AGIOS PHARMACEUTICALS INC
Form 8-K
May 23, 2016

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

Date of Report (Date of earliest event reported): May 17, 2016

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.)**
88 Sidney Street, 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 May 17, 2016, Agios Pharmaceuticals, Inc. (the Company) entered into a master research and collaboration agreement with Celgene Corporation and Celgene RIVOT Ltd. (the 2016 Collaboration Agreement) and a letter agreement with Celgene Corporation regarding AG-120 (the AG-120 Letter Agreement). In the following descriptions of the 2016 Collaboration Agreement and the AG-120 Letter Agreement, all references to we or us shall refer to the Company and/or its applicable affiliate, as applicable, and all references to Celgene shall refer to Celgene Corporation and/or Celgene RIVOT Ltd., as applicable.

Master Research and Collaboration Agreement

The 2016 Collaboration Agreement establishes a new global collaboration focused on the research and development of immunotherapies against certain metabolic targets that exert their antitumor efficacy primarily via the immune system. In April 2010 we entered into a discovery and development collaboration and license agreement with Celgene that focused on targeting cancer metabolism (the 2010 Collaboration Agreement). In addition to new programs identified under the 2016 Collaboration Agreement, we and Celgene have also agreed that all future development and commercialization of two programs that were conducted under the 2010 Collaboration Agreement will now be governed by the 2016 Collaboration Agreement.

During the research term of the 2016 Collaboration Agreement, we plan to conduct research programs focused on discovering compounds that are active against metabolic targets in the immuno-oncology, or IO, field. The initial four-year research term will expire on May 17, 2020. Celgene may extend the research term for up to two additional one-year terms.

For each program under the 2016 Collaboration Agreement, we may nominate compounds that meet specified criteria as development candidates, and, in limited circumstances, Celgene may also nominate compounds as development candidates for each such program. Celgene may designate the applicable program for further development following any such nomination, after which we may conduct, at our expense, additional pre-clinical and clinical development for such program through completion of an initial Phase I dose escalation study.

At the end of the research term, Celgene may designate for continued development up to three research programs for which development candidates have yet to be nominated, which we refer to as continuation programs. We may conduct further research and pre-clinical and clinical development activities on any continuation program, at our expense, through completion of an initial Phase I dose escalation study.

We have granted Celgene the right to obtain exclusive options to development and commercialization rights for each program that Celgene has designated for further development, and for each continuation program. Celgene may exercise each such option beginning on the designation of a development candidate for such program (or on the designation of such program as a continuation program) and ending on the earlier of the end of a specified period after we have furnished Celgene with specified information about the initial Phase I dose escalation study for such program, or January 1, 2030. Research programs that have applications in the inflammation or autoimmune, or I&I, field that may result from the 2016 Collaboration Agreement will also be subject to the exclusive options described above.

We will retain rights to any program that Celgene does not designate for further development or as to which Celgene does not exercise its option.

Development and Commercialization Agreements. Under the terms of the 2016 Collaboration Agreement, following Celgene s exercise of its option with respect to a program, we (and, if applicable, one of our affiliates) and Celgene will enter into either a co-development and co-commercialization agreement if such program is in the IO field, or a license agreement if such program is in the I&I field. Under each co-development and co-commercial agreement, we and Celgene will co-develop and co-commercialize licensed products worldwide. Either we or Celgene will lead development and commercialization of licensed products for the United States and Celgene will lead development and commercialization of licensed products outside of the United States. Depending on the country, we and Celgene will each have the right to provide a portion of field-based marketing activities. Under each license agreement, Celgene will have the sole right to develop and commercialize licensed products worldwide.

Financial Terms. Under the terms of the 2016 Collaboration Agreement, Celgene will make an initial upfront payment to us in the amount of $200 million for the initial four-year research term. Celgene has specified rights to extend the research term for up to two, or in specified cases, up to four, additional years by paying a per-year extension fee. Celgene will pay us a designation fee for each program that Celgene designates for further development and for each continuation program. For each program as to which Celgene exercises its option to develop and commercialize, subject to antitrust clearance, Celgene will pay us an option exercise fee of at least $30 million for any designated development program and for any continuation programs. We will remain responsible for the initial Phase I dose escalation study for each program under the 2016 Collaboration Agreement, including associated costs.

Co-development and co-commercialization agreements. Under each co-development and co-commercialization agreement we enter into under the 2016 Collaboration Agreement, we and Celgene will split all post-option-exercise worldwide development costs, subject to specified exceptions, as well as any profits from any net sales of, or commercialization losses related to, licensed products. Celgene has the option to designate one program in the IO field as the 65/35 program, for which Celgene will be the lead party for the United States and will have a 65% profit or loss share. For programs in the IO field other than the 65/35 program, we and Celgene will alternate, on a program-by-program basis, being the lead party for the United States, with Agios having the right to be the lead party for the first such program, and we and Celgene will each have a 50% profit or loss share. The lead party for the United States will book commercial sales of licensed products, if any, in the United States, and Celgene will book commercial sales of licensed products, if any, outside of the United States. We are eligible to receive up to $169 million (or up to $209 million for the 65/35 program) in developmental and regulatory milestone-based payments under each co-development and co-commercialization agreement.

