrants

For U.S. federal income tax purposes, a holder’s acquisition of the Series C warrants and common stock or Series D 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 D pre-funded warrant, as applicable) and a Series C-1 warrant and a Series C-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 D pre-funded warrant, as applicable) and the Series C warrants included in each investment unit. The separability of the share of common stock (or Series D pre-funded warrant, as applicable) and the Series C 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 C 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 C warrant. The U.S. Holder will take a tax basis in the shares acquired on the exercise of a Series C warrant equal to the exercise price of the Series C warrant, increased by the U.S. Holder's adjusted tax basis in the Series C 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 C warrant will begin on the date of exercise of the Series C warrant, and will not include any period for which the U.S. Holder held the Series C warrant.

In certain limited circumstances, a U.S. Holder may be permitted to undertake a cashless exercise of Series C warrants into our common stock. The U.S. federal income tax treatment of a cashless exercise of Series C 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 C 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 C warrants.

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

Certain Adjustments to and Distributions on the Series C Warrants

Under Section 305 of the Code, an adjustment to the number of shares of common stock issued on the exercise of the Series C warrants, or an adjustment to the exercise price of the Series C warrants, may be treated as a constructive distribution to a U.S. Holder of the Series C 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 C warrants, then we may, in certain circumstances, make a corresponding distribution to a Series C warrant holder. The taxation of a distribution received with respect to a Series C 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 C 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 D 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 D 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 D pre-funded warrants, as applicable, as described below under the section titled "Disposition of Our Common Stock, Series D Pre-Funded Warrants or Series C Warrants."

Disposition of Our Common Stock, Series D Pre-Funded Warrants or Series C Warrants

Upon a sale or other taxable disposition of our common stock, Series D pre-funded warrants or Series C 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 D pre-funded warrants or Series C 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 D pre-funded warrant or Series C 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 D pre-funded warrants or Series C 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 D pre-funded warrants and Series C warrants and to the proceeds of a sale or other disposition of common stock, Series C warrants and Series D 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 C Warrants

In general, a Non-U.S. Holder will not be subject to U.S. federal income tax on the exercise of the Series C warrants into shares of common stock. As described under "U.S. Holders — Exercise and Expiration of Series C Warrants," the U.S. federal income tax treatment of a cashless exercise of Series C 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 C warrants.

The expiration of a Series C warrant will be treated as if the Non-U.S. Holder sold or exchanged the Series C warrant and recognized a capital loss equal to the Non-U.S. Holder's tax basis in the Series C warrant. However, a Non-U.S. Holder will not be able to utilize a loss recognized upon expiration of a Series C 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 C Warrants

As described under "U.S. Holders — Certain Adjustments to and Distributions on the Series C Warrants," an adjustment to the Series C 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 C 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 C 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 D 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 D 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 D 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 D 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 D pre-funded warrants, as applicable, as described under “Disposition of Our Common Stock, Series D Pre-Funded Warrants or Series C 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 D Pre-Funded Warrants or Series C 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 D pre-funded warrants or Series C 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 D pre-funded warrant or Series C 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 D pre-funded warrants or Series C 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 D pre-funded warrants or Series C 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 D pre-funded warrants or Series C 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 D pre-funded warrants and Series C 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 D pre-funded warrants or Series C 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 D pre-funded warrants or Series C warrants, including the consequences of any proposed changes in applicable laws.

PLAN OF DISTRIBUTION

We engaged H.C. Wainwright & Co., LLC (“H.C. Wainwright” 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. H.C. Wainwright 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 sixty (60) days from closing of the offering, subject to certain exceptions. H.C. Wainwright 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 sixty (60) days.

Fees and Expenses

The following table shows the per share and Series C warrants and Series D pre-funded warrant and Series C 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 C warrants placement agent cash fees	\$	0.277
Per Series D pre-funded warrant and Series C warrants placement agent cash fees	\$	0.277
Total	\$	525,000

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 \$0.9 million. After deducting the placement agent fees and our estimated offering expenses, we expect the net proceeds from this offering to be approximately \$6.6 million.

Placement Agent Warrants

We have agreed to grant placement agent warrants to H.C. Wainwright, 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 D pre-funded warrants sold to the investors in this offering. The placement agent warrants will have an exercise price of \$4.9439 (125% of the combined public offering price per share of common stock and Series C 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.

Other Relationships

The placement agent acted as the placement agent in connection with our previous offering consummated in June 2022, for which it has received customary fees and expenses, and has served as sales agent for our at the market offerings pursuant to the sales agreements dated April 27, 2022, January 10, 2022 and January 23, 2019. The placement agent may, from time to time, engage in transactions with or perform services for us in the ordinary course of its business and may continue to receive compensation from us for such services.

Determination of Offering Price

The combined public offering price per share and Series C warrants and the combined public offering price per Series D pre-funded warrant and Series C 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 sixty (60) days following the date of this prospectus. This means that, during the applicable lock-up period, we 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 exception such as issuing stock options to directors, officers, employees and consultants under our existing plans. 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 shares of common stock or securities exercisable or convertible into shares of common stock for a period of sixty (60) days following the closing date of this offering, subject to certain exceptions, and 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.

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 May 18, 2023, the reported closing price per share of our common stock was \$4.17. 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. The placement agent is being represented by Ellenoff Grossman & Schole LLP, New York, New York, in connection with this offering.

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:

- [our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 filed with the SEC on March 23, 2023;](#)
- [our Definitive Proxy Statement on Schedule 14A, filed with the SEC on April 28, 2023;](#)
- [our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, filed with the SEC on May 11, 2023;](#)
- our Current Reports on Form 8-K filed with the SEC on [January 26, 2023](#), [February 27, 2023](#); [March 14, 2023](#); [March 30, 2023](#); [April 10, 2023](#); [April 26, 2023](#); and [May 17, 2023](#); and
- the description of our common stock, which is registered under Section 12 of the Exchange Act, in our registration statement on [Form 8-A, filed with the SEC on May 20, 2014](#), including any amendments or reports filed for the purpose of updating such description, including [Exhibit 4.5 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 filed with the SEC on March 1, 2021](#).

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.



\$7,500,000

**1,896,286 Shares of Common Stock and
Accompanying Series C-1 Warrants to Purchase 1,896,286 Shares of Common Stock and Series C-2
Warrants to Purchase 1,896,286 Shares of Common Stock**

or

**Series D Pre-funded Warrants to Purchase 1,896,286 Shares of Common Stock and
Accompanying Series C-1 Warrants to Purchase 1,896,286 Shares of Common Stock and Series C-2
Warrants to Purchase 1,896,286 Shares of Common Stock**

Placement Agent Warrants to Purchase 94,814 Shares of Common Stock

Prospectus

H.C. Wainwright & Co.

May 22, 2023
