

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

May 23, 2022
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.)

500 College Road East, Suite 310
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 5.02. Departure of Directors or Principal Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

As previously disclosed, on May 20, 2022, Dennis P. Reilly, Chief Financial Officer of Agile Therapeutics, Inc. (the “Company”), notified the Company that he will voluntarily resign from his position in order to retire, which is expected to be effective on May 31, 2022.

On May 23, 2022, the Board of Directors of the Company appointed Jason Butch, the Company’s Vice President and Chief Accounting Officer, to serve as Principal Financial Officer, in addition to his current role as Principal Accounting Officer, effective upon the effective date of Mr. Reilly’s resignation. Mr. Butch’s compensation will remain unchanged at this time.

Mr. Butch, age 45, has served as the Company’s Vice President and Chief Accounting Officer since July 2020. Prior to joining Agile, Mr. Butch served as Corporate Controller at Teligent, Inc., a publicly traded pharmaceutical company, from April 2019 to July 2020. Prior to that, Mr. Butch served in roles of increasing responsibility at MISTRAS Group, Inc., a publicly traded engineering services company, including as Products and Systems Controller from February 2012 to October 2013, and as Corporate Controller from October 2013 to October 2018. Previously, Mr. Butch served as Audit Senior Manager at BDO USA, LLP. Mr. Butch holds both a B.B.A. and an M.B.A. from Saint Bonaventure University.

There are no arrangements or understandings between Mr. Butch and any other person pursuant to which he was selected for the positions to which he was appointed. There are no family relationships between Mr. Butch and any director or executive officer of the Company and Mr. Butch has no direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K.

Item 7.01. Regulation FD Disclosure.

As previously announced, the Company will participate in the H.C. Wainwright Global Investment Conference in Miami, Florida, which is being held on Tuesday, May 24, 2022, at 10:00 a.m. Eastern Time, and has updated the corporate presentation that it intends to use at the conference. Specifically, the Company has provided a business update and guidance on demand for Twirla and expected operating expenses in the second quarter 2022. In addition to implementing its business plan to grow demand for Twirla®, the Company is evaluating its operating expenses. The Company’s goal is to optimize its available cash by engaging in targeted, focused spending in support of growing Twirla, while also seeking reductions in its spending in other areas of its operations.

As previously disclosed in the Company’s Form 8-K filed on May 23, 2022, based on its current performance and a review of operating expenses, the Company is providing guidance indicating that it expects total cycles of Twirla® in the range of 20,000 to 22,000 in the second quarter of 2022, which represents growth of approximately 21% to 33% over the first quarter of 2022. The Company also projects operating expenses for the second quarter of 2022 in the range of \$12.5 million to \$13.5 million, which represents a 15% to 21% reduction in operating expenses over the first quarter of 2022.

The reduction of expenses in the second quarter is expected to be driven by the elimination of cash bonuses for the Company’s officers and members of senior management, which was previously disclosed on May 12, 2022, and reductions in general and administrative spending. Additionally, the first quarter 2022 operating expenses included the purchase of samples which are expected to be utilized through-out 2022, and the Company does not plan to purchase additional samples in the second quarter of 2022. The Company continues to evaluate its operating structure and the second quarter 2022 reductions are intended to be part of a longer-term strategy to reduce the Company’s operating expenses on a continuing basis. The Company has focused its reduced spending in the areas of general and administrative support, research and development activities, timing of its direct-to-consumer activities, and non-essential operational activities.

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 product demand and operating expenses, the updates primarily involve the Company’s marketing and commercialization plans for Twirla®.

