AGILE THERAPEUTICS INC
Form 424B5
January 23, 2019

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ABOUT THIS PROSPECTUS

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Filed pursuant to Rule 424(b)(5)
Registration No. 333-228149

PROSPECTUS SUPPLEMENT
(To Prospectus dated November 14, 2018)

$10,000,000

Common Stock

We have entered into a common stock sales agreement, or the sales agreement, with H.C. Wainwright & Co., LLC, or Wainwright, relating to shares of our common stock, $0.0001 par value per share. In accordance with the terms of the sales agreement, we may offer and sell shares of our common stock from time to time having an aggregate offering price of up to $10,000,000 through or to Wainwright, as agent or principal, pursuant to this prospectus supplement and the accompanying prospectus.

Upon our delivery of a placement notice and subject to the terms and conditions of the sales agreement, Wainwright may sell shares of our common stock by methods deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act. Wainwright will act as sales agent using its commercially reasonable efforts consistent with its normal trading and sales practices, on mutually agreed terms between Wainwright and us. There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

Wainwright will be entitled to compensation at a fixed commission rate of 3% of the gross proceeds of each sale of shares of our common stock. In connection with the sale of our shares of common stock on our behalf, Wainwright will be deemed to be an "underwriter" within the meaning of the Securities Act and the compensation of Wainwright will be deemed to be underwriting commissions or discounts. We have also agreed to provide indemnification and contribution to Wainwright with respect to certain liabilities, including liabilities under the Securities Act.

Our common stock is listed on The Nasdaq Capital Market under the symbol "AGRX". The last reported sale price of our common stock on The Nasdaq Capital Market on January 18, 2019 was $0.891 per share.

The aggregate market value of our outstanding common stock held by non-affiliates as of January 18, 2019 was approximately $30.3 million based on 34,377,329 shares of common stock outstanding on such date, of which 34,046,228 were held by non-affiliates, and a closing price of $0.891 (the closing price on January 18, 2019). Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell securities registered on this registration statement in a public primary offering with a value exceeding more than one-third of the aggregate market value of our voting and non-voting common equity held by non-affiliates in any 12-month period so long our public float remains below $75 million. During the 12 calendar months prior to and including the date hereof, we have not offered any securities pursuant to General Instruction I.B.6 of Form S-3.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus supplement and future filings.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page S-4 and in the documents incorporated by reference in this prospectus supplement.

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.

January 23, 2019

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ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus form part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or SEC, utilizing a "shelf" registration process. This document contains two parts. The first part consists of this prospectus supplement, which provides you with specific information about this offering. The second part, the accompanying prospectus, provides more general information, some of which may not apply to this offering. Generally, when we refer only to the "prospectus," we are referring to both parts combined. This prospectus supplement may add, update or change information contained in the accompanying prospectus. To the extent that any statement we make in this prospectus supplement is inconsistent with statements made in the accompanying prospectus or any documents incorporated by reference herein or therein, the statements made in this prospectus supplement will be deemed to modify or supersede those made in the accompanying prospectus and such documents incorporated by reference herein and therein. You should read this prospectus supplement and the accompanying prospectus, including the information incorporated by reference herein and therein, and any related free writing prospectus that we have authorized for use in connection with this offering.

You should rely only on the information that we have included or incorporated by reference in this prospectus supplement, the accompanying prospectus and any related free writing prospectus that we may authorize to be provided to you. We have not authorized any dealer, salesman or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus supplement, the accompanying prospectus or any related free writing prospectus that we may authorize to be provided to you. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus supplement, the accompanying prospectus or any related free writing prospectus. This prospectus supplement, the accompanying prospectus and any related free writing prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus supplement, the accompanying prospectus or any related free writing prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction.

You should not assume that the information contained in this prospectus supplement, the accompanying prospectus or any related free writing prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference herein or therein is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus supplement, accompanying prospectus or any related free writing prospectus is delivered, or securities are sold, on a later date.

This prospectus supplement contains or incorporates by reference 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 or will be filed or have been or will be incorporated by reference as exhibits to the registration statement of which this prospectus supplement forms a part, and you may obtain copies of those documents as described in this prospectus supplement under the heading "Where You Can Find More Information."

