

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(D)
of the Securities Exchange Act of 1934

February 26, 2020

Date of report (Date of earliest event reported)

Agile Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36464
(Commission
File Number)

23-2936302
(IRS Employer
Identification No.)

101 Poor Farm Road
Princeton, New Jersey
(Address of principal executive offices)

08540
(Zip Code)

Registrant's telephone number, including area code **(609) 683-1880**
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12).
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)).

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	AGRX	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter)

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure

On February 26, 2020, Agile Therapeutics, Inc. (the “Company”) updated its corporate presentation that it intends to use at conferences and in meetings with investors. The updates include information on the approval of its first product, its plan for the commercialization of that product and recent financing activities, including the net proceeds from its recent public offering of common stock, which included the exercise in full by the underwriters of their option to purchase additional shares of common stock. The aggregate net proceeds to Agile Therapeutics from the offering were approximately \$48.4 million, after deducting underwriting discounts, commissions, and estimated offering expenses. The Company is furnishing herewith a copy of the corporate presentation, which is attached hereto as Exhibit 99.1.

In accordance with General Instructions B.2 and B.6 of Form 8-K, the information included in this Item 7.01 (including Exhibit 99.1 attached hereto), shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Exchange Act or the Securities Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
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99.1	Agile Therapeutics, Inc. Corporate Presentation dated February 26, 2020.
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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

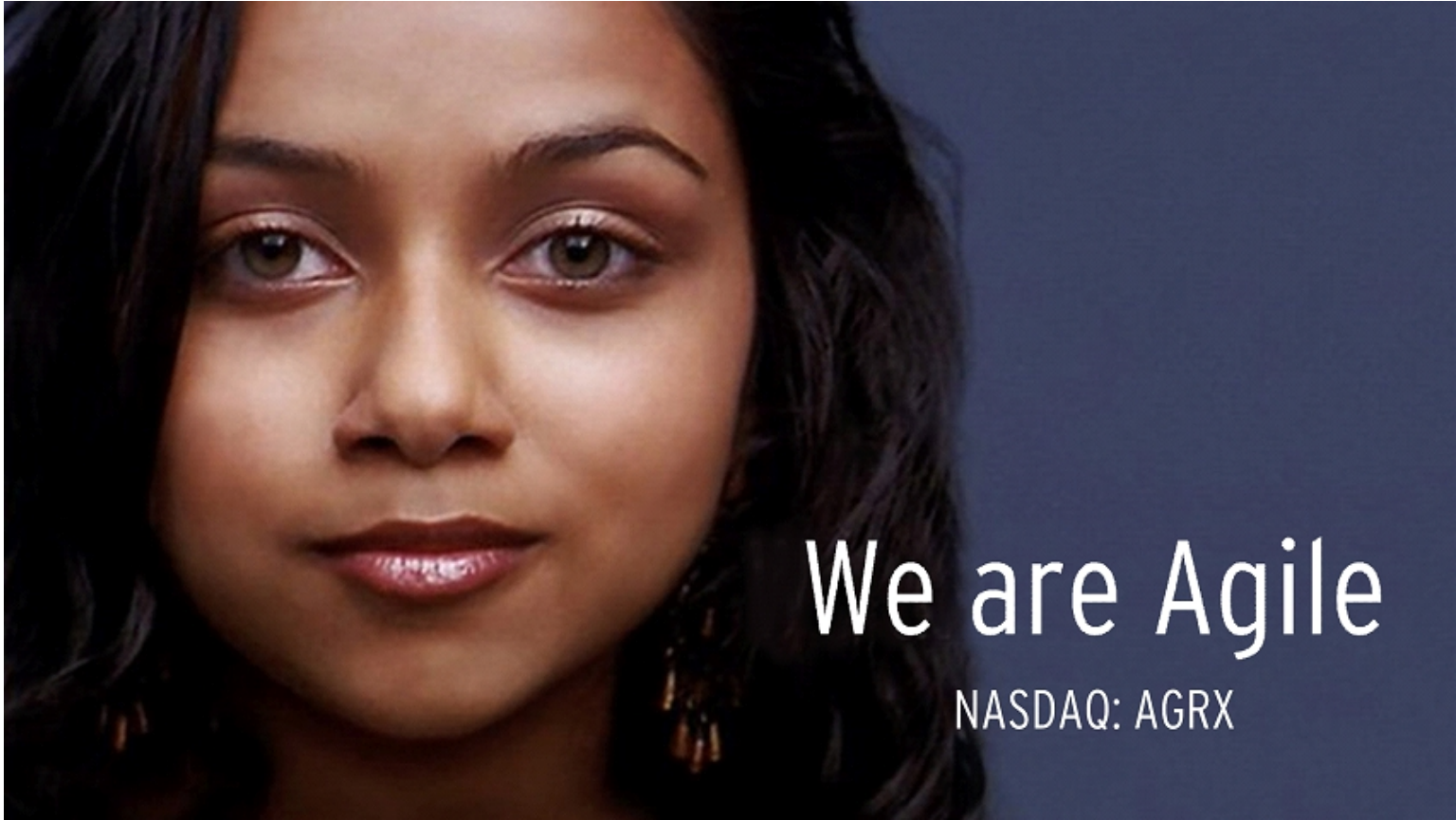
Agile Therapeutics, Inc.