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 this Item 7.01, including Exhibit 99.1 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 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 planned management changes, strategy and business plans, including with respect to Twirla, projected product sales, cost reduction measures and operating expenses 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 and the labeling under any approval we obtain, the ability of Corium to produce commercial supply in quantities and quality sufficient to satisfy market demand for Twirla, our ability to successfully enhance the commercialization and increase the uptake for Twirla, the size and growth of the markets for Twirla and our ability to serve those markets, regulatory and legislative developments in the United States and foreign countries, our ability to obtain and maintain intellectual property protection for Twirla and our product candidates, the effects of the ongoing COVID-19 pandemic on our commercialization efforts, clinical trials, supply chain, operations and the operations of third parties we rely on for services such as manufacturing, marketing support and sales support, as well as on our potential customer base, our ability to maintain compliance with the listing requirements of the Nasdaq Capital Market, 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Investor Presentation dated May 23, 2022
104	Cover Page Interactive Data File (Embedded within the Inline XBRL Document).

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: May 24, 2022

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: Chairman and Chief Executive Officer

Agile Therapeutics Corporate Presentation

May 2022

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. Our forward-looking statements are based on current beliefs and expectations of our management team that involve risks, potential changes in circumstances, assumptions, and uncertainties, including statements regarding our ongoing and planned manufacturing and commercialization of Twirla®, the potential market acceptance and uptake of Twirla®, including the increasing demand for Twirla, our partnership with Afaxys and its ability to promote growth, our future plans with respect to our debt financing from Perceptive Advisors, our operating expenses, financial condition, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures and our expected financing needs and sources of financing, our ability to maintain compliance with the listing requirements of the Nasdaq Capital Market, regulatory and legislative developments in the United States, and the expected benefits of our marketing and sales distribution strategies generally. Any or all of the forward-looking statements may turn out to be wrong or be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. These forward-looking statements are subject to risks and uncertainties including risks related to our ability to maintain regulatory approval of Twirla and the labeling under any approval we obtain, the ability of Corium to produce commercial supply in quantities and quality sufficient to satisfy market demand for Twirla, our ability to successfully enhance the commercialization and increase the uptake for Twirla, the size and growth of the markets for Twirla and our ability to serve those markets, regulatory and legislative developments in the United States and foreign countries, our ability to obtain and maintain intellectual property protection for Twirla and our product candidates, the effects of the ongoing COVID-19 pandemic on our commercialization efforts, clinical trials, supply chain, operations and the operations of third parties we rely on for services such as manufacturing, marketing support and sales support, as well as on our potential customer base, our ability to maintain compliance with the listing requirements of the Nasdaq Capital Market, and the other risks set forth in our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q. 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.

Company Overview

Who We Are

- Agile Therapeutics® is a women's healthcare company dedicated to fulfilling the unmet health needs of today's women
- Commercial-stage company aspiring to build a robust Women's Health Franchise
- Our product and product candidates are designed to offer women more freedom and flexibility through additional contraceptive options
- Currently focused on contraception, specifically our first FDA-approved product Twirla® (levonorgestrel and ethinyl estradiol) transdermal system
- Headquartered in Princeton, NJ and senior leadership largely comprised of J&J alumni responsible for the launch of Ortho Evra

Establish Agile in
Contraceptive Market
with Twirla®

Become a Contraceptive
Market Leader

Broaden Women's
Health Portfolio in Areas
of Unmet Need



NASDAQ: AGRX

Agile Therapeutics Outlook

Key Elements of Our Investment Thesis

- 1. We Believe Twirla is Gaining Revenue Momentum**
 - Successive quarters of double-digit growth and demand, which we expect to continue into Q2 2022
- 2. Planning Significant Reductions in OPEX Spending**
 - We have reduced OPEX over the past few quarters and plan further reductions in Q2 2022
- 3. We have sought out and will continue to explore partnerships and opportunities that leverage our existing infrastructure**

AGRX Plan to Accelerate Demand (Cycles) and Reduce OPEX*



Our Product

Twirla® is the first and only birth control patch delivering a low dose of estrogen.¹⁻⁵

A LOWER ESTROGEN DOSE THAN OTHER CONTRACEPTIVE PATCHES

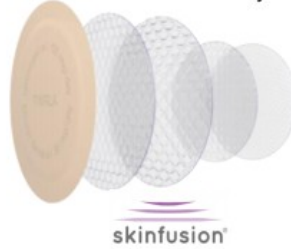
Twirla delivers 30 mcg of estrogen daily, **the lowest exposure of estrogen in a transdermal contraceptive option.**²⁻⁴



Not actual size.
For illustrative purposes only.