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SUMMARY

This summary highlights information contained in other parts of this prospectus supplement. 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 supplement, the accompanying 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 forward-thinking women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Twirla® and our other current potential product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. Our lead product candidate, Twirla, also known as AG200-15, is a once-weekly prescription contraceptive patch that is at the end of Phase 3 clinical development. Twirla is a combined hormonal contraceptive, or CHC, patch that contains the active ingredients ethinyl estradiol, or EE, which is a synthetic estrogen, and levonorgestrel, or LNG, which is a type of progestin, a synthetic steroid hormone, both of which have an established history of efficacy and safety in currently marketed combination low-dose, oral contraceptives.

We have conducted a comprehensive clinical program, with completed Phase 1, Phase 2, and Phase 3 trials enrolling over 2,100 women, over 1,500 of whom received Twirla. We have filed a Section 505(b)(2) New Drug Application, or NDA, for approval of Twirla by the U.S. Food and Drug Administration, or FDA, which is required before marketing a new drug in the United States. Our 505(b)(2) NDA relies in part on clinical trials that we conducted and in part on the FDA's findings of safety and efficacy from investigations for approved products containing the active ingredients and published scientific literature for which we have not obtained a right of reference. In December 2017, the FDA indicated in a Complete Response Letter, or 2017 CRL, that our NDA was not sufficient for approval as submitted. In June 2018, we submitted a formal dispute resolution request, or FDRR, with the FDA for Twirla to appeal FDA's determination that concerns surrounding the *in vivo* adhesion properties of Twirla prevent the approval of the NDA. In October 2018, the FDA's Office of New Drugs, or OND, formally denied our appeal and provided a path forward that may not require that we reformulate Twirla or conduct a bioequivalence study between formulations, as previously suggested by the FDA's Division of Bone, Reproductive, and Urologic Products, orDBRUP, in the April 2018 Type A meeting. Specifically, OND suggested that we conduct a wear study to evaluate whether Twirla demonstrates a generally similar adhesion performance to Xulane®, the generic version of the previously marketed Ortho Evra® contraceptive patch, a product the FDA considers to have acceptable adhesion. If this result is demonstrated, OND stated that the study would support the conclusion of adequate Twirla adhesion. OND recommended that we first meet with DBRUP to gain agreement on the specific design and success criteria of a wear study for Twirla.

In December 2018, we met with DBRUP to discuss the comparative wear study. In our meeting, we discussed the specific design and success criteria of the comparative wear study, which is intended to demonstrate adequate adhesion via non-inferiority of Twirla to Xulane. After consultation with DBRUP, we initiated a crossover wear study in approximately 80 healthy women with a Body Mass Index of less than 35 kg/m^2 who will be randomized to wear either Twirla or Xulane for the first week and then switched to the patch not initially worn for the second week. The overall design of this comparative wear study follows the FDA's guidance with respect to abbreviated new drug applications, entitled *Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs*.

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The wear study suggested by OND to address adhesion provides a path forward but is not intended to address efficacy. Rather, if the wear study is successful, Twirla's safety and efficacy, including the Pearl Index that FDA noted is substantially higher than other previously approved combined hormonal contraceptives, will need to be reviewed by FDA after we resubmit the NDA for Twirla. This is an issue that the FDA plans to bring to Advisory Committee after the adhesion issue has been resolved. We can make no assurances that we can successfully complete the wear study suggested by the FDA or that the results will demonstrate adequate adhesion of Twirla. If we are unable to successfully complete our wear study of Twirla and Xulane to support the conclusion of adequate Twirla adhesion, the FDA will likely require us to reformulate Twirla and conduct additional clinical or bioequivalence studies before we can resubmit the Twirla NDA. We also expect that the FDA will conduct a pre-approval inspection of the our third-party manufacturer's facility, which must be successfully completed prior to approval.

If we are able to successfully complete the comparative wear study, then we plan to resubmit our Twirla NDA along with our collective responses to the items raised by the FDA in the 2017 CRL and in our related meetings and correspondence with the FDA. We currently plan to resubmit our Twirla NDA in the first half of 2019, and, assuming we receive a six-month review from the FDA, we would expect that the Prescription Drug User Fee Act (PDUFA) goal date assigned to us by the FDA would be no later than December 31, 2019.

In addition to Twirla, we have a potential pipeline of other new transdermal contraceptive products, including AG200-ER, which is a regimen designed to allow a woman to extend the length of her cycle, AG200-SP, which is a regimen designed to provide a shortened hormone-free interval, and AG890, which is a progestin-only contraceptive patch intended for use by women who are unable or unwilling to take estrogen.

