AGILE THERAPEUTICS INC
Form 424B5
August 02, 2017

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Registration No. 333-205120

The information contained in this preliminary prospectus supplement and the accompanying prospectus is not complete and may be changed. A registration statement relating to the securities has been declared effective by the Securities and Exchange Commission. This preliminary prospectus supplement and the accompanying prospectus do not constitute an offer to sell these securities and we are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED AUGUST 2, 2017

PRELIMINARY PROSPECTUS SUPPLEMENT
(To Prospectus dated July 1, 2015)

Shares

Common Stock

Agile Therapeutics, Inc. is offering of shares of common stock.

Our common stock is listed on The NASDAQ Global Market under the symbol "AGRX". The last reported sale price of our common stock on The NASDAQ Global Market on August 1, 2017 was $4.60 per share.

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-6 and in the documents incorporated by reference in this prospectus supplement.

	Per Share	Total

Public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Offering proceeds to us, before expenses	$	$

(1) We refer you to the section entitled "Underwriting" beginning on page S-18 of this prospectus supplement for additional information regarding total underwriter compensation.

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.

We have granted the underwriters the right to purchase up to of additional shares of common stock. The underwriters can exercise this right at any time within 30 days after the offering. The underwriters expect to deliver the shares of common stock to investors on or about , 2017.

Joint Book-Running Managers

William Blair **RBC Capital Markets** **Cantor Fitzgerald & Co.**

, 2017

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Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained or incorporated by reference in this prospectus supplement, the accompanying prospectus or in any free writing prospectuses we have authorized for use in connection with this offering. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus supplement and the accompanying prospectus together constitute an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus supplement, the accompanying prospectus and any free writing prospectuses that we have authorized for use in connection with this offering is current only as of its date. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, the accompanying prospectus, the documents incorporated by reference herein and therein, and any free writing prospectus that we have authorized for use in connection with this offering when making your investment decision. You should also read and consider the information in the documents we have referred you to in the section of the accompanying prospectus entitled "Information Incorporated by Reference."

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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. Our current product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. We have developed a proprietary transdermal patch technology, called Skinfusion®, which is designed to provide advantages over currently available patches and is intended to optimize patch adherence and stability as well as patient comfort. 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.

Prior to our SECURE clinical trial, as discussed below, we conducted a comprehensive clinical program and completed Phase 1, Phase 2 and Phase 3 trials, which together enrolled 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 February 2013, the FDA indicated in a Complete Response Letter, or CRL, that our NDA was not sufficient for approval as originally submitted. After multiple communications with the FDA, we received significant guidance as to what additional clinical development and other activities need to be completed prior to approval.

In accordance with the FDA's advice and comments, we conducted an additional Phase 3 clinical trial, referred to as the SECURE clinical trial, in which we enrolled over 2,000 women for up to one year of treatment. We announced top-line data in early January 2017. In March 2017, at our request, we met with the FDA to share preliminary data from the SECURE clinical trial, including key safety data and body mass index-related efficacy findings, and to seek FDA input as to whether the SECURE clinical trial results constitute a basis for addressing the clinical deficiencies cited in the CRL. We also requested feedback on whether the proposed Twirla NDA content will meet the FDA's requirements for submission. The FDA did not provide us with any guidance on whether the results of the SECURE clinical trial and the contents of the planned, resubmitted NDA will be sufficient to obtain regulatory approval of Twirla. Based on our feedback from the FDA, we filed our NDA resubmission, which was received by the FDA on June 26, 2017. On July 27, 2017, we announced that the FDA had acknowledged the resubmitted NDA for Twirla as a complete response to the CRL, and provided a target Prescription Drug User Fee Act, or PDUFA, goal date of December 26, 2017. Our business plan assumes the FDA will complete its review of our NDA resubmission by the target PDUFA goal date of December 26, 2017.

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We intend to commercialize Twirla in the United States, if approved, through a direct sales force. Obstetricians and gynecologists, or ObGyns, contribute 43% of the U.S. contraception prescription volume, and Nurse Practitioners and Physician Assistants, or NP/PAs, who are often affiliated with an ObGyn practice, contribute an additional 29% of the U.S. prescriptions. We anticipate that a targeted sales force focused initially on ObGyns, NPs, PAs and primary care providers, who comprise the top prescribers of contraceptives, will be highly effective. We believe that we can address this market with a specialty sales force of approximately 70 to 100 representatives. We also intend to augment our sales force through the use of digital marketing and other techniques designed to market directly to patients. We will require additional capital for the commercial launch of Twirla, if approved.

In addition to Twirla, we are developing a pipeline of other new transdermal contraceptive product candidates, including AG200-SP, which is a regimen designed to provide shorter, lighter periods; AG200-ER, which is a regimen designed to allow a woman to extend the length of her cycle; and AG890, which is a progestin-only contraceptive patch intended for use by women who are unable or unwilling to take estrogen. AG200-SP and AG200-ER are intended to be Twirla line extensions that would expand the use of Twirla beyond its initial, approved use. Substantially all of our resources are currently dedicated to developing and seeking regulatory approval for Twirla. We will require additional capital for advancing the development of our other product candidates.