WOVEN, FLEXIBLE FABRIC

Only Twirla uses **Skinfusion® patch technology** for consistent drug delivery and to help maintain adhesion. Twirla is made with a soft, flexible fabric designed to contour with a woman's body.



skinfusion®

DEMONSTRATED SAFETY PROFILE

In the SECURE Trial, conducted in a large and diverse group of women, **Twirla was found to be a safe and well-tolerated weekly option** in women with a BMI <30 kg/m² for whom a combined hormonal contraceptive is appropriate.^{1,2}

PURPOSEFULLY INCLUSIVE TRIAL

Efficacy and safety were established in a purposefully inclusive trial that featured a diverse study population, **closely representative of the demographics of women across the US.**¹

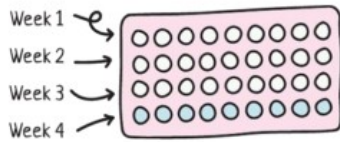
Twirla® is a weekly hormonal birth control patch for women with a body mass index (BMI) less than 30 kg/m² who can become pregnant. Twirla is less effective in women with a BMI of 25 kg/m² or more and should not be used in women whose BMI is 30 kg/m² or more.

References: 1. Nelson AL, Kaunitz AM, Kroll R, et al. Efficacy, safety, and tolerability of a levonorgestrel/ethinyl estradiol transdermal delivery system: phase 3 clinical trial results. *Contraception*. 2021;103(3):137-143. 2. Twirla [prescribing information]. Princeton, NJ: Agile Therapeutics, Inc.; 2020. 3. Xulane [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals; 2020. 4. Zafemy [prescribing information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; 2021. 5. Centers for Disease Control and Prevention. U.S. medical eligibility criteria for contraceptive use, 2016. *MMWR Morb Mortal Wkly Rep*. 2016;65(3):1-104.

Twirla: Birth Control Designed to Fit Her Life

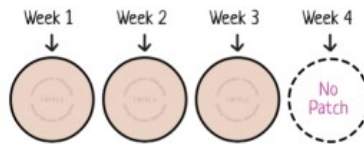
Weekly. Self-Administered. Just 3 Patches a Month.

THE DAILY PILL ROUTINE:



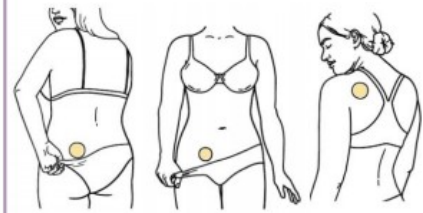
Stop and take it every day, ideally at the same time each day for at least 21 days each month.

WITH TWIRLA, SHE CHANGES THE PATCH JUST ONCE A WEEK FOR 3 WEEKS EACH MONTH



During the fourth week of the cycle, she wears no patch and should expect her period.