Dated: February 26, 2020

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: Chairman and Chief Executive Officer



We are Agile

NASDAQ: AGRX

Forward Looking Statement

Certain information contained in this presentation and other matters discussed today or answers that may be given in response to questions may include “forward-looking statements”. We may, in some cases, use terms such as “predicts,” “believes,” “potential,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements.

In particular, the Company’s statements regarding projections and potential future results are examples of such forward-looking statements. The forward-looking statements are subject to important factors, risks and uncertainties, including, but not limited to, risks related to our ability to maintain regulatory approval of Twirla®, our ability along with our third-party manufacturer, Corium, to complete successfully the scale-up of the commercial manufacturing process for Twirla, including the qualification and validation of equipment related to the expansion of Corium’s manufacturing facility, the performance and financial condition of Corium or any of the suppliers to our third-party manufacturer, the ability of Corium to produce commercial supply in quantities and quality sufficient to satisfy market demand for Twirla, our ability to successfully commercialize Twirla, the successful development of our sales and marketing capabilities, the accuracy of our estimates of the potential market for Twirla, regulatory and legislative developments in the United States and foreign countries, our ability to obtain and maintain intellectual property protection for Twirla, our strategy, business plans and focus, and unforeseen market factors or events in our clinical, regulatory and manufacturing development plans; and other factors, including general economic conditions and regulatory developments, not within the Company’s control.

These factors could cause actual results and developments to be materially different from those expressed in or implied by such statements. The forward-looking statements are made only as of the date of this presentation and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstance. For additional information about the risks and uncertainties that may affect our business please see the factors discussed in “Risk Factors” in the Company’s periodic reports filed with the SEC.



- A champion for healthcare choices women deserve, headquartered in Princeton, NJ
- Dedicated to building a robust Women's Health Franchise
- Twirla[®] is our first FDA-approved product

 <p>Twirla[™] (levonorgestrel/ethinyl estradiol) 120/30 mcg/day transdermal system</p>	<p>Weekly Contraceptive Patch</p> <hr/> <p>\$3.7B Addressable Market</p>	
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TWIRLA is indicated as a method of contraception for use in women with a BMI < 30 kg/m² for whom a combined hormonal contraceptive is appropriate. Consider TWIRLA's reduced effectiveness in women with a BMI ≥ 25 to < 30 kg/m² before prescribing TWIRLA. TWIRLA is contraindicated in women with a BMI ≥ 30 kg/m².