Corporate Information

Information concerning our business is contained in the documents that we file with the SEC as a reporting company under the Securities Exchange Act of 1934, 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 101 Poor Farm Road, Princeton, New Jersey 08540, and our telephone number is (609) 683-1880.

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THE OFFERING

Common stock offered by us	Shares of our common stock having an aggregate offering price of not more than $10,000,000.
Common stock to be outstanding after this offering	Up to 45,600,674 shares, assuming sales at a price of $0.891 per share, which was the closing price of our common stock on the Nasdaq Capital Market on January 18, 2019. The actual number of shares issued will vary depending on the price at which shares may be sold from time to time.
Manner of offering	"At the market offering" that may be made from time to time through or to our sales agent, H.C. Wainwright & Co., LLC. See "Plan of Distribution" on page S-10 of this prospectus supplement.
Use of proceeds	We intend to use the net proceeds for working capital and general corporate purposes, which include pursuing regulatory approval for Twirla, preparation for an anticipated Advisory Committee meeting to discuss safety and efficacy of Twirla, the completion of our commercial plan for Twirla, which primarily includes validation of the commercial manufacturing process and the commercial launch of Twirla, if approved, and advancing the development of our other potential product candidates. We may also use a portion of the net proceeds 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. See "Use of Proceeds" on page S-8 of this prospectus supplement.
Risk factors	You should read the "Risk Factors" section of this prospectus supplement beginning on page S-4 and the documents referred to therein for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Nasdaq Capital Market symbol	AGRX

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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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, which is incorporated by reference in this prospectus supplement and the accompanying prospectus, as updated by our subsequent annual, quarterly and other reports and documents that are incorporated by reference into this prospectus supplement and the accompanying prospectus, together with other information in this prospectus supplement, the accompanying 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.

Risks Related to This Offering

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 public offering price.

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:

- the results of our comparative wear study do not support a conclusion by the FDA that Twirla demonstrates a generally similar adhesion performance to Xulane®, the generic version of the previously marketed Ortho Evra® contraceptive patch, a product the FDA considers to have acceptable adhesion;
- a pre-approval inspection of Corium International, Inc.'s, our third-party manufacturer, facility is not successfully completed prior to approval;
- an Advisory Committee convened by the FDA takes actions that are adverse to the approval or commercial prospects of Twirla;
- regulatory actions with respect to Twirla, including, for example, the FDA's failure to approve Twirla or the issuance of another complete response letter in connection with our planned NDA resubmission;
- any adverse development or perceived adverse development with respect to the FDA's review of our resubmission of the NDA for Twirla or any change to or inability by the FDA to meet a target PDUFA goal date;
- our failure to commercialize Twirla, if approved, or develop and commercialize additional product candidates;
- unanticipated efficacy, safety or tolerability concerns related to the use of Twirla;
- inability to obtain adequate product supply of Twirla or inability to do so at acceptable prices;
- inability for Twirla to receive reimbursement from third party payors or other actions that limit a patient's access to Twirla;

our lack of sufficient funds to commercially launch Twirla, if approved, and need to raise additional capital;

changes in laws or regulations applicable to Twirla or any future product candidates, including but not limited to clinical trial requirements for approvals;

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- 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 management or scientific personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section and in Part II, Item 1A "Risk Factors" of our Quarterly Report on Form 10-Q filed with the SEC on November 2, 2018.

In addition, the stock market has recently 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. For example, as previously disclosed, following the drop in the price of our stock after we announced the top-line results of our Phase 3 SECURE clinical trial in January 2017, we were the subject of a complaint alleging violations of the federal securities laws based on public statements made regarding our Phase 3 SECURE clinical trial and seeking an unspecified amount of damages to be determined at trial. The action was dismissed with prejudice as to all defendants on July 13, 2017. We also may face securities class-action litigation if we cannot obtain regulatory approvals for, or if we otherwise fail to commercialize, our product candidates, including Twirla. 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.

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 supplement 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

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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.

You will 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 is substantially higher than the net tangible book value per share of our common stock outstanding prior to this offering, you will 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 $10,000,000 at an assumed offering price of $0.891 per share (the last reported sale price of our common stock on The NASDAQ Capital Market on January 18, 2019), and after deducting estimated offring commissions and expenses payable by us, you would suffer immediate dilution of $0.18 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.