We may elect to opt out of the cost and profit share under any co-development and co-commercialization agreement, subject to specified exceptions. If we opt out, Celgene will have the sole right to develop, manufacture and commercialize the applicable licensed products throughout the world, at its cost, and we will undertake transitional activities reasonably necessary to transfer the development, manufacture and commercialization of such licensed products to Celgene, at our cost. If we opt out, then, in lieu of the profit or loss sharing described above, we would be eligible to receive royalties at tiered, double-digit percentage rates on Celgene s net sales, if any, of the applicable licensed products. We would continue to be eligible to receive the developmental and regulatory milestone-based payments described above.

License agreements. Under each license agreement under the 2016 Collaboration Agreement, Celgene will be responsible for all post-option-exercise worldwide development and associated costs, subject to specified exceptions, as well as worldwide commercialization and associated costs, for licensed products.

We are eligible to receive royalties at tiered, double-digit percentage rates on Celgene s net sales, if any, of the applicable licensed products and up to $386 million in developmental, regulatory and commercial milestone-based payments under each license agreement.

Exclusivity. While any of Celgene s options remain available under the 2016 Collaboration Agreement, subject to specified exceptions, we may not directly or indirectly develop, manufacture or commercialize, outside of the 2016 Collaboration Agreement, any therapeutic modality in the IO field or the I&I field with specified activity against a metabolic target.

During the term of each co-development and co-commercialization agreement and license agreement, subject to specified exceptions, neither we nor Celgene may directly or indirectly develop, manufacture or commercialize outside of such agreement any therapeutic modality in any field with specified activity against the metabolic target that is the focus of the program licensed under such agreement.

Term. The term of the 2016 Collaboration Agreement will commence on May 17, 2016 and, if not terminated earlier, will expire upon later of the last-to-expire of the research term and all option exercise periods, or, if an option is exercised by Celgene for one or more programs in the collaboration, upon the termination or expiration of the last-to-exist co-development and co-commercialization agreement or license agreement, as applicable, for any such program.

Termination. Subject to specified exceptions, Celgene may terminate the 2016 Collaboration Agreement in its entirety for any reason by providing Agios with prior written notice if there are no active co-development and co-commercialization agreements or license agreements in place or on a program-by-program basis if there are no active co-development and co-commercialization agreements or license agreements in place for the terminated program(s). Either party may terminate the 2016 Collaboration Agreement for the insolvency of the other party. On a program-by-program basis, prior to the exercise of an option, either party may terminate the 2016 Collaboration Agreement either in its entirety or with respect to one or more programs on prior written notice to the other party in the case of an uncured material breach by the other party that frustrates the fundamental purpose of the 2016 Collaboration Agreement. Following the exercise of an option for a program, either party may terminate the 2016 Collaboration Agreement with respect to such program if such party terminates the co-development and co-commercialization agreement or license agreement for such program for an uncured material breach by the other party that frustrates the fundamental purpose of such agreement. Either party may terminate a co-development and co-commercialization agreement or a license agreement upon the bankruptcy or insolvency of the other party. Either party also has the right to terminate the co-development and co-commercialization agreement or license agreement if the other party or any of its affiliates challenges the validity, scope or enforceability of or otherwise opposes, any patent included within the intellectual property rights licensed to the other party under such agreement.

The foregoing description of the 2016 Collaboration Agreement does not purport to be complete and is qualified in its entirety by the full text of the 2016 Collaboration Agreement, a redacted copy of which will be filed with the exhibits to the Company s quarterly report on Form 10-Q for the quarter ending June 30, 2016.

AG-120 Letter Agreement

Under the AG-120 Letter Agreement, we and Celgene have agreed to terminate the 2010 Collaboration Agreement, effective as of August 15, 2016, as to the program directed to the IDH1 target, for which AG-120 is the lead development candidate.

Under the 2010 Collaboration Agreement, Celgene had held development and commercialization rights to the IDH1 program outside of the United States, and we held such rights inside the United States. As a result of the AG-120 Letter Agreement, we will obtain global rights to AG-120 and the IDH1 program. Neither party will have any financial obligation, including royalties or milestone payments, to the other concerning AG-120 or the IDH1 program after final reconciliation of specified shared development costs. Under the AG-120 Letter Agreement, the parties have also agreed to conduct specified transitional activities in connection with the termination. In addition, pursuant to the AG-120 Letter Agreement, the parties are released from their exclusivity obligations under the 2010 Collaboration Agreement with respect to the IDH1 program. The AG-120 Letter Agreement does not alter our global collaboration with Celgene pursuant to the collaboration and license agreements we entered into with Celgene on April 27, 2015 concerning AG-881, which is directed to both the IDH1 target and the IDH2 target.

Item 8.01 Other Events.

The full text of the press release announcing the Company s entry into the 2016 Collaboration Agreement and the AG-120 Letter Agreement is attached as Exhibit 99.1 hereto and is incorporated herein by reference.

In addition, on May 17, 2016, the Company updated its cash guidance in connection with the 2016 Collaboration Agreement and