



## Agile Therapeutics Reports First Quarter 2022 Financial Results and Provides Corporate Update

May 12, 2022

*Twirla Experienced Another Quarter of Double-Digit Demand Growth in First Quarter 2022*

*Twirla Business Plan Progressing*

*Company Anticipates Future 2022 Quarterly Operating Expenses to be Lower*

*Management to Host Conference Call Today, Thursday, May 12, 2022 at 4:30 p.m. ET*

PRINCETON, N.J., May 12, 2022 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today reported financial results for the three months ended March 31, 2022 and provided a corporate update.

"We produced another quarter of double-digit growth in key prescription data for Twirla while also increasing revenue and reducing cash burn," said Agile Therapeutics Chairman and Chief Executive Officer Al Altomari. "Based on the prescription data trends we are seeing so far in the second quarter and the advancement of our Twirla business plan, we currently expect to report a fourth consecutive quarter of strong demand growth for the second quarter 2022 and provide further confidence that our business plan is delivering."

### **First Quarter and Recent Corporate Updates**

- As previously reported in April 2022, Twirla experienced another quarter of double-digit demand growth. From the end of the fourth quarter 2021 to the end of the first quarter 2022, key metrics for Twirla demand increased:
  - Total cycles dispensed grew 29%
  - Total prescriptions (TRx) grew 27%
  - New prescriptions (NRx) grew 22%
  - Refills (RRx) grew 31%
  - Total prescribers grew 26%
- The Company's three-part Twirla business plan for 2022 is contributing to continued growth momentum for Twirla. Updates include:
  - Partnership with Afaxys
    - In January 2022, the Company launched a co-promotion program with Afaxys, through their group purchasing organization (GPO), which primarily provides services to the non-retail channel, and Afaxys Pharma, which has potential access to over 25,000 accounts, including college and university student health centers and Planned Parenthoods.
    - During the first quarter of 2022, the Company focused on initiating and mobilizing the Afaxys partnership and believes it is beginning to contribute to Twirla revenue into April and May 2022. The Company expects that the alliance with Afaxys can continue to drive non-retail growth throughout 2022.
  - Targeted Focus on California
    - The Company is focused on growing the Twirla brand in California, the largest U.S. market for contraceptives, through preferred positioning on Medi-Cal formulary.
    - 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 through direct-to-consumer (DTC) marketing is a priority.
    - The Company is beginning to see an increase in Twirla market share and Twirla prescribers in California, both of which it believes are attributable to the existing sales team and advertising via both general and targeted media.
  - Launch of DTC Commercial on Connected TV (CTV)
    - In late March 2022, the Company launched its first connected TV (or CTV) advertisement, focusing on women in the targeted Twirla age demographic of 18-24 years in states that have large markets for contraceptives and potentially strong commercial coverage for Twirla.
    - The first month of data for the ad suggests that target consumers are being effectively exposed to the ad at a frequency of approximately twice per week and that a significant majority of the viewers are not skipping through the ad.

- Updates on financing plan:
  - Part 1: Work Down Debt Facility with Perceptive Advisors (“Perceptive”)
    - There are no plans to further leverage the Company and additional funds will not be added under the debt facility.
    - In January 2022, the Company paid back \$5 million to Perceptive, reducing its outstanding debt to \$15 million.
    - In the second quarter 2022, the Company plans to make another payment of \$5 million in principal to Perceptive in exchange for relief on financial covenants.
  - Part 2: Regain Compliance with Nasdaq
    - As previously reported, the Company was notified by Nasdaq that it was out of compliance with the Nasdaq Stock Market minimum bid price requirement.
    - The Company’s stock is now trading above the minimum bid price requirement and, on May 11, 2022, the Company was notified by Nasdaq that it had regained compliance.
  - Part 3: Raise Additional Capital
    - The Company plans to remain flexible and will continue to evaluate all available financing options, including the recently established at-the-market offering (ATM) program, and further equity offerings. The Company also believes that an important part of its plan moving forward is to explore all strategic options to grow or transform its business.
- On April 26, 2022, the Company announced a 1-for-40 reverse stock split of its common shares (the “Reverse Stock Split”). The Reverse Stock Split became effective at 5:00 p.m. Eastern time on April 26, 2022 and the Company’s common stock opened for trading on The Nasdaq Capital Market on a post-split basis under the Company’s existing trading symbol “AGRX” on April 27, 2022. At such time, the Company’s common stock also commenced trading under a new CUSIP number, 00847L209. All issued and outstanding shares of common stock, warrants, common stock options, and unvested restricted stock units and the related per share amounts contained in the financial statements have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented.