The shares of common stock offered under this prospectus supplement and the accompanying prospectus may be sold in "at the market offerings," and investors who buy shares at different times will likely pay different prices.

Investors who purchase shares under this prospectus supplement and the accompanying prospectus at different times will likely pay different prices, and so may experience different outcomes in their investment results. We will have discretion, subject to market demand, to vary the timing, prices, and numbers of shares sold, and there is no minimum or maximum sales price. Investors may experience declines in the value of their shares as a result of share sales made at prices lower than the prices they paid.

It is not possible to predict the aggregate proceeds resulting from sales made under the sales agreement.

Subject to certain limitations in the sales agreement and compliance with applicable law, we have the discretion to deliver a placement notice to Wainwright at any time throughout the term of the sales agreement. The number of shares that are sold through Wainwright after delivering a placement notice will fluctuate based on a number of factors, including the market price of our common stock during the sales period, the limits we set with Wainwright in any applicable placement notice, and the demand for our common stock during the sales period. Because the price per share of each share sold will fluctuate during the sales period, it is not currently possible to predict the aggregate proceeds to be raised in connection with those sales.

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FORWARD-LOOKING STATEMENTS

From time to time, in reports filed with the Securities and Exchange Commission (including this prospectus), in press releases and in other communications to stockholders or the investment community, we may provide forward-looking statements concerning possible or anticipated future results of operations or business developments. These statements are based on our management's current expectations or predictions of future conditions, events or results based on various assumptions and our management's estimates of trends and economic factors in the markets in which we are active, as well as our business plans. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates," "projects," "forecasts," "may," "should," and variations of such words and similar expressions are intended to identify such forward-looking statements. The forward-looking statements may include, without limitation, statements regarding product candidate development, product candidate potential, regulatory environment, sales and marketing strategies, capital resources or operating performance. The forward-looking statements are subject to risks and uncertainties, which may cause results to differ materially from those set forth in the statements. Forward-looking statements in this prospectus should be evaluated together with the many uncertainties that affect our business and our market, particularly those discussed in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2017 and our subsequent filings, which are incorporated by reference into this prospectus, to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. Forward-looking statements are not guarantees of future performance, and actual results may differ materially from those projected. The forward-looking statements are representative only as of the date of this prospectus and except as required by law, we assume no responsibility to update any forward-looking statements, whether as a result of new information, future events or otherwise.

You should read this prospectus and the documents that we reference in this prospectus and have been filed as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any issuance or sale of our common shares. Except as required by law, we do not assume any obligation to update any forward-looking statements.

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USE OF PROCEEDS

We estimate that the net proceeds from the sale of the shares of common stock that we are offering may be up to approximately $9.4 million, after deducting Wainwright's estimated discounts and commissions and estimated offering expenses payable by us. The amount of the proceeds from this offering will depend upon the number of shares of our common stock sold and the market price at which they are sold. There can be no assurance that we will be able to sell any shares under or fully utilize the sales agreement as a source of financing.

We intend to use the net proceeds, if any, for working capital and general corporate purposes, which include pursuing regulatory approval for Twirla, preparation for an anticipated Advisory Committee meeting to discuss safety and efficacy of Twirla, the completion of our commercial plan for Twirla, which primarily includes validation of the commercial manufacturing process and the commercial launch of Twirla, if approved, and advancing the development of our other potential product candidates. We may also use a portion of the net proceeds 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, the status of and results from 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.

DIVIDEND POLICY

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. 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.

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DILUTION

If you invest in our common stock, your interest will be diluted immediately to the extent of the difference between the public offering price per share you will pay in this offering and the as adjusted net tangible book value per share of our common stock after this offering. Net tangible book value per share represents our total tangible assets less total liabilities, divided by the number of shares of our common stock outstanding.

As of September 30, 2018, our net tangible book value was $23.2 million, or $0.67 per share of common stock. After giving effect to our issuance and sale of the aggregate amount of $10,000,000 of shares of common stock in this offering at the assumed public offering price of $0.891 per share (the last reported sale price of our common stock on The Nasdaq Capital Market on January 18, 2019), after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us, the as adjusted net tangible book value as of September 30, 2018 would have been $32.6 million, or $0.71 per share. This represents an immediate increase in as adjusted net tangible book value to existing stockholders of $0.04 per share and an immediate dilution to new investors purchasing common stock in this offering of $0.18 per share.