TWIRLA MAY BE APPLIED TO ONE OF THE FOLLOWING LOCATIONS ON THE SKIN



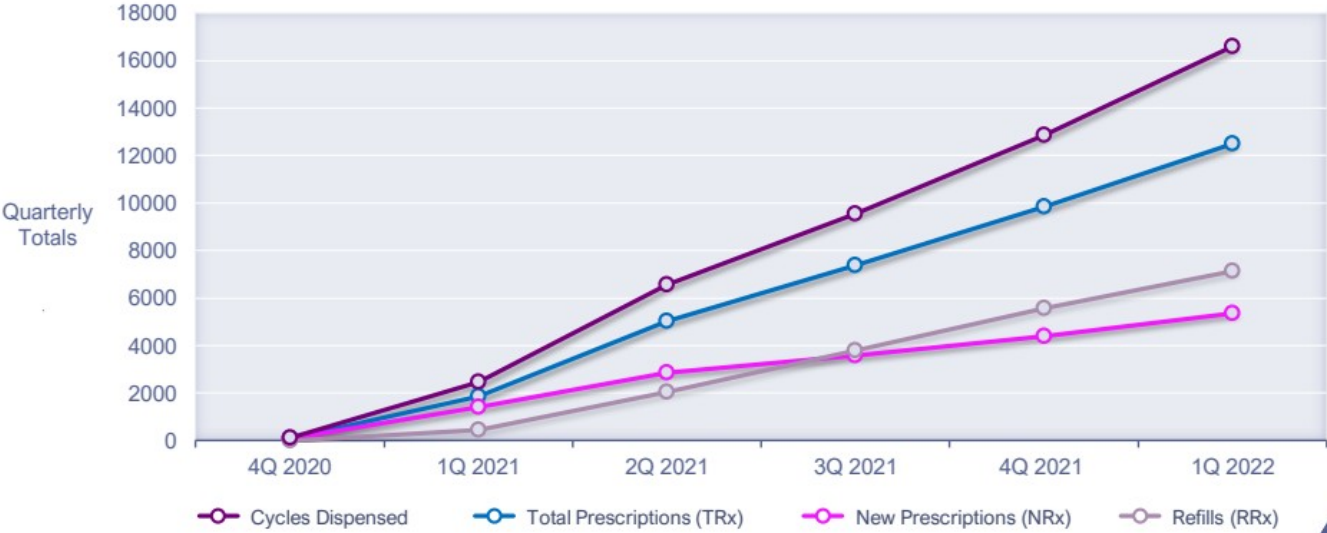
Buttock

Abdomen

Upper Torso
(excluding
breasts)

Twirla Performance Update: Building Momentum

Twirla Growth Based on Key Performance Metrics (Quarterly)



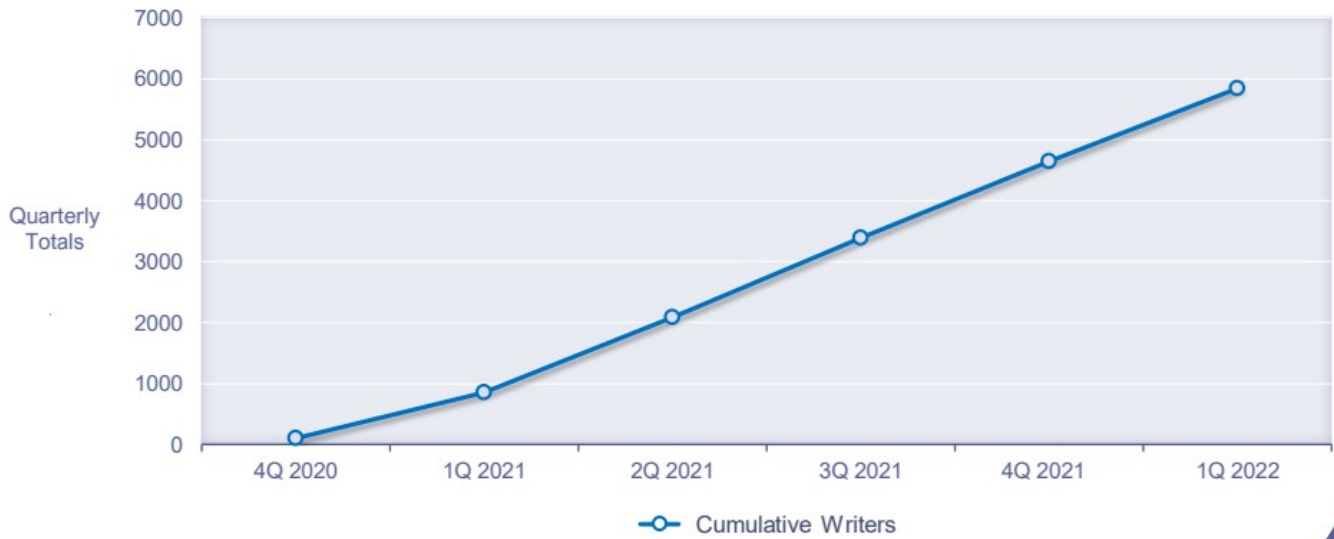
Cycles Dispensed Reflects All Channels as Reported by Symphony Metys
TRx, NRx, and RRx Reflect Retail-Only Data as Reported by Symphony Metys

