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

January 14, 2021
Date of report (Date of earliest event reported)

Agile Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-36464**	**23-2936302**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

101 Poor Farm Road **Princeton, New Jersey**	**08540**
(Address of principal executive offices)	(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 2.02 Results of Operations and Financial Condition.

As discussed below, in connection with its participation in the 39th Annual J.P. Morgan Healthcare Conference on January 14th, 2021, Agile Therapeutics, Inc. (the "Company") updated its corporate presentation to include disclosure that the Company had an estimated $54.5 million of cash and cash equivalents on hand as of December 31, 2020. In the presentation, the Company also reaffirms its projections that, based on the Company's current business plan and the launch of Twirla, its current cash, cash equivalents and marketable securities will be sufficient to meet its projected operating requirements through the end of 2021 and that it expects its gross revenue will be approximately $1 million, reflecting expectations of initial stocking of Twirla by wholesalers.

Because the Company's financial statements for the year ended December 31, 2020 have not yet been finalized or audited, this preliminary statement regarding the Company's cash and cash equivalents as of December 31, 2020 is subject to change, and the Company's actual cash and cash equivalents on hand as of the end of this period may differ materially from this preliminary estimate. Accordingly, you should not place undue reliance on this preliminary estimate.

Item 7.01. Regulation FD Disclosure.

The information set forth in Item 2.02 of this Current Report on Form 8-K (this "Report") is incorporated into this Item 7.01 by reference.

The Company will participate in the 39th Annual J.P. Morgan Healthcare Conference in San Francisco, California, which is being held virtually, on Thursday, January 14, 2021 at 9:10 a.m. Eastern Time, and has updated the corporate presentation that it intends to use at the conference. The Company may use this updated corporate presentation in meetings with investors from time to time as well. In addition to the above-referenced disclosure regarding the Company's cash and cash equivalents as of December 31, 2020, the updates primarily involve financial projections on cash runway and gross revenue, and the Company's commercialization of Twirla® (levonorgestrel and ethinyl estradiol) transdermal system, its first FDA-approved product.

A copy of the Company's updated corporate presentation is attached hereto as Exhibit 99.1 and is hereby incorporated by reference herein.

In accordance with General Instructions B.2 and B.6 of Form 8-K, the information included in Item 2.02 and Item 7.01 of this Report 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 of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Forward-Looking Statements

Certain information contained in this Report may include "forward-looking statements." Our use of 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 may identify these forward-looking statements.

In particular, statements regarding our projected cash position and gross revenue are examples of such forward-looking statements. Such forward-looking statements are subject to important risks and uncertainties, including, but not limited to, risks related to our ability to maintain regulatory approval of Twirla, the ability of our third party manufacturer, Corium, to produce commercial supply in quantities and quality sufficient to satisfy market demand for Twirla, our ability to successfully commercialize and obtain market access for Twirla, the successful development of our sales and marketing capabilities, the accuracy of our estimates of the potential market for Twirla, our ability to achieve our target formulary access goals, 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, the effects of the COVID-19 pandemic on our operations and the operations of third parties we rely on as well as on our potential customer base, 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. These forward-looking statements are made only as of the date of this Report and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances. 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Agile Therapeutics, Inc. Presentation dated January 14, 2021.

SIGNATURES

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

Agile Therapeutics, Inc.

Dated: January 14, 2021

By: /s/ Alfred Altomari
Name: Alfred Altomari
Title: Chairman and Chief Executive Officer


Agile Therapeutics (AGRX)
39th Annual J.P. Morgan Healthcare Conference
January 14, 2021
Agile THERAPEUTICS
NASDAQ: AGRX
1

Forward-Looking Statements

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 the market availability and uptake of Twirla®, our projected cash position, the expected effects of COVID-19 on our business and the expected structure of our commercialization plan for Twirla are examples of such forward-looking statements. These forward-looking statements are subject to important risks and uncertainties, including, but not limited to, risks related to our ability to maintain regulatory approval of Twirla, the ability of our third party manufacturer, Corium, to produce commercial supply in quantities and quality sufficient to satisfy market demand for Twirla, our ability to successfully commercialize and obtain market access for Twirla, the successful development of our sales and marketing capabilities, the accuracy of our estimates of the potential market for Twirla, our ability to achieve our target formulary access goals, 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, the effects of the COVID-19 pandemic on our operations and the operations of third parties we rely on as well as on our potential customer base, 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. These 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 circumstances. 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.