The following table illustrates this per share dilution to the new investors purchasing shares of common stock in this offering:

Assumed public offering price per share		$ 0.891
Net tangible book value per share at September 30, 2018	$ 0.67	
Increase in net tangible book value per share attributable to new investors purchasing shares in this offering	$ 0.04	
As adjusted net tangible book value per share after this offering		$ 0.71
Dilution per share to new investors in this offering		$ 0.18

Each $0.25 increase or decrease in the assumed public offering price of $0.891 per share would increase or decrease, as applicable, our as adjusted net tangible book value per share by approximately $0.05 and $(0.06), respectively, and would increase or decrease, as applicable, dilution per share to new investors in this offering by $0.21 and $(0.19), respectively, assuming that the aggregate dollar amount of the shares offered by us remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The foregoing as adjusted information is illustrative only and will be adjusted based on the actual public offering price of this offering determined at pricing.

The foregoing table and calculations are based on 34,377,329 shares of our common stock outstanding as of September 30, 2018, and exclude:

- 5,687,901 shares of common stock issuable upon the exercise of outstanding options to purchase common stock as of September 30, 2018 at a weighted average exercise price of $4.34 per share;
- 147,554 shares of common stock issuable upon vesting of restricted stock units as of September 30, 2018;
- 393,750 shares of common stock issuable upon the vesting of performance restricted stock units as of September 30, 2018;
- 2,381,819 shares of common stock reserved for future issuance under our 2014 Amended and Restated Incentive Compensation Plan as of September 30, 2018; and
- 242,779 shares of common stock issuable upon the exercise of outstanding warrants as of September 30, 2018 at a weighted average exercise price of $5.92 per share.

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PLAN OF DISTRIBUTION

We have entered into a sales agreement with H.C. Wainwright & Co., LLC, or Wainwright, under which we may issue and sell from time to time shares of our common stock through or to Wainwright as our sales agent or principal. In accordance with the terms of the sales agreement, we may offer and sell shares of our common stock from time to time having an aggregate offering price of not more than $10,000,000 pursuant to this prospectus supplement and the accompanying prospectus.

Sales of the common stock, if any, will be made by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act. Wainwright will offer our common stock at prevailing market prices subject to the terms and conditions of the sales agreement as agreed upon by us and Wainwright. We will designate the number or dollar value of shares which we desire to sell, the time period during which sales are requested to be made, any limitation on the number of shares that may be sold in one day and any minimum price below which sales may not be made. Subject to the terms and conditions of the sales agreement, Wainwright will use its commercially reasonable efforts to sell on our behalf all of the shares of common stock requested to be sold by us. We or Wainwright may suspend the offering of the common stock being made through Wainwright under the sales agreement upon proper notice to the other party.

Settlement for sales of common stock will occur on the second trading day or such shorter settlement cycle as may be in effect under Exchange Act Rule 15c6-1 from time to time, following the date on which any sales are made, or on some other date that is agreed upon by us and Wainwright in connection with a particular transaction, in return for payment of the net proceeds to us. There is no arrangement for funds to be received in an escrow, trust or similar arrangement.

We will pay Wainwright in cash, upon each sale of our shares of common stock pursuant to the sales agreement, a commission equal to 3.0% of the gross proceeds from each sale of shares of our common stock. Because there is no minimum offering amount required as a condition to this offering, the actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time. Pursuant to the terms of the sales agreement, we agreed to reimburse Wainwright for the documented fees and costs of its legal counsel reasonably incurred in connection with entering into the transactions contemplated by the sales agreement in an amount not to exceed $50,000 in the aggregate. Additionally, pursuant to the terms of the sales agreement, we agreed to reimburse Wainwright for the documented fees and costs of its legal counsel reasonably incurred in connection with Wainwright's ongoing diligence, drafting and other filing requirements arising from the transactions contemplated by the sales agreement in an amount not to exceed $2,500 in the aggregate per calendar quarter. We estimate that the total expenses of the offering payable by us, excluding commissions payable to Wainwright under the sales agreement, will be approximately $300,000. We will report at least quarterly the number of shares of common stock sold through Wainwright under the sales agreement, the net proceeds to us and the compensation paid by us to Wainwright in connection with the sales of common stock.