#### ***First Quarter 2022 Financial Results***

- **Net revenue:** In the first quarter 2022, the Company realized net product sales revenue of \$1.8 million, which was within the guidance of \$1.7 million to \$1.9 million communicated by the Company in April 2022.
- **Cost of product revenues:** Cost of product revenues for the first quarter 2022 was \$1.5 million, which consisted of direct and indirect costs related to the manufacturing of Twirla sold during the first quarter. The Company had no charges for obsolescence during the first quarter of 2022 and remains focused on managing its inventory levels to meet the needs of its customers’ demand while avoiding oversupply.
- **Total operating expenses:** Total operating expenses were \$15.8 million for the quarter ended March 31, 2022, compared to \$15.2 million for the comparable period in 2021. The \$15.8 million amount was within the guidance of \$15.5 million to \$16.5 million communicated by the Company in April 2022. The Company plans to continue to optimize its spending by engaging in targeted, focused spending in support of growing Twirla, while seeking reductions in other areas of its operations. Based on this plan, the Company anticipates future 2022 quarterly operating expenses to be lower than that experienced in the first quarter 2022. The Company is examining other areas within its operations that can be reduced in a way that will not compromise its plan to grow Twirla. The Company’s officers and senior management team have voluntarily forgone the annual bonuses for 2021 performance that were awarded in January of 2022, which is estimated to result in a savings of approximately \$700,000 and will be used for general corporate purposes.
- **Cash and cash equivalents:** As of March 31, 2022, the Company had \$3.7 million of cash and cash equivalents, compared to \$19.1 million of cash and cash equivalents as of the end of the fourth quarter 2021. In April 2022, the Company added cash of \$4.7 million from the sale of its New Jersey Net Operating Losses, for which a receivable was recorded in the first quarter. The decrease in cash on hand reflects working capital burn during the quarter and a \$5 million pay down of the debt with Perceptive in January, offset by proceeds from a \$4.85 million registered direct offering of preferred stock with a single healthcare-focused institutional investor.
- **Net loss:** Net loss was \$11.8 million, or \$3.78 per share, for the quarter ended March 31, 2022, compared to a net loss of \$17.1 million, or \$8.00 per share, for the comparable period in 2021.
- **Shares Outstanding:** As of March 31, 2022, Agile had 3,365,422 shares of common stock outstanding. This number has been retroactively adjusted to reflect the Reverse Stock Split effected in April 2022.

#### **Conference Call and Webcast**

Date	Thursday, May 12, 2022
Time	4:30 p.m. ET
Webcast (live and archived)	<a href="#">Events &amp; Presentations</a>
Dial-in numbers	(888) 330-2454 (U.S. toll-free) or (240) 789-2714
Conference ID	7871426

Investors interested in listening to the conference call may do so by dialing (888) 330-2454 for domestic callers or (240) 789-2714 for international callers. The required Conference ID is 7871426. A live webcast will be available in the Events and Presentations section of the Investor Relations page at <https://ir.agiletherapeutics.com/events-and-presentations/>, or by [clicking here](#).

Please log in approximately 10 minutes prior to the scheduled start time. The archived webcast will be available in the Events and Presentations section of the Company's website.

#### **About Twirla®**

Twirla (levonorgestrel and ethinyl estradiol) transdermal system is a once-weekly combined hormonal contraceptive (CHC) patch that contains the active ingredients levonorgestrel (LNG), a type of progestin, and ethinyl estradiol (EE), a type of estrogen. Twirla is indicated for use as a method of contraception by women of reproductive potential with a body mass index (BMI) < 30 kg/m<sup>2</sup> for whom a combined hormonal contraceptive is appropriate. Healthcare providers (HCPs) are encouraged to consider Twirla's reduced efficacy in women with a BMI ≥ 25 to <30 kg/m<sup>2</sup> before prescribing. Twirla is contraindicated in women with a BMI ≥ 30 kg/m<sup>2</sup>. Twirla is also contraindicated in women over 35 years old who smoke. Cigarette smoking increases the risk of serious cardiovascular events from CHC use. Twirla is designed to be applied once weekly for three weeks, followed by a week without a patch.

#### **About Agile Therapeutics, Inc.**

Agile Therapeutics is a women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Our product and product candidates are designed to provide women with contraceptive options that offer freedom from taking a daily pill, without committing to a longer-acting method. Our initial product, Twirla®, (levonorgestrel and ethinyl estradiol) transdermal system, is a non-daily prescription contraceptive. Twirla is based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to allow drug delivery through the skin. For more information, please visit the company website at [www.agiletherapeutics.com](http://www.agiletherapeutics.com). The Company may occasionally disseminate material, nonpublic information on the Company's website.