Who We Are

- A commercial-stage company dedicated to building a robust Women's Health Franchise
- Launched Twirla® (levonorgestrel and ethinyl estradiol) transdermal system, our first FDA-approved product, in December 2020
  - A new non-daily, non-invasive contraceptive patch
  - Lowest dose of estrogen available in a transdermal option, along with a 120 mcg daily dose of levonorgestrel, a well-known progestin with a long history of use in the category
  - Twirla enters a $4.1B addressable market

Twirla™
(levonorgestrel/ethinyl estradiol)
120/30 mcg/day transdermal system

Weekly Contraceptive Patch

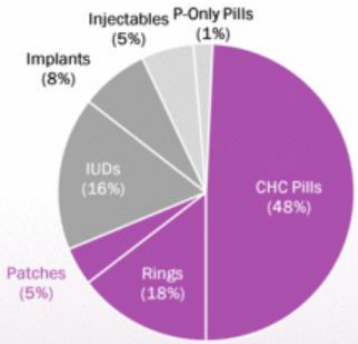
$4.1B
Addressable Market

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.

U.S. Hormonal Contraceptive Market is a Significant Opportunity

$5.7 Billion U.S. Contraceptive Market (2019 Estimates)

Combined Hormonal Contraception (CHC)	Progestin-Only (P-Only)	Long-Acting Reversible Contraception (LARC)
CHC Pill, Ring, Patch	P-only Pill, Injection	IUD, Implant
$4.1 Billion	*$300 Million*	*$1.3 Billion*



CHC Pills + Ring + Patch =
$4.1 Billion
Potential Addressable Market for
Twirla™

Twirla WAC of $159.75
vs Top-16 branded CHC products of approximately $169 avg. per unit or month of contraception

P-only Pills category includes emergency contraceptive prescriptions. Not Shown: "All Other" category with <1M TRx
Sources: IQVIA NSP through Dec 2018; ACOG FAQs; IMS NPA December 2019 (MAT) and MediSpan Price Rx Select March 2020

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

Twirla Designed to Fill A Hormonal Birth Control Market Need

Twirla™

HORMONE PROFILE

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

NON-DAILY

Patch Regimen: Once-a-week

Pill Regimen: Once-a-day

LESS INVASIVE

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

Source: Qualitative consumer market research, Adelphi Research 2016

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	Average of Analog Brands
15%	9.6%

Twirla™ 5-8%*

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

Qualitative and Quantitative HCP and Consumer market research, Adelphi Research 2016
Quantitative HCP market research, MarketVision Research 2019

Partnership with Syneos Provides Ability to Launch with an Insight-Driven Innovative Sales Approach

Syneos Capabilities

- 3,000+ Field Personnel
- 50,000 Called on HCPs
- Weekly Sales Team Focus Groups
- 19 Virtual Launch Meetings

Critical Insights

Key Insights

- The pandemic highlighted that traditional representatives were not effective in virtual interactions and resources were not approved for virtual utilization
- Field teams often brought on too close to launch with very condensed preparation time
- Traditional call plan approaches and call plan targeting can lead to inefficient territory design

Partnership with Syneos Provides Ability to Launch with an Insight-Driven Innovative Sales Approach

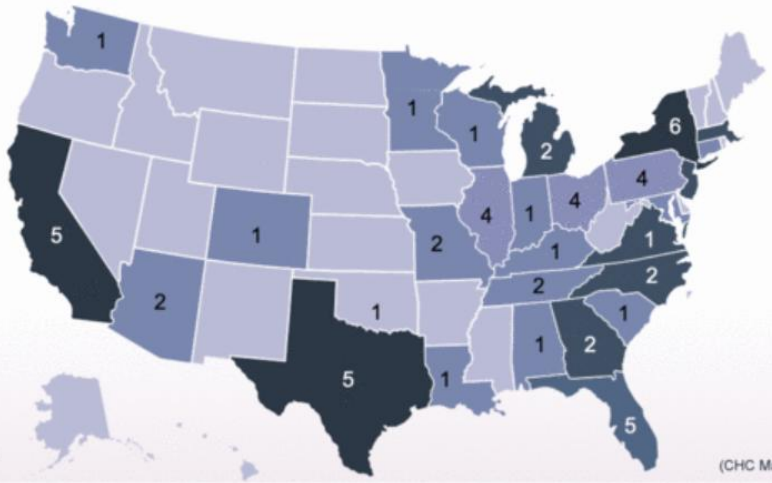
Key Insights	The pandemic highlighted that traditional representatives were not effective in virtual interactions and resources were not approved for virtual utilization	Field teams often brought on too close to launch with very condensed preparation time	Traditional call plan approaches and call plan targeting can lead to Inefficient territory design
Strategies	• New Recruiting Profile: effective virtual interaction • Enhanced training on effective virtual interactions • All materials approved for virtual/F2F interactions • Upgraded technology for virtual interactions	• Leadership team hired/engaged early. Field teams hired/trained/engaged in mid-October, several months prior to launch • Territories/targets profiled to understand office protocols/COVID-19 policies/appointments secured • 8-week virtual training program: best in class clinical knowledge, virtual selling skills, competitive/ reimbursement landscape understanding	• Targeting based on office decile vs individual HCP's • Virtual representatives aligned/reporting to regional leaders with aligned goals/incentives • Region Sales Leaders empowered to allocate resources to ensure most effective coverage within geographies