Agile's Corporate Strategy: Become a Leader in Women's Health

- **Short-Term Goal** - Establish Agile in the prescription contraceptive market with Twirla, our first FDA-approved product
- **Long-Term Mission** - Broaden our women's health portfolio, including in areas of unmet medical need



Agile's Women's Health Mission Starts with Contraception

WHY CONTRACEPTION?	Women use contraception for an average of 30 years, and nearly all women use contraception at some point ^{1,2}
	Nearly half of pregnancies in U.S. women are unintended ³
WHY DO WOMEN NEED MORE BIRTH CONTROL OPTIONS?	Nearly half of unintended pregnancies are due to inconsistent and/or improper use of contraception ⁴
	Women's individual preferences for contraceptive methods vary and change across their lifetimes as their needs change ⁵
	Women are more consistent with contraceptive use and stay with a method for longer when using a method of their choosing ⁴

1-Hamilton BE, Kirmeyer SE., National Center for Health Statistics. 2017; 2-Daniels K et al, National Center for Health Statistics. 2013
3-Finer LB and Zolna MR, NEJM 2016; 4-Frost JJ and Darroch J., Perspectives on Sexual and Reproductive Health 2008
5-Mansour D, Int J Women's Health 2014

What is Missing From Available Hormonal Birth Control Options?

“Some women are just not good at remembering to take a pill at the same time every day...Others don’t want something in their vagina while others don’t want an injection.”

- Ob/Gyn

LOWER
ESTROGEN
DOSE

The dose of estrogen in CHCs is believed to be the primary factor contributing to unwanted side effects¹

The only other non-daily transdermal patch currently available delivers a high dose of estrogen²

NON-
DAILY
OPTIONS

Potential to reduce burden associated with daily pills

49% of contraception users prefer non-daily method³

52% are frustrated with taking the pill daily³

LESS
INVASIVE
METHODS

May be preferred by some women⁴

Some women prefer to avoid injections, implants, and intrauterine devices

1-Poindexter, A., Fertility and Sterility 2001; 2-Xulane Package Insert; 3-Mansour D., International Journal of Women's Health 2014;
4 Qualitative and quantitative HCP research, Kantar Health 2010; Third party research, 2017

Twirla Designed to Fill A Hormonal Birth Control Market Need



HORMONE
PROFILE

NON-
DAILY

LESS
INVASIVE

30µg/day Ethinyl Estradiol (EE)
120µg/day Levonorgestrel (LNG)

Patch Regimen: Once-a-week							Pill Regimen: Once-a-day						
S	M	T	W	T	F	S	SUN	MON	TUE	WED	THU	FRI	SAT
1	2	3	4	5	6	7	1	2	3	4	5	6	7
8	9	10	11	12	13	14	8	9	10	11	12	13	14
15	16	17	18	19	20	21	15	16	17	18	19	20	21
22	23	24	25	26	27	28	22	23	24	25	26	27	28
7 days no patch													

Less invasive than some methods
(vaginal ring, IUDs, injections, implants)

"I want to eliminate the forgetfulness... but I don't want to lose that control either."
- Consumer, October 2016

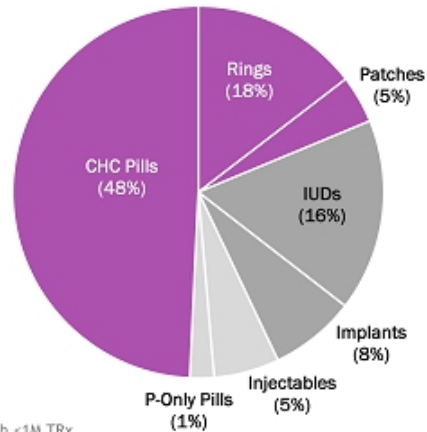
Agile
THERAPEUTICS
NASDAQ: AGRX

U.S. Hormonal Contraceptive Market is a Significant Opportunity

US Market Estimates (2018)

\$5.3 Billion U.S. Contraceptive Market

Combined Hormonal Contraception (CHC)	Progestin-Only (P-Only)	Long Acting Reversible Contraception (LARC)
CHC Pill, Ring, Patch	P-only Pill, Injection	IUD, Implant
\$3.7 Billion	\$300 Million	\$1.3 Billion



P-only Pills category includes emergency contraceptive prescriptions. Not Shown: "All Other" category with <1M TRx
 Sources: IQVIA NSP through Dec 2018; ACOG FAQs

Twirla has the Potential for Significant Market Share

Peak TRx Share Estimate Based on Consumer & Physician Market Research and Market Analogs