#### **About Prescription Data**

The Company receives prescription data for Twirla from Symphony Health Solutions, and the data are not created or owned by the Company. Prescription data are available through other subscription services as well, such as IQVIA. The prescription data results reported in this press release are reported as of April 29, 2022, by Symphony Health Solutions. The prescription data terms are defined as follows: Twirla cycles dispensed are the number of 3-patch packages dispensed. Each 3-patch package represents one 28-day cycle of therapy. Total Cycles Dispensed represents every cycle dispensed from both retail and non-retail channels. Retail channels include retail pharmacies, mail order, and long-term care while non-retail channels include clinics and hospitals and other entities where prescriptions are dispensed directly to the patient. Total prescriptions (TRx) are the total number of prescriptions dispensed through the retail channels. This represents both new and refill prescriptions. New prescriptions (NRx) are new prescriptions dispensed through retail channels. Refill prescriptions (RRx) are refill prescriptions filled through retail channels. Total prescribers are the cumulative number of prescribers whose prescriptions were filled through retail channels since launch.

#### **Forward-Looking Statements**

Certain information contained in this press release includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We may in some cases use terms such as "predicts," "believes," "potential," "continue," "anticipates," "estimates," "expects," "plans," "intends," "may," "could," "might," "likely," "will," "should" or other words that convey uncertainty of the 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 existing debt financing from Perceptive Advisors, our prospects for future financing arrangements, our ability to maintain compliance with the listing requirements of Nasdaq, our operating expenses, financial condition, growth and strategies, 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 Nasdaq 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. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which are made only as of the date of this press release. We undertake no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

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**Agile Therapeutics, Inc.**  
**Balance Sheets**  
**(Unaudited)**  
(in thousands, except par value and share data)

	March 31, 2022	December 31, 2021
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 3,743	\$ 19,143
Accounts receivable, net	1,665	1,533
Income taxes receivable	4,675	—
Inventory, net	2,693	966
Prepaid expenses and other current assets	1,576	2,283
<b>Total current assets</b>	<b>14,352</b>	<b>23,925</b>
Property and equipment, net	12,047	12,447
Right of use asset	888	949
Other non-current assets	2,012	2,012
<b>Total assets</b>	<b>\$ 29,299</b>	<b>\$ 39,333</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Long-term debt, current portion	\$ 12,252	\$ 16,833
Accounts payable	9,537	8,707
Accrued expenses	3,828	3,563
Lease liability, current portion	231	175
<b>Total current liabilities</b>	<b>25,848</b>	<b>29,278</b>
Lease liabilities, long-term	708	784
Long-term debt	—	—
<b>Total liabilities</b>	<b>26,556</b>	<b>30,062</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity</b>		
Preferred stock, \$.0001 par value, 10,000,000 shares authorized, 4,850 issued and 2,425 outstanding at March 31, 2022 and no shares issued and outstanding at December 31, 2021	887	—
Common stock, \$.0001 par value, 300,000,000 shares authorized, 3,365,422 and 3,034,901 issued and outstanding at March 31, 2022 and December 31, 2021, respectively	—	—
Additional paid-in capital	400,742	396,388
Accumulated deficit	(398,886)	(387,117)
<b>Total stockholders' equity</b>	<b>2,743</b>	<b>9,271</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 29,299</b>	<b>\$ 39,333</b>

**Agile Therapeutics, Inc.**  
**Statements of Operations**  
**(Unaudited)**  
(in thousands, except per share and share data)

	Three Months Ended March 31,	
	2022	2021
Revenues, net	\$ 1,761	\$ 116
Cost of product revenues	1,527	1,161
Gross profit (loss)	234	(1,045)
Operating expenses:		
Research and development	\$ 1,257	\$ 2,123
Selling and marketing	10,553	9,253
General and administrative	3,997	3,801

Total operating expenses	15,807	15,177
Loss from operations	<u>(15,573)</u>	<u>(16,222)</u>
Other income (expense)		
Interest income	1	16
Interest expense	<u>(872)</u>	<u>(922)</u>
Total other income (expense), net	<u>(871)</u>	<u>(906)</u>
Loss before benefit from income taxes	(16,444)	(17,128)
Benefit from income taxes	4,675	—
Net loss	<u>\$ (11,769)</u>	<u>\$ (17,128)</u>
Net loss per share (basic and diluted)	<u>\$ (3.78)</u>	<u>\$ (8.00)</u>
Weighted-average common shares (basic and diluted)	<u>3,115,211</u>	<u>2,190,650</u>