Strong Sales Team with Deep Experience and Commitment to Success

Experience	National Sales Leader	Regional Leaders	Region Virtual Representatives	Territory Representatives
Pharmaceutical Industry	34 years	AVG 16 years	AVG 25.3 years	AVG 9.5 years
Sales Leadership	30 years	AVG 17.2 years		
Women's Health	18 years	AVG 8.2 years	AVG 8.1 years	AVG 4.8 years
Launch	>15 launches	>60 launches	90% with a minimum of one launch	>85% with a minimum of one launch

65 Sales Professionals Aligned to Highest-Volume Geographies and Target Provider Offices

In Addition, 8 Virtual Sales Professionals Aligned to Sales Leaders to Drive Region Success



MA – 1, CT – 2, RI – 1, NJ – 3, MD – 1, DC - 1

Total CHC TRXs

- 0- <985K
- 985K- <2.0M
- 2.0M- <3.0M
- 3.0M- <3.9M
- 3.9M- <4.9M
- 4.9M- <5.9M

Source: Symphony Health Metys

(CHC Market 12 Months Ending December 2019)

Critical Customer Insights: HCP

OB/GYNs and NPs/PAs invest significant time into contraceptive counseling to inform patient shared decision-making approach.

There is a "method gap" between OCPs and LARCs where Twirla can fit in.

The TWIRLA clinical trial design and diverse study population help overcome historic "Patch Baggage" and skepticism, allowing HCPs to provide representative data to more of their patients.

