# 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**

**September 29, 2014**
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**<br>**Princeton, New Jersey**<br>(Address of principal executive offices) | **08540**<br>(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))

**Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

On October 1, 2014, the Board of Directors (the "Board") of Agile Therapeutics, Inc. (the "Company"), appointed James P. Tursi, M.D., as a director and as a member of the Board's Compensation Committee. Dr. Tursi will serve as a Class I member of the Board. The terms of Class I directors expire at the 2015 Annual Meeting of Shareholders.

Since 2011, Dr. Tursi has served as the Chief Medical Officer of Auxilium Pharmaceuticals. He served as Vice President of Clinical Research and Development from 2009 to 2011. Prior to Auxilium, Dr. Tursi was at GlaxoSmithKline Biologicals from 2006 to 2009, where he was the Director of Medical Affairs for cervical cancer vaccines in North America. From 2004 to 2006, Dr. Tursi served as a Medical Director for Procter & Gamble Pharmaceuticals where he worked in various therapeutic areas including female sexual dysfunction, overactive bladder, and osteoporosis. Dr. Tursi is a board certified OB/GYN and practiced medicine for over 10 years. He was the founder of the medical education company, I Will Pass®, which assisted physicians in the process of board certification. Dr. Tursi received his doctor of medicine degree from the Medical College of Pennsylvania and completed his residency fellowship training at The Johns Hopkins Hospital. The Company believes Dr. Tursi's significant clinical and regulatory expertise in the pharmaceutical industry coupled with established experience as an OB/GYN physician will make him a valuable addition to the Board.

Dr. Tursi will receive the standard compensation amounts payable to non-employee directors of the Company, as described in the Company's final prospectus relating to its initial public offering. His annual cash retainer will be pro-rated for 2014 to reflect his expected term of service during the calendar year. Also pursuant to these arrangements, on October 1, Dr. Tursi received an initial grant of an option to purchase 21,000 shares of the Company's common stock with an exercise price equal to the closing price of the Company's common stock on the date of grant. The option vests in three equal annual installments beginning on October 1, 2015, subject to his continued service on the Company's Board through each vesting date and provided that he attends at least 75% of the Board meetings held during each respective year of Board service.

**Item 7.01 Regulation FD Disclosure**

On September 29, 2014, the Company issued a press release announcing that the first patients have been dosed in its SECURE study. The SECURE study is a single-arm, open-label, multicenter Phase 3 trial that will assess the efficacy, safety and tolerability of the Company's investigational once-weekly transdermal contraceptive patch, Twirla® (AG200-15). The Company also stated that it anticipates completing the enrollment period within the next four to six months. The Company is furnishing a copy of the press release, which is attached hereto as Exhibit 99.1.

On October 1, 2014, the Company issued a press release announcing that Dr. James P. Tursi, M.D. had been appointed to the Company's Board. The Company is furnishing a copy of the press release, which is attached hereto as Exhibit 99.2.

In accordance with General Instructions B.2 and B.6 of Form 8-K, the information included in Item 7.01 of this Current Report on Form 8-K (including Exhibits 99.1 and 99.2 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 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 | Agile Therapeutics, Inc. Press Release dated September 29, 2014 relating to the Dosing of the First Patient in the SECURE Study. |
| 99.2 | Agile Therapeutics, Inc. Press Release dated October 1, 2014 relating to the Appointment of Dr. James Tursi to the Agile Board. |



**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: October 2, 2014

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

**Exhibit 99.1**

**Agile Announces Dosing of First Patients in Twirla® Phase 3 SECURE Study**

**PRINCETON, N.J., Sept. 29, 2014** — Agile Therapeutics, Inc., (Nasdaq: AGRX) a women's health specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products, today announced that the first patients have been dosed in its SECURE study. The SECURE study is a single-arm, open-label, multicenter Phase 3 trial that will assess the efficacy, safety and tolerability of Agile's investigational once-weekly transdermal contraceptive patch, Twirla® (AG200-15).

"The successful dosing of the first patients marks a critical milestone in the SECURE development program. Throughout the planning of this trial, we focused on selecting the right investigators who will identify patients with a high potential for compliance and on implementing measures that will facilitate conducting a trial with rigor and close oversight," said Elizabeth Garner, M.D., M.P.H., Chief Medical Officer and Senior Vice President at Agile. "We are encouraged by the high level of interest in this study shown by both investigators and patients and anticipate completing the enrollment period within the next four to six months."