In connection with the sales of common stock on our behalf, Wainwright will be deemed to be an "underwriter" within the meaning of the Securities Act, and the compensation paid to Wainwright will be deemed to be underwriting commissions or discounts. We have agreed in the sales agreement to provide indemnification and contribution to Wainwright against certain liabilities, including liabilities under the Securities Act.

The offering of our shares of common stock pursuant to the sales agreement will terminate upon the earlier of the (i) sale of all of our shares of common stock provided for in this prospectus supplement, or (ii) termination of the sales agreement as permitted therein.

Our common stock is listed for trading on The Nasdaq Capital Market under the symbol "AGRX".

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Wainwright and its affiliates may in the future provide various investment banking and other financial services for us and our affiliates, for which services they may in the future receive customary fees. To the extent required by Regulation M, Wainwright will not engage in any market making activities involving our shares of common stock while the offering is ongoing under this prospectus supplement. This summary of the material provisions of the sales agreement does not purport to be a complete statement of its terms and conditions.

LEGAL MATTERS

The validity of the common stock being offered in this offering will be passed upon for us by Morgan, Lewis & Bockius LLP, Princeton, New Jersey. H.C.Wainwright & Co., LLC is being represented in connection with this offering by Duane Morris LLP, New York, New York.

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, 2017 have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon, included therein, and incorporated herein by reference. Such financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus supplement and the accompanying prospectus form part of a registration statement on Form S-3 that we filed with the SEC. This prospectus supplement and the accompanying prospectus do 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 supplement, 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 supplement or the accompanying 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 front page of this prospectus supplement, regardless of the time of delivery of this prospectus supplement 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 supplement, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The documents incorporated by reference into this prospectus supplement contain important information that you should read about us. Notwithstanding the foregoing, unless specifically stated to the contrary, none of the information that is not deemed "filed" with the SEC, including information furnished under Items 2.02 or 7.01 of any Current Report on Form 8-K, will be incorporated by reference into, or otherwise included in, this prospectus supplement.

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The following documents are incorporated by reference into this document:

- our annual report on Form 10-K for the fiscal year ended December 31, 2017 filed with the SEC on March 12, 2018 (the "Form 10-K");
- the information contained in our definitive proxy statement on Schedule 14A for our 2018 annual meeting of stockholders filed with the SEC on April 25, 2018, to the extent incorporated by reference in Part III of the Form 10-K;
- our quarterly report on Form 10-Q for the quarter ended March 31, 2018 filed with the SEC on May 7, 2018;
- our quarterly report on Form 10-Q for the quarter ended June 30, 2018 filed with the SEC on August 3, 2018;
- our quarterly report on Form 10-Q for the quarter ended September 30, 2018 filed with the SEC on November 2, 2018;
- our current reports on Form 8-K filed with the SEC on January 26, 2018, April 27, 2018, May 4, 2018, May 18, 2018, June 7, 2018, June 21, 2018, July 9, 2018, July 24, 2018, October 5, 2018, October 9, 2018, October 24, 2018 November 1, 2018, January 3, 2019, January 7, 2019, and January 10, 2019; and
- our description of our common stock contained in the registration statement on Form 8-A, filed on May 20, 2014, and all amendments and reports updating such description.

We also incorporate by reference into this prospectus all documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items) that are filed by us with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus supplement 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, 101 Poor Farm Road, 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.

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PROSPECTUS

$100,000,000

AGILE THERAPEUTICS, INC.

Common Stock
Preferred Stock
Warrants
Debt Securities
Rights to Purchase Common Stock, Preferred Stock, Debt Securities or Units
Units

We may offer and sell from time to time our shares of common stock, shares of preferred stock, warrants, debt securities and rights to purchase common stock, preferred stock, debt securities or units, as well as units that include any of these securities. We may sell any combination of these securities in one or more offerings with an aggregate offering price of up to $100,000,000.

This prospectus provides you with a general description of the securities we may offer. Each time we offer securities pursuant to this prospectus, we will provide a prospectus supplement containing specific terms of the particular offering together with this prospectus. You should read this prospectus and the applicable prospectus supplement carefully before you invest in any securities. The prospectus supplement also may add, update or change information contained in this prospectus. This prospectus may not be used to offer and sell securities unless accompanied by the applicable prospectus supplement.