Twirla Demand Metrics: Q2 2022 is Off to a Strong Start in Retail and Non-Retail Channels



Prescription data contained herein is from Symphony Health Solutions. Similar data is available from other sources. Cycles = number of 3-patch packages dispensed; TRx = total prescriptions dispensed through retail channels; Non-retail = clinics, hospitals, and other entities dispensing prescriptions direct to patient

Growing Number of Twirla Prescribers (Quarterly)



Reflects Retail-Only Data as Reported by Symphony Metys

Business Plan Designed to Grow Twirla

Business Plan Execution to Sustain Momentum



- In Jan. 2022, co-promotion program launched with Afaxys through their group purchasing organization (GPO) and Afaxys Pharma
- GPO provides services to non-retail channel, while Afaxys Pharma gains potential access to over 25,000 accounts, including college/university health centers and Planned Parenthoods
- Agile believes Afaxys alliance can drive non-retail growth and expects to see contribution from this channel ramp up throughout 2022

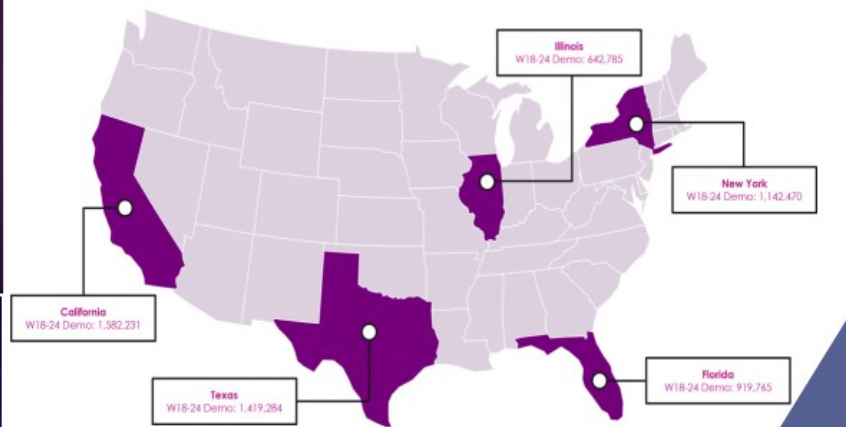
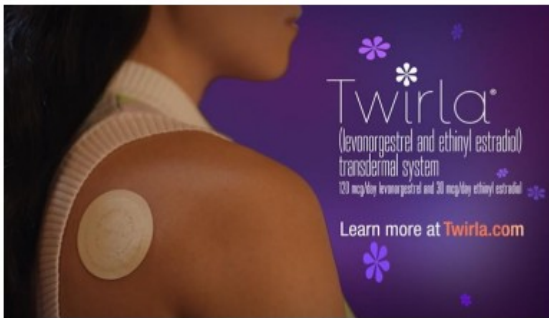


- Agile has placed targeted focus on California, the largest U.S. market for contraceptives, through preferred positioning on Medi-Cal formulary
- California is also the largest Medicaid program in the U.S. and one-third of the existing contraceptive patch market comes from Medicaid
- Medi-Cal provides healthcare to approximately 15 million beneficiaries, and with Twirla now active on the Medi-Cal formulary, increasing Twirla awareness and adoption in California is a priority

Introducing the Twirla Connected TV (CTV) Commercial

Refined Consumer Target Audience to Maximize Impact:

Initial Phase of Regional Strategy Covered an estimated 41-45% of W18-24 Across the Country



Update on Affordable Care Act and Reimbursement

Government Scrutiny on Compliance with Contraceptive Mandate

As plans begin to evaluate their practices to comply with requirements, access to newer contraceptives expected to improve

Health
The ACA has a birth control guarantee. Senators are pushing for better enforcement.
Patients and health care providers have reported contraception-related medical bills that should not be permitted under the law, they say.