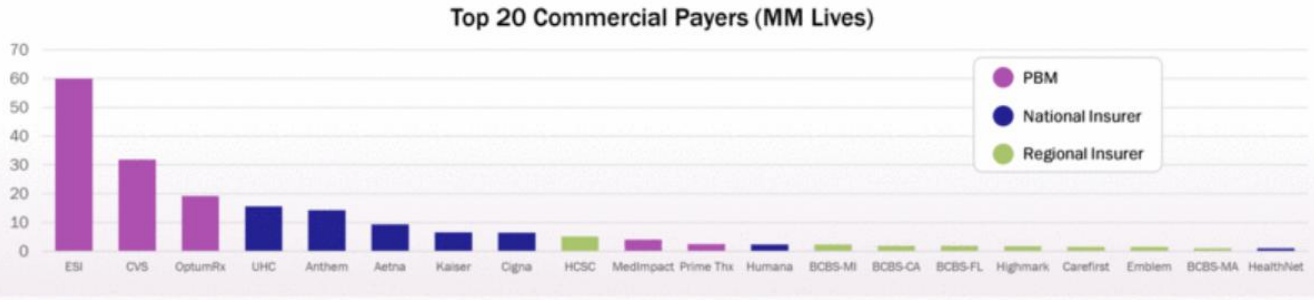
HCP Flexible and Adaptable Launch

Managed Care Strategy: Minimize Access Barriers

Twirla® Managed Care Strategy

- Affordable Care Act
- State Mandates
- Pricing Strategy

→ Strategy Informed Sales Force Rollout



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

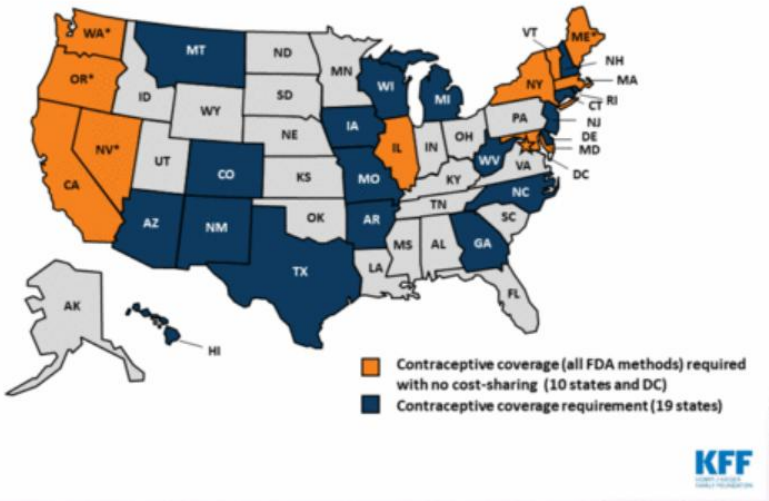
Minimize Access Barriers for Patients and Providers by Obtaining Rapid Formulary Positions ($0 Co-Pay)

- Current negotiations underway with all key PBMs/health plans to secure rapid formulary reviews
- Achieved ~50% formulary access at launch
  - Target Goal: 85% formulary access by end of 2021
- Market access support at launch
  - Education and third-party support to assist HCPs with immediate submission of medical need requests for no-cost coverage
  - Co-Pay card reimbursement assistance for limited/no out-of-pocket costs
  - Full-month sample supplies for patient trial

Partnership with Ashfield Market Access to Support Reimbursement Strategies and Execution

- Contraceptive class behaves differently from most other categories as a result of contraceptive mandates at both the federal and state levels
- A limited number of PBMs and their associated health plans control the majority of prescriptions for contraception
- Limited management within the category, however each PBM/plan has its own processes and policies in place related to timing of formulary reviews for new products
  - Approximately 90-180 days from product availability to review

Ten States Require Contraceptive Coverage of All FDA Methods and Prohibit Restrictions and Delays



Source: Kaiser Family Foundation State Health Facts

The Affordable Care Act (ACA) Was Designed with Goal of Enabling Women to Access Contraceptives at No Cost

- Federal Contraceptive Mandate requires coverage of a minimum of one option in each of 18 contraception categories, of which patch is included.
- If a provider recommends a specific product, plans must cover it without cost-sharing.

We Are Providing Tools to Help Patients with Limited Coverage to Twirla

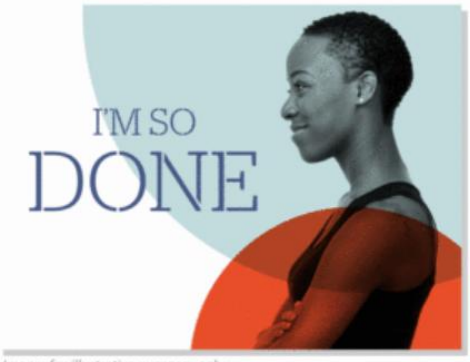
ACA education and letters of medical necessity will be provided to prescribing HCPs.

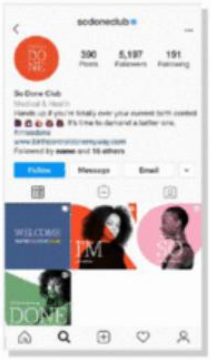
Since plans are required to have a "waiver" process for women who have a medical need for contraceptives, our reps will provide educational support on the ACA to HCPs who wish to prescribe Twirla to patients without coverage.

A Twirla Co-Pay card reimbursement assistance will be available to offer limited/no out-of-pocket costs.

As little as $0 co-pay assistance offered for the first month's fill of Twirla, with as little as $25 co-pay assistance following for each of the next 5 months.
This will allow HCPs time to request coverage under the ACA.

Unbranded Campaign: "I'm So Done"





Images for illustrative purposes only.

I'm so done with worrying so much ◆ I'm so done with not knowing my options ◆ I'm so done with kale ◆ I'm so done with diaphragm's whole put-it-in, take-it-out process ◆ I'm so done with dieting ◆ I'm so done with winter ◆ I'm so done wondering if _____ ◆ I'm so done following the crowd

Unbranded Campaign Ecosystem

Each tactic will have its own user path, but ultimately the goal of the campaign is to educate engagers on their birth control options and enter them into the CRM system.