Our current product candidate pipeline is summarized in the graphic below:

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 public can also obtain copies of these filings by

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visiting the SEC's Public Reference Room at 100 F Street NE, Washington D.C. 20549, or by calling the SEC at 1-800-SEC-0330. 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.

Implications of Being an Emerging Growth Company

As a company with less than $1.07 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from specified disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until December 31, 2019, or until such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.07 billion in annual revenues, have more than $700 million in market value of our capital stock held by non-affiliates or issue more than $1 billion of non-convertible debt over a three-year period. We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of some reduced reporting burdens in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein. Accordingly, such information may be different than the information you receive from other public companies in which you hold stock.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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THE OFFERING

Common stock offered by us	shares
Total common stock to be outstanding after this offering	shares, or shares if the underwriters exercise their option to purchase additional shares in full.
Option to purchase additional shares	The underwriters have an option for a period of 30 days to purchase up to additional shares of our common stock.
Use of proceeds	We intend to use the net proceeds of this offering to pursue regulatory approval for Twirla, to fund activities related to commercial scale-up of our third party manufacturing operations and other activities related to the commercial launch of Twirla, if approved, and for working capital and other general corporate purposes. We may also use a portion of the net proceeds for research and development activities related to our other product candidates, and 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."
Risk factors	You should read the "Risk Factors" section of this prospectus supplement beginning on page S-6 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 Global Market symbol	AGRX

The number of shares of our common stock to be outstanding after this offering is based on 28,806,398 shares of our common stock outstanding as of June 30, 2017, and excludes:

- 3,779,915 shares of common stock issuable upon the exercise of outstanding options to purchase common stock as of June 30, 2017 at a weighted average exercise price of $5.83 per share;
- 264,361 shares of common stock issuable upon vesting of restricted stock units as of June 30, 2017;
- 260,000 shares of common stock issuable upon the vesting of performance restricted stock units as of June 30, 2017;
- 283,141 shares of common stock reserved for future issuance under our 2014 Incentive Compensation Plan as of June 30, 2017; and
- 242,779 shares of common stock issuable upon the exercise of outstanding warrants as of June 30, 2017 at a weighted average exercise price of $5.92 per share.

Except as otherwise indicated herein, all information in this prospectus supplement, including the number of shares of common stock that will be outstanding after this offering, assumes the following:

- no exercise by the underwriters' of their option to purchase additional shares in this offering; and
- no exercise of outstanding options or warrants and no additional vesting of any outstanding restricted stock unit or performance restricted stock unit, each after June 30, 2017.

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SUMMARY FINANCIAL DATA

The following summary financial data for the three years ended December 31, 2016 have been derived from our audited financial statements incorporated by reference in this prospectus supplement. The following summary financial data for the six months ended June 30, 2016 and 2017 and as of June 30, 2017 have been derived from our unaudited financial statements incorporated by reference in this prospectus supplement. Our unaudited financial statements have been prepared on the same basis as the audited financial statements and, in the opinion of our management, include all adjustments, consisting of normal recurring adjustments and accruals, necessary for a fair statement of the information for the interim periods. Our historical results for any prior periods are not necessarily indicative of results to be expected for a full year or for any future period. You should read this information together with our financial statements and related notes incorporated by reference in this prospectus supplement and the information under "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing in our most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, each as incorporated by reference herein.

	Year Ended December 31,			Six Months Ended June 30,	
	2014	2015	2016	2016	2017
				(unaudited)	
	(in thousands, except share and per share data)				
Statement of Operations Data:					
Operating expenses:					
Research and development	$ 13,365	$ 25,622	$ 20,929	$ 10,505	$ 8,519
General and administrative	5,150	7,467	8,792	4,316	5,603
Total operating expenses	18,515	33,089	29,721	14,821	14,122
Operating loss	(18,515)	(33,089)	(29,721)	(14,821)	(14,122)
Total other (expense) income	(1,215)	(3,218)	(2,095)	(915)	(839)
Loss before benefit from income taxes	(19,730)	(36,307)	(31,816)	(15,736)	(14,961)
Benefit from income taxes	3,653	5,972	3,075		
Net loss	$ (16,077)	(30,335)	(28,741)	(15,736)	(14,961)
Net Loss per share:					
Basic and diluted	$ (1.41)	$ (1.38)	$ (1.02)	$ (0.57)	$ (0.52)
Weight average shares:					
Basic and diluted	11,394,971	22,017,229	28,273,331	27,785,113	28,785,827

	As of June 30, 2017

	Actual	As Adjusted(1)
	(unaudited, in thousands)	
Balance Sheet Data		