Insurance Companies Are Giving Ridiculous Reasons For Not Covering New Birth Control Methods
Private insurers are doing everything they can to shirk the government's birth control coverage requirement.

DENIED
The ACA guarantees full contraceptive coverage. Why are women getting denied?
Birth control is a right, but insurance companies are defying the law. They must be held accountable.
By Shannon Shelton Miller | Feb 23, 2022
ACCESS & AFFORDABILITY
ACCESS

POLITICS
(Not so) free birth control: White House puts pressure on insurance companies over ACA requirement

HOUSE COMMITTEE LEADERS URGE BIDEN ADMINISTRATION TO ENSURE HEALTH INSURANCE COMPANIES COVER FULL RANGE OF FDA-APPROVED CONTRACEPTIVES
Oct 7, 2021 | Press Release
The Letter Comes After Reports of Coverage Denials and Extensive Medical Management

HEALTH & CONSUMER AFFAIRS
Why Protecting Birth Control Is Needed Now More Than Ever
Feb 25, 2022, 10:15am Julie F. Kay
It's been over a decade since the Affordable Care Act mandated contraception access—and yet many people still struggle to get the birth control they need.

Democratic Women's Caucus, Pro-Choice Caucus Send Letter to the Departments of Health and Human Services, Labor, and Treasury to Improve Birth Control Access
March 10, 2022 | Press Release
CONTRACEPTION, MICHIGAN, MICHIGAN, GR...

Financial Update & Outlook

Guidance & Recent Financial Results

Second Quarter 2022 Guidance

Total Cycles: We expect Total Cycles in Second Quarter 2022 to be in the range of 20,000 to 22,000 - representing approximately 21% to 33% quarter-on-quarter growth.

Total Operating Expenses: We expect Operating Expense spending in Second Quarter 2022 to be in the range of \$12.5 million to \$13.5 million - representing approximately 15% to 21% quarter-on-quarter reduction in OPEX.

First Quarter 2022 Financial Results

Net Revenue: In the first quarter 2022, the Company reported net product sales revenue of \$1.8 million.

Total Operating Expenses: Total operating expenses were \$15.8 million for the first quarter of 2022. The Company plans to continue to optimize its cash by engaging in targeted, focused spending in support of growing Twirla, while seeking reductions in other areas of its operations.

Cash and Cash Equivalents: As of March 31, 2022, the Company had \$3.7 million of cash and cash equivalents. On April 8, 2022, the Company received \$4.7 million of proceeds from the sale of net operating losses under the state of New Jersey's Technology Business Tax Certificate Transfer Program.

Update on Financing Plan

1.

Work Down Debt Facility with Perceptive Advisors

- In Jan. 2022, Company paid back \$5M to Perceptive, reducing outstanding debt to \$15M
- Company plans to make additional payment of \$5M in exchange for relief on financial covenants

2.

Regain Compliance with Nasdaq

- The Company's stock is now trading above the minimum bid requirement and was notified by Nasdaq on May 11, 2022 that it had regained compliance

3.

Raise Additional Capital

- Company plans to remain flexible and will continue to evaluate all financing options, including recently-established ATM and further equity offerings

Commitment to Enhancing 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.

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.
- Other opportunities that will enhance shareholder value

Beyond Twirla, opportunities include:

- Evaluation of our internal pipeline candidates will continue in 2022
- Explore potential acquisition of new assets to expand our reach in women's health

Agile Therapeutics Outlook

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 - We have reduced OPEX over the past few quarters and plan further reductions in Q2 2022
- 3. We have sought out and will continue to explore partnerships and opportunities that leverage our existing infrastructure**

Continue To Follow Along

Agile Therapeutics

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

Twirla

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



[Click Here to View a Snapshot of Our Twirla Consumer Advertising](#)

or visit:

www.agiletherapeutics.com/our-product/

Investor Contact

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