HCP Market Research (% CHC Market TRx)		
Study Year	Stated Share	Calibrated for Overstatement
2019	20%	14%
2016	23%	14%

Consumers "Extremely Likely" to Ask for Twirla
15%

Average of Analog Brands
9.6%

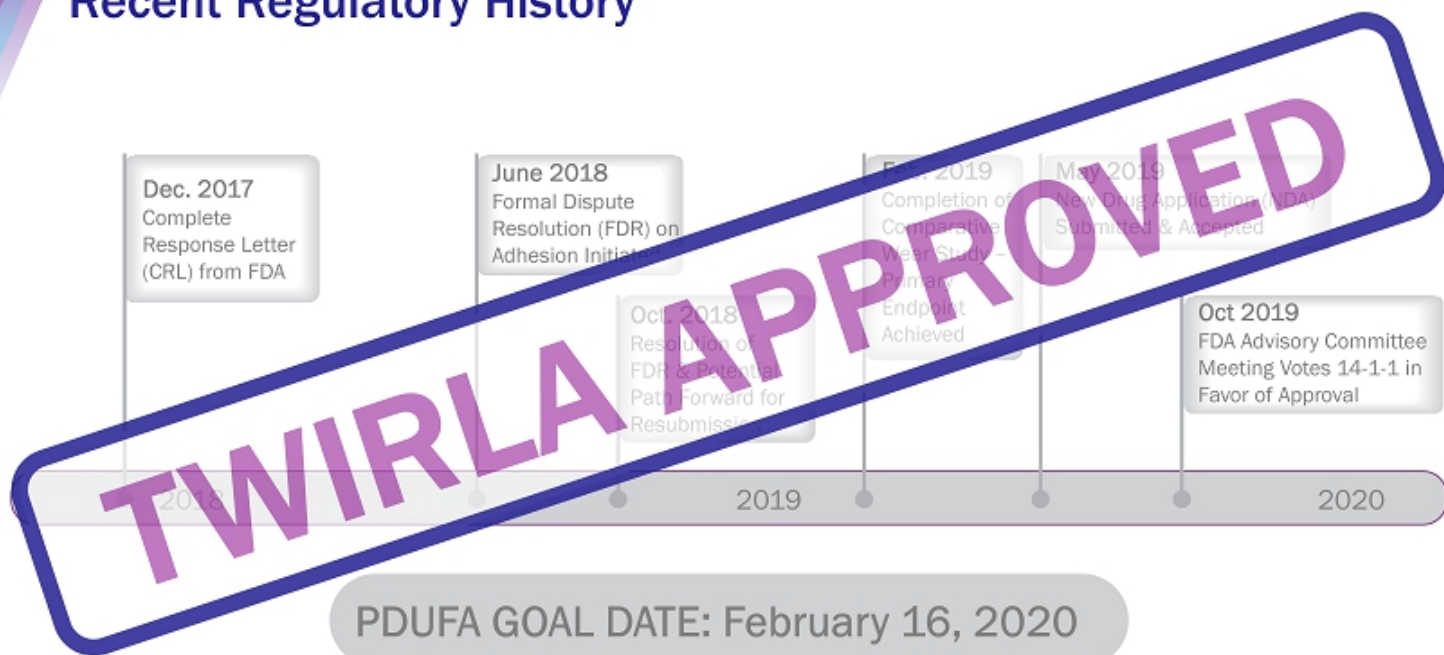


* Will continue to analyze market and update market research based on approved labeling

Sources: IMS NPA, 2002-2014
Qualitative and Quantitative HCP and Consumer market research, Adelphi Research 2016
Quantitative HCP market research, MarketVision Research 2019