Our common stock is listed on the Nasdaq Global Market under the symbol "AGRX." On November 1, 2018, the closing price of our common stock was $0.92.

The aggregate market value of our outstanding common shares held by non-affiliates as of November 1, 2018 was approximately $31.2 million based on 34,377,329 shares of common stock outstanding, of which 33,953,593 were held by non-affiliates, and a closing price on The Nasdaq Global Market of $0.92 (the closing price on November 1, 2018). Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell securities registered on this registration statement in a public primary offering with a value exceeding more than one-third of the aggregate market value of our voting and non-voting common equity held by non-affiliates in any 12-month period so long our public float remains below $75 million. During the 12 calendar months prior to and including the date hereof, we have not offered any securities pursuant to General Instruction I.B.6 of Form S-3.

Investing in our securities involves significant risks. We strongly recommend that you read carefully the risks we describe in this prospectus and in any accompanying prospectus supplement, as well as the risk factors that are incorporated by reference into this prospectus from our filings made with the Securities and Exchange Commission. See "Risk Factors" on page 6 of this prospectus.

We may sell the securities directly or to or through underwriters or dealers, and also to other purchasers or through agents. The names of any underwriters or agents that are included in a sale of securities to you, and any applicable commissions or discounts, will be stated in an

accompanying prospectus supplement. In addition, the underwriters, if any, may over-allot a portion of the securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is November 14, 2018

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, (the "SEC"), using a "shelf" registration process. Under this shelf registration process, we may offer and sell from time to time any combination of the securities described in this prospectus in one or more offerings in amounts, at prices and on terms that we determine at the time of the offering, with an aggregate offering price of up to $100,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we offer securities under this registration statement we will provide a prospectus supplement that describes the terms of the relevant offering. The prospectus supplement also may add, update or change information contained in this prospectus. Before making an investment decision, you should read carefully both this prospectus and any prospectus supplement together with the documents incorporated by reference into this prospectus as described below under the heading "Information Incorporated by Reference."

The registration statement that contains this prospectus, including the exhibits to the registration statement and the information incorporated by reference, provides additional information about us and our securities. That registration statement can be read at the SEC website (www.sec.gov) or at the SEC public reference room, as discussed below under the heading "Where You Can Find More Information."

You should rely only on the information provided in the registration statement, this prospectus and in any prospectus supplement, including the information incorporated by reference. We have not authorized anyone to provide you with different information. You should not assume that the information in this prospectus or any supplement to this prospectus is accurate at any date other than the date indicated on the cover page of these documents or the filing date of any document incorporated by reference, regardless of its time of delivery. We are not making an offer to sell the securities in any jurisdiction where the offer or sale is not permitted.

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We may sell our securities to or through underwriters, initial purchasers, dealers or agents, directly to purchasers or through a combination of any of these methods of sale, as designated from time to time. We and our agents reserve the sole right to accept or reject in whole or in part any proposed purchase of our securities. An applicable prospectus supplement, which we will provide each time we offer the securities, will set forth the names of any underwriters, initial purchasers, dealers or agents involved in the sale of our securities, and any related fee, commission or discount arrangements. See "Plan of Distribution."

The terms "Agile," the "Company," "our," "us" and "we," as used in this prospectus, refer to Agile Therapeutics, Inc., unless we state otherwise or the context indicates otherwise.

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AGILE THERAPEUTICS, INC.

We are a forward-thinking women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Twirla® and our other current potential product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. Our lead product candidate, Twirla, also known as AG200-15, is a once-weekly prescription contraceptive patch that is at the end of Phase 3 clinical development. Twirla is a combined hormonal contraceptive, or CHC, patch that contains the active ingredients ethinyl estradiol, or EE, which is a synthetic estrogen, and levonorgestrel, or LNG, which is a type of progestin, a synthetic steroid hormone, both of which have an established history of efficacy and safety in currently marketed combination low-dose, oral contraceptives.

We have conducted a comprehensive clinical program, with completed Phase 1, Phase 2, and Phase 3 trials enrolling over 2,100 women, over 1,500 of whom received Twirla. We have filed a Section 505(b)(2) New Drug Application, or NDA, for approval of Twirla by the U.S. Food and Drug Administration, or FDA, which is required before marketing a new drug in the United States. Our 505(b)(2) NDA relies in part on cli