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

October 26, 2018
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** (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 is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12).

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 x

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. x

Item 1.01. Entry into a Material Definitive Agreement.

On October 26, 2018, Agile Therapeutics, Inc. (the "Company") entered into a Clinical Research Agreement ("CRA") with TKL Research, Inc. ("TKL") to conduct clinical research services from time to time at the request of the Company. The Company intends to utilize the CRA to perform a comparative wear study between Twirla® (AG200-15), the Company's investigational non-daily, low-dose combination hormonal contraceptive patch and Xulane®, the generic version of the previously marketed Ortho Evra® contraceptive patch, in connection with guidance provided by U.S. Food and Drug Administration. The Company and TKL will execute individual statements of work under the CRA that detail the scope and conduct of requested services as well the budget and payment schedule associated with a particular study.

The CRA provides customary terms and conditions, including those for performance of services by TKL in compliance with the applicable statement of work and all applicable laws. The CRA has a term of five years, provided that, the Company may terminate the CRA or any individual statement of work upon 30 days prior written notice to TKL. In addition, either party may terminate the CRA or any applicable statement of work upon 30 days prior written notice for a material breach by the other party. In the event of termination, TKL shall provide termination assistance for a period of 30 days and will be compensated for such assistance on an hourly rate in accordance with the then-existing statement of work.

The foregoing summary does not purport to be complete and is qualified in its entirety by reference to the CRA, a copy of which will be filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ending December 31, 2018. Readers should review such agreement for a complete understanding of the terms and conditions associated with this transaction.

Xulane® is a registered trademark of Mylan N.V., and Ortho Evra® is a registered trademark of Johnson & Johnson.

Item 2.02 Results of Operations and Financial Condition

On November 1, 2018, the Company issued a press release announcing its financial results for the third quarter ended September 30, 2018 and an update on the Company's operations for the same period. The Company is furnishing a copy of the press release, which is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information included in this Item 2.02, 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 Securities Act of 1933, as amended, 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
99.1	Press release issued by Agile Therapeutics, Inc. dated November 1, 2018.

SIGNATURES

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

Agile Therapeutics, Inc.

Dated: November 1, 2018

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

Exhibit 99.1

Agile Therapeutics Reports Third Quarter 2018 Financial Results

Cash Expected to Enable Company to Fund Operations into Second Quarter 2019

PRINCETON, New Jersey, November 1, 2018 - Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today reported financial results for the three and nine months ended September 30, 2018 and provided a corporate update.

Third quarter 2018 and other recent corporate developments:

Twirla® Update — As previously announced, Agile initiated formal dispute resolution with the U.S. Food and Drug Administration's (FDA) Office of Drug Evaluation III (ODE III) on June 6, 2018 to appeal the complete response letter (CRL) the FDA issued in December 2017 relating to the New Drug Application (NDA) for Twirla (AG200-15), the Company's investigational non-daily, low-dose combination hormonal contraceptive patch. In October 2018, the FDA's Office of New Drugs (OND) formally denied the Company's appeal and provided a path forward for resubmission of the NDA for Twirla that may not require that the Company reformulate Twirla or conduct a bioequivalence study between formulations, as previously suggested by the FDA's Division of Bone, Reproductive and Urologic Products, (DBRUP).

Specifically, OND suggested that the Company conduct a wear study to evaluate whether Twirla demonstrates a generally similar adhesion performance to Xulane®, the generic version of the previously marketed Ortho Evra® contraceptive patch, a product the FDA considers to have acceptable adhesion. If this result is demonstrated, OND stated that the study would support the conclusion of adequate Twirla adhesion. OND has recommended that the Company meet with DBRUP to gain agreement on the specific design and success criteria of a wear study for Twirla. The Company has submitted a request for a Type A meeting and plans to discuss the specifics of the proposed wear study with the FDA at that meeting. The wear study suggested by OND provides a path forward for resubmission of the Twirla NDA, but is not intended to address efficacy. Rather if the wear study is successful, Twirla's safety and efficacy, including the Pearl Index that FDA noted is substantially higher than other previously approved combined hormonal contraceptives, will need to be reviewed by FDA after the Company resubmits the NDA for Twirla. This is an issue the FDA plans to bring to an Advisory Committee after the adhesion issue has been resolved.