Agile[®]
THERAPEUTICS
NASDAQ: AGRX

Recent Regulatory History



The Path To Potential Twirla Approval

ISSUE RAISED BY FDA CRL	CLARIFICATION FROM FDA FOR NEXT STEPS
Adhesion Test Methods	<input checked="" type="checkbox"/> New method appears reasonable and will be a resolved issue
Manufacturing Inspection Observations	<input checked="" type="checkbox"/> Responses to initial PAI submitted, likely subject to another PAI
In Vivo Adhesion	<input checked="" type="checkbox"/> FDA completed: Pre-approval required Comparative Wear Study with Xulane®
High Bone Index	<input checked="" type="checkbox"/> FDA anticipated reviewing efficacy and benefit/risk at Advisory Committee
REGULATORY MILESTONES ACHIEVED TO DATE	<input checked="" type="checkbox"/> Achieved Primary Endpoint in Comparative Wear Study & Demonstrate Non-Inferior Adhesion to Xulane® <input checked="" type="checkbox"/> Completed NDA Submission to FDA <input checked="" type="checkbox"/> Completed PAI at Corium <input checked="" type="checkbox"/> Favorable FDA Advisory Committee on Efficacy and Benefit/Risk

TWIRLA APPROVED

PDUFA GOAL DATE: February 16, 2020

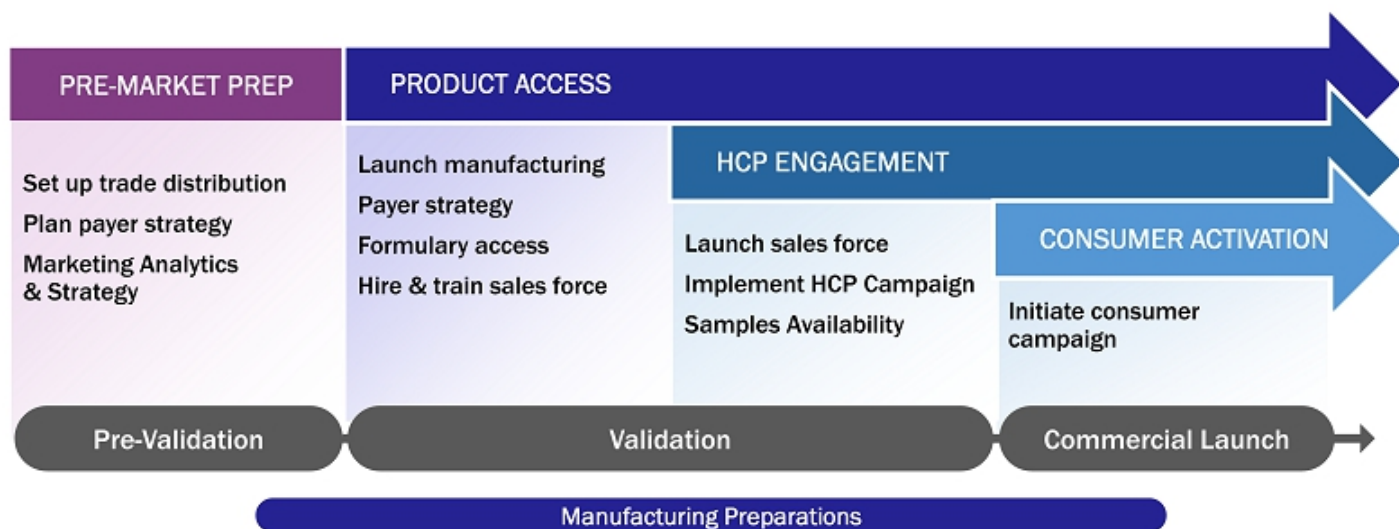
Agile Has Activated Partners to Prepare for Twirla Commercial Readiness

MANUFACTURING	MARKET ACCESS	LAUNCH NETWORK	SALES FORCE
<ul style="list-style-type: none"> ▪ Corium is an experienced contract patch manufacturer ▪ Qualification of commercial scale equipment in final stages ▪ Plan for completion of validation in fourth quarter 	<ul style="list-style-type: none"> ▪ Agile knows its market ▪ Top 8 payers expected to cover majority of commercial lives¹ ▪ Strategic contracting intended to place Twirla in competitive reimbursement position 	<ul style="list-style-type: none"> ▪ Relationships with experienced vendors to facilitate commercial launch ▪ Vendors have expertise in marketing, PR, market access, and supply chain 	<ul style="list-style-type: none"> ▪ Small, targeted sales force (70-100 reps) to launch ▪ Phased hiring linked to formulary acceptance ▪ Focus on high-prescribing Ob/Gyns and women's health NP/PAs