Approximately 2,100 female subjects are expected to be enrolled at up to 70 sites in the United States. Patients meeting all eligibility criteria will use the patch for up to one year. The study will assess the effectiveness of the patch in preventing pregnancy using the Pearl Index as the primary contraceptive efficacy measure. Safety and tolerability will also be evaluated.

"The start of the SECURE study is an important milestone towards achieving our goal of addressing the substantial unmet need for a more convenient method of contraception for today's busy young women," said Al Altomari, President and Chief Executive Officer at Agile. "The commencement of patient dosing marks a significant achievement for all involved."

Twirla, an investigational prescription contraceptive patch, is a combined hormonal contraceptive patch that contains the active ingredients ethinyl estradiol and levonorgestrel, both of which have an established history of efficacy and safety in currently marketed combination low-dose oral contraceptives. Developed using Agile's proprietary Skinfusion® technology to deliver both hormones over a seven-day period at levels comparable to currently marketed low-dose oral contraceptives, Twirla is applied once weekly for three weeks followed by a patch-free week, and is designed to promote patient compliance.

More information on the clinical trial is available at www.clinicaltrials.gov.

**About Agile**

Agile Therapeutics is a women's health specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products. Our product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. Our lead product candidate, Twirla, (ethinyl estradiol and levonorgestrel transdermal system), also known as AG200-15, is a once-weekly prescription contraceptive patch currently in Phase 3 clinical development. Twirla is based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to provide advantages over currently available patches and is intended to optimize patch adherence and patient acceptability. For more information, please visit the company website at www.agiletherapeutics.com.

**Forward-Looking Statement**

Certain information contained in this press release includes "forward-looking statements" related to the Company's timeline for clinical trials and potential market opportunity for its product candidates. We may, in some cases use terms such as "predicts," "believes," "potential," "continue," "anticipates", "estimates," "expects," "plans," "intends," "may," "could," 'might," "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 expectations that involve risks, potential changes in circumstances, assumptions and uncertainties. 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. For example, our statements about the timing and conduct of our clinical trial could be affected by the potential that we experience difficulty in identifying and initiating sites and enrolling subjects, we identify serious side effects or other safety issues, we do not have clinical supply of our product candidate that is adequate in amount and quality and supplied in a timely fashion, and the inherent risks of clinical development; our statements about the potential commercial opportunity could be affected by the potential that our product does not receive regulatory approval, does not receive reimbursement by third party payors, or a commercial market for the product does not develop because of any of the risks inherent in the commercialization of contraceptive products. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. All forward looking statements are subject to risks

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detailed in our filings with the U.S. Securities and Exchange Commission, including the Company's Registration Statement on Form S-1, and the prospectus filed in connection therewith and our Report on Form 10-Q. 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

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**Exhibit 99.2**

**Agile Therapeutics Appoints James P. Tursi, M.D. to its Board of Directors**

**PRINCETON, N.J., Oct. 01, 2014** — Agile Therapeutics, Inc., (Nasdaq: AGRX) announced today that James P. Tursi, M.D. has been appointed to the Company's Board of Directors effective October 1, 2014. Dr. Tursi will serve on the Compensation Committee.

"James has significant clinical and regulatory expertise in the pharmaceutical industry coupled with established clinical experience as an OB/GYN physician that will complement our board and management team," stated Al Altomari, President and Chief Executive Officer of Agile. "With his extensive clinical and regulatory background, we believe James will offer valuable insight on our clinical and regulatory strategies for Twirla®. We are pleased that he has joined our board."

Dr. Tursi currently serves as Chief Medical Officer for Auxilium Pharmaceuticals and is responsible for all clinical research and development, medical affairs and safety activities. He joined Auxilium in 2009 serving as Vice President of Clinical Research and Development until 2011. While at Auxilium, Dr. Tursi has expanded the company's research and development capabilities and played a significant leadership role in the regulatory approvals for XIAFLEX® for multiple indications.

Previously, Dr. Tursi was at GlaxoSmithKline Biologicals from 2006 to 2009, and directed all medical affairs responsibilities for cervical cancer vaccines in North America and helped launch the product globally. He entered the pharmaceutical industry in 2004 serving as a Medical Director for Procter & Gamble Pharmaceuticals where he worked on in various therapeutic areas including female sexual dysfunction, overactive bladder, and osteoporosis.

Dr. Tursi is a board certified OB/GYN and practiced medicine for over 10 years. He was the founder of the medical education company, I Will Pass®, which assisted physicians in the process of board certification. Dr. Tursi received his doctor of medicine degree from the Medical College of Pennsylvania and completed his residency fellowship training at The Johns Hopkins Hospital.

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Source: Agile Therapeutics