"We are pleased that the FDA has provided us with a potential path forward for resubmitting our NDA for Twirla and are moving forward with our plans to meet with the Agency to discuss the specifics of the proposed comparative wear study," said Al Altomari, Chairman and Chief Executive Officer of Agile. "Our immediate goal is to complete the comparative wear study as soon as possible, and, upon successful completion of that study, to focus on the resubmission of our NDA. We continue to believe that Twirla, if approved, will provide women with an important contraception option they do not currently have — a once-weekly contraceptive patch designed to deliver a low dose of estrogen."

Third Quarter Financial Results

- **Cash and cash equivalents:** As of September 30, 2018, Agile had $16.9 million of cash and cash equivalents compared to $35.9 million of cash and cash equivalents as of December 31, 2017. The Company believes its cash and cash equivalents as of September 30, 2018, will be sufficient to meet its projected operating requirements into the second quarter of 2019, which include an estimate of the costs to complete a comparative wear study. The Company anticipates providing a further business update after it agrees with the FDA on the parameters of the wear study for Twirla. The Company will require additional capital to fund operating needs for the remainder of the second quarter of 2019 and beyond, including among other items, preparation for an anticipated Advisory Committee meeting, the completion of its commercial plan for Twirla, which primarily includes validation of the commercial manufacturing process and the commercial launch of Twirla, if approved, and advancing the development of its other potential product candidates.

- **Research and development (R&D) expenses:** R&D expenses were $1.6 million for the quarter ended September 30, 2018, compared to $3.2 million for the comparable period in 2017. The decrease in R&D expenses was primarily due to a decrease in manufacturing and commercialization expenses reflecting reduced activity associated with the scale-up process and the on-going qualification process of the commercial manufacturing equipment primarily as a result of the receipt of the 2017 CRL.

- **General and administrative (G&A) expenses:** G&A expenses were $1.8 million for the quarter ended September 30, 2018, compared to $3.5 million for the comparable period in 2017. The decrease in G&A expenses was primarily due to the suspension of pre-commercialization activities as a result of the receipt of the CRL in December 2017.

- **Net loss:** Net loss was $3.8 million, or $0.11 per share, for the quarter ended September 30, 2018, compared to a net loss of $7.1 million, or $0.22 per share, for the quarter ended September 30, 2017.

- **Shares Outstanding:** At September 30, 2018, Agile had 34,377,329 shares of common stock outstanding.

About Twirla® (AG200-15)

Twirla (ethinyl estradiol and levonorgestrel transdermal system) or AG200-15 is an investigational low-dose, once-weekly combined hormonal contraceptive (CHC) patch that contains the active ingredients ethinyl estradiol (EE), a type of estrogen and levonorgestrel (LNG), a type of progestin. Twirla is designed to be applied once weekly for three weeks, followed by a week without a patch. The Company has completed its Phase 3 clinical trials of Twirla and is pursuing regulatory approval in the U.S. Agile received a complete response letter (CRL) from the FDA in December 2017 relating to the New Drug Application (NDA) for Twirla. In the CRL, the FDA informed the Company that the product could not be approved in its present form due to deficiencies related to, among other things, the *in vivo* adhesion properties of Twirla and their potential relationship to the Company's Phase 3 clinical trial results. The Company initiated formal dispute resolution with the FDA in June 2018 in response to the FDA's position on Twirla's in vivo adhesion properties and in October 2018, the FDA's Office of New Drugs formally denied the Company's appeal but provided a path forward for seeking regulatory approval for Twirla. Agile intends to meet with the FDA's Division of Bone, Reproductive and Urological Products to further discuss what is necessary to resubmit its NDA for Twirla and continue to pursue regulatory approval.