Sources: 1-Berchick E, Hood E, Barnett J., Health Insurance Coverage in the United State 2017
 Haefner, M. America's largest health insurers in 2018

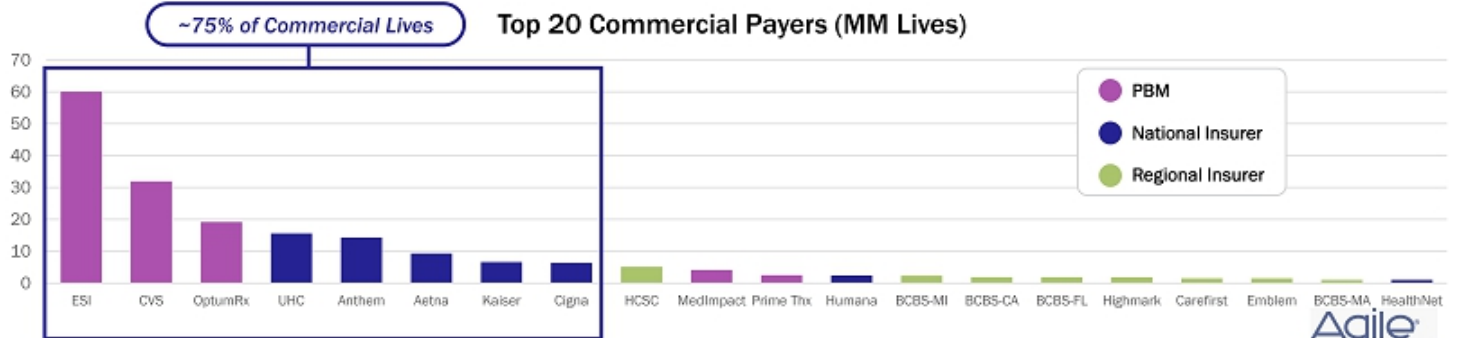
Phased Approach to Commercial Strategy



FDA post marketing requirement and commitment:

- Long-term prospective, observational post-marketing study comparing risks of venous thromboembolism (VTE) and arterial thromboembolism (ATE) in new users of Twirla to new users of other CHCs
- Small residual drug study to analyze EE and LNG content after prescribed wear and to monitor adhesion

Managed Care Strategy: Minimize Access Barriers



Sources: 1-Berchick E, Hood E, Barnett J., Health Insurance Coverage in the United State 2017
 Haefner, M. America's largest health insurers in 2018

AGRX Financial Overview

BALANCE
SHEET

Cash Balances

- \$34.5 million in cash and cash equivalents as of December 31, 2019

FEB. 2020
PERCEPTIVE
DEBT
FACILITY

\$35.0 Million debt facility signed February 10, 2020

- \$20 million disbursed
 - \$5 million in proceeds at signing
 - \$15 million in proceeds at Twirla® approval
- \$15 million upon \$20 million TTM revenue milestone

FEB. 2020
PUBLIC
OFFERING

\$48.4 Million estimated net proceeds from public offering of common stock

- 17.3 million shares sold including underwriters exercise of option
- 87.1 million estimated common shares outstanding at February 25, 2020