Images for illustrative purposes only

Support Resources are Available for All Twirla Patients

Nurse Educator Support

Dedicated Twirla Nurse Educators available as not only the entry point for patch replacement requests, but also for questions about Twirla

Patch Replacement Program

For eligible patients, convenient access to a Twirla patch replacement, at no additional out of pocket cost to the patient, with home delivery

"The Loop": Insight-Driven Content

The Loop will live within the Twirla.com website and offer support, resources and ever-changing fun content to keep Twirla top of mind as women navigate through their birth control journey

Critical Customer Insights: Patient

Her life is full by design and she desires a birth control method that enables her to remain active and on-the-go.

She has birth control discussions with her trusted friends — a key source for her information about various methods and side effects.

She is hindered by the **same-time-every-day pill burden** and **finds invasive methods unsettling.**

360° Consumer Launch

LEARNING CURVE SUPPORT
Application video
Nurse educator hotline

MEDIA ECOSYSTEM
Brand social media
Influencer partnerships
Paid and earned media

ADHERENCE TOOLS
Text and email reminders

TWIRLA.COM
Product information
Conversation starters
Application video
The LOOP:
Unique bonus content

POINT OF CARE TOOLS
Digital displays
New Patient brochure
User brochure
Copay cards

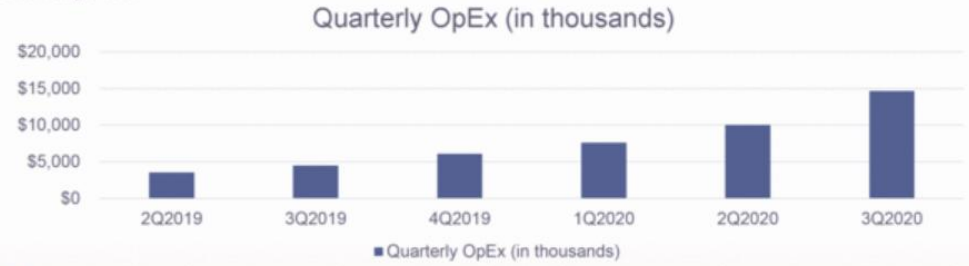
PATCH REPLACEMENT
Premium box with support brochure

COPAY SUPPORT
Print or digital card

AGRX 2020 Financial Snapshot

Operating Expenses

- As of November 6, 2020, the Company narrowed its operating expense guidance for the full year 2020 to be in the range of $52 million to $54 million, with general and administrative expenses accounting for approximately 70% of the spending as we build out our commercial infrastructure. The Company's operating expense guidance includes $2.7 million to $3 million of non-cash stock compensation expense.



2020 Revenue

- The Company expects its gross revenue in the fourth quarter of 2020, reflecting expectations of initial stocking of Twirla by wholesalers, to be approximately $1 million.

Access to Capital/Cash Guidance

Based on the Company's current business plan and ongoing launch of Twirla, the Company believes its estimated $54.5 million of cash, cash equivalents, and marketable securities as of December 31, 2020 (unaudited) will be sufficient to meet its projected operating requirements through the end of 2021.

PERCEPTIVE ADVISORS 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
- Additional $15 million potentially available in 2021

SHARES OUTSTANDING

- Approximately 87.6 million common shares outstanding as of December 31, 2020
- The Company filed a new universal shelf registration statement with the SEC for the issuance of common stock, preferred stock, warrants, rights, and debt securities

Strategy To Enhance Shareholder Value

The Company believes that building a U.S. women's health franchise on the foundation of Twirla's commercial success can enhance value for our shareholders. A successful launch of Twirla is our primary focus.

- Reevaluation and potential development of our internal pipeline candidates will commence in 2021
- We are open to potentially acquiring news assets to expand our reach in women's health

We have sought out and will continue to explore partnerships and opportunities that leverage our existing infrastructure:

- Co-promotion within the U.S.
- Partnerships outside of the U.S.
- Any other opportunities that will enhance shareholder value

Continue To Follow Along

Agile Therapeutics

- Website: www.agiletherapeutics.com
- Twitter: @AgileTher
- LinkedIn: @Agile Therapeutics

Investor Contact

- Matt Riley
- Head of Investor Relations & Corporate Communications
- mriley@agiletherapeutics.com

Twirla

- Website: www.twirla.com
- Instagram: @twirla_us
- Facebook: Twirla® (levonorgestrel and ethinyl estradiol) transdermal system

I'm So Done

- Website: www.BirthControlDoneMyWay.com
- Instagram: @SoDoneClub
- Facebook: @SoDoneClub