Xulane® is a registered trademark of Mylan N.V., and Ortho Evra® is a registered trademark of Johnson & Johnson.

About Agile Therapeutics, Inc.

Agile Therapeutics is a forward-thinking women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Our 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 lead product candidate, Twirla®, (ethinyl estradiol and levonorgestrel transdermal system), also known as AG200-15, is an investigational low-dose, 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. The Company may occasionally disseminate material, nonpublic information on the Company's website.

Forward-Looking Statement

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, related to our regulatory submissions and projected cash position. 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 the fact that our existing cash and cash equivalents likely will not be sufficient to fund our current and planned operations beyond the second quarter of 2019, which raises substantial doubt about our ability to continue as a going concern, and which, in turn, may create negative reactions to the price

of our common stock making it more difficult to obtain financing in the future, our intention to meet with the FDA, the timing of which is subject to FDA's discretion and which may not result in a clear agreement on the issues discussed, and our belief that a reformulation of Twirla may not be necessary. 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 manage costs and execute on our operational and budget plans, the FDA requiring us to reformulate Twirla, our ability to develop a reformulation that will address the FDA's concerns, including showing bioequivalence, if necessary, our ability to successfully complete the suggested wear study and that the results do not support a conclusion by the FDA that Twirla has demonstrated adequate adhesion, and, the potential that we may be required to conduct an additional Phase 3 trial, the likelihood that we will require additional correspondence with the FDA prior to the resubmission of our NDA, in addition to the planned correspondence regarding the design of the suggested wear study, our ability to resubmit and the timing of our resubmission of the NDA for Twirla, FDA acceptance and approval of the resubmitted NDA, or whether other issues will arise that will negatively impact acceptance, review, and approval of Twirla by the FDA, including a determination by the Advisory Committee that Twirla should not be approved, our ability to address the deficiencies identified by the FDA in the CRL issued in December 2017 and in the Type A meeting minutes issued in May 2018, the fact that our existing cash and cash equivalents may not be sufficient to fund the completion of the development and regulatory review process for Twirla, our ability to raise capital when needed to complete the development and regulatory review process for Twirla, and unforeseen market factors or events in our clinical and manufacturing development plans 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.

Source: Agile Therapeutics

Contact: Investor Relations — 609-683-1880

Agile Therapeutics, Inc.
Condensed Balance Sheets

(in thousands)
(Unaudited)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 16,926	$ 35,952
Prepaid expenses	731	762
Total current assets	17,657	36,714
Property and equipment, net	13,921	13,863
Other assets	18	18
Total assets	$ 31,596	$ 50,595
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,510	$ 3,636
Loan payable, current portion	5,905	10,607
Warrant liability	—	29
Total liabilities	8,415	14,272
Stockholders' equity		
Common stock	3	3
Additional paid-in capital	260,919	258,092
Accumulated deficit	(237,741)	(221,772)
Total stockholders' equity	23,181	36,323
Total liabilities and stockholders' equity	$ 31,596	$ 50,595

Agile Therapeutics, Inc.
Condensed Statements of Operations

(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 1,549	$ 3,175	$ 7,921	$ 11,694
General and administrative	1,767	3,526	7,173	9,130
Restructuring costs	299	—	715	—
Total operating expenses	3,615	6,701	15,809	20,824
Loss from operations	(3,615)	(6,701)	(15,809)	(20,824)
Other income (expense)				
Interest expense	(268)	(459)	(955)	(1,509)
Interest income	91	78	289	187
Change in fair value of warrants	—	(20)	29	82
Loss before benefit from income taxes	(3,792)	(7,102)	(16,446)	(22,064)
Benefit from income taxes	—	—	477	—
Net loss	$ (3,792)	$ (7,102)	$ (15,969)	$ (22,064)
Net loss per share - basic and diluted	$ (0.11)	$ (0.22)	$ (0.47)	$ (0.74)
Weighted-average shares outstanding — basic and diluted	34,377,329	31,937,628	34,295,240	29,847,972