Summary of Agile Therapeutics Opportunity

<p>WHAT IS OUR INITIAL FOCUS?</p>	<ul style="list-style-type: none"> ▪ A non-daily, less invasive contraceptive option – Twirla® ▪ Expect to launch into \$3.7B addressable market ▪ 5-8% peak TRx market share estimate 								
<p>WHY ARE WE WELL-POSITIONED TO EXECUTE OUR PLAN?</p>	<ul style="list-style-type: none"> ▪ Experienced management team with the ability to plan and execute ▪ Activated partners to prepare for commercial readiness ▪ Building out internal capabilities 								
<p>WHAT DID WE SUCCESSFULLY COMPLETE IN 2019?</p>	<table border="1"> <thead> <tr> <th data-bbox="448 566 647 589">2019 MILESTONE</th> <th data-bbox="1257 566 1318 589">DATE</th> </tr> </thead> <tbody> <tr> <td data-bbox="448 600 1094 622">Conduct Comparative Wear Study & Meet Primary Endpoint</td> <td data-bbox="1171 600 1404 622">Completed Feb 2019</td> </tr> <tr> <td data-bbox="448 633 948 656">Pre-Approval (PAI) Inspection at Manufacturer</td> <td data-bbox="1171 633 1404 656">Completed Oct 2019</td> </tr> <tr> <td data-bbox="448 667 770 689">Advisory Committee on Twirla</td> <td data-bbox="1171 667 1404 689">Completed Oct 2019</td> </tr> </tbody> </table>	2019 MILESTONE	DATE	Conduct Comparative Wear Study & Meet Primary Endpoint	Completed Feb 2019	Pre-Approval (PAI) Inspection at Manufacturer	Completed Oct 2019	Advisory Committee on Twirla	Completed Oct 2019
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<p>WHAT'S NEXT FOR 2020?</p>	<table border="1"> <thead> <tr> <th data-bbox="448 728 647 750">2020 MILESTONE</th> <th data-bbox="1257 728 1318 750">DATE</th> </tr> </thead> <tbody> <tr> <td data-bbox="448 761 695 784">Twirla FDA-Approval</td> <td data-bbox="1161 761 1420 784">Completed Feb 2020</td> </tr> <tr> <td data-bbox="448 795 783 817">Initial Shipment of Product</td> <td data-bbox="1171 795 1410 817">Projected 2H 2020</td> </tr> </tbody> </table>	2020 MILESTONE	DATE	Twirla FDA-Approval	Completed Feb 2020	Initial Shipment of Product	Projected 2H 2020		
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Appendix

Contraceptive Use by U.S. Women

CONTRACEPTIVE METHOD CHOICE

Most effective method used in the past month by U.S. women, 2014

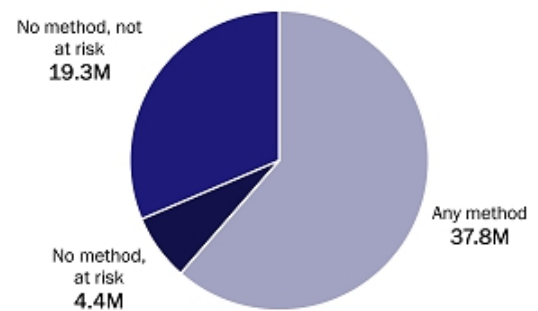
METHOD	No. of women	% of women aged 15-44	% of women at risk of unintended pregnancy	% of contraceptive users
Pill	9,572,477	15.6	22.7	25.3
Tubal (female) sterilization	8,225,149	13.4	19.5	21.8
Male condom	5,496,905	8.9	13.0	14.6
IUD	4,452,344	7.2	10.6	11.8
Vasectomy (male sterilization)	2,441,043	4.0	5.8	6.5
Withdrawal	3,042,724	5.0	7.2	8.1
Injectable	1,481,902	2.4	3.5	3.9
Vaginal ring	905,896	1.5	2.1	2.4
Fertility awareness-based methods	832,216	1.3	2.0	2.2
Implant	965,539	1.6	2.3	2.6
Patch	69,106	0.1	0.2	0.2
Emergency contraception	69,967	0.1	0.2	0.2
Other methods*	234,959	0.4	0.6	0.6
No method, at risk of unintended pregnancy	4,408,474	7.2	10.5	na
No method, not at risk	19,302,067	31.4	na	na
Total	61,491,766	100.0	100.0	100.0

*Includes diaphragm, female condom, foam, cervical cap, sponge, suppository, jelly/cream and other methods. NOTE: "At risk" refers to women who are sexually active; not pregnant, seeking to become pregnant or postpartum; and not noncontraceptively sterile. na=not applicable.

*In 2014

Source: Fact Sheet - Contraceptive Use In the United States, Guttmacher Institute, July 2018

Contraceptive Method Choice (Number of U.S. Women*)



Number of U.S. women using a CHC method* (pill, ring, patch)

10,547,479

Average Price Per Cycle for Branded CHCs (\$WAC)

