AGIOS PHARMACEUTICALS INC
Form 8-K
May 01, 2015

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, DC 20549**

# FORM 8-K

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d)**

**of the Securities Exchange Act of 1934**

**Date of report (Date of earliest event reported): April 27, 2015**

**Agios Pharmaceuticals, Inc.**

**(Exact Name of Registrant as Specified in Charter)**

| **Delaware** | **001-36014** | **26-0662915** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

**38 Sidney Street, 2nd Floor**

**Cambridge, MA** **02139**
**(Address of Principal Executive Offices)** **(Zip Code)**
**Registrant s telephone number, including area code: (617) 649-8600**

**(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 (see General Instruction A.2. below):

¨ 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))

**Item 1.01 Entry into a Material Definitive Agreement.**

On April 27, 2015, Agios Pharmaceuticals, Inc. (the Company ) entered into a collaboration and license agreement (the AG-881 US Agreement ) with Celgene Corporation, and the Company s wholly owned subsidiary, Agios International Sarl ( AIS ), entered into a collaboration and license agreement (the AG-881 ROW Agreement and, together with the AG-881 US Agreement, the AG-881 Agreements ) with Celgene International II Sarl ( CIS II ). In the following description of the AG-881 Agreements, all references to we or us shall refer to the Company and/or AIS, as applicable, and all references to Celgene shall refer to Celgene Corporation and/or CIS II, as applicable.

The AG-881 Agreements establish a worldwide collaboration focused on the development and commercialization of licensed AG-881 products. AG-881 is a small molecule that has shown in preclinical studies to fully penetrate the blood brain barrier and inhibit isocitrate dehydrogenase-1 (IDH1) and IDH2 mutant cancer cells. We have an ongoing discovery and development collaboration and license agreement with Celgene that we entered into in April 2010, focused on targeting cancer metabolism (the 2010 Agreement ). We and Celgene have agreed that the future development and commercialization of licensed AG-881 products will be governed by the AG-881 Agreements and not the 2010 Agreement.

**Financial.** Under the terms of the AG-881 Agreements, Celgene will make a payment in the amount of $10 million to us and we are eligible to receive up to $70 million in milestone-based payments. We and Celgene will equally split all worldwide development costs, subject to specified exceptions, as well as any profits from any net sales of, or commercialization losses related to, licensed AG-881 products. Celgene will book commercial sales of licensed AG-881 products, if any, on a worldwide basis.

**Commercialization**. Under the terms of the AG-881 Agreements, we will lead commercialization of licensed AG-881 products within the United States and Celgene will lead commercialization of licensed AG-881 products outside of the United States. Depending on the market, we and Celgene will each have the right to provide a portion of field-based marketing activities.

**Opt-Out Right.** Under the AG-881 Agreements, we may elect to opt out of the cost and profit split of the collaboration at any time after April 27, 2016 by providing at least 12 months written notice to Celgene. If we opt out, Celgene will have the sole right to develop, manufacture and commercialize licensed AG-881 products throughout the world, at its cost, and we will undertake transitional activities reasonably necessary to transfer the development, manufacture and commercialization of licensed AG-881 products to Celgene, at our cost.

If we elect to opt-out of the AG-881 Agreements, then, in lieu of the profit or loss sharing described above, we would be eligible to receive royalties at tiered, low to mid-teen percentage rates on Celgene s net sales of licensed AG-881 products.

**Exclusivity.** Until termination or expiration of the AG-881 Agreements, neither we nor Celgene may directly or indirectly develop, manufacture or commercialize, outside of the AG-881 Agreements or the 2010 Agreement, any therapeutic modality with specified activity against both IDH1 and IDH2.

**Term.** The term of the AG-881 Agreements will continue, unless earlier terminated, as long as we and Celgene continue to develop or commercialize licensed AG-881 products, or, in the event we opt out of the AG-881 Agreements, until expiration of the royalty term for AG-881 products.

**Termination.** Celgene may terminate the AG-881 Agreements for convenience upon ninety days written notice to us. Either we or Celgene may terminate the AG-881 Agreements if the other party is in material

breach and fails to cure such breach within the specified cure period. Either we or Celgene may terminate the AG-881 Agreements in the event of specified insolvency events involving the other party. If one of the AG-881 Agreements terminates, the other will terminate automatically.

The foregoing description of the AG-881 Agreements does not purport to be complete and is qualified in its entirety by the full text of the AG-881 Agreements, copies of which will be filed with the exhibits to the Company s quarterly report on Form 10-Q for the quarter ending June 30, 2015.

**Item 8.01 Other Events.**

The full text of the press release announcing the Company s entry into the AG-881 Agreements is attached as Exhibit 99.1 hereto and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) The following exhibits are included in this report:

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release issued April 29, 2015. |

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.

AGIOS PHARMACEUTICALS, INC.

Date: May 1, 2015

By: /s/ David P. Schenkein
David P. Schenkein, M.D.

Chief Executive Officer

**EXHIBIT INDEX**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release issued April 29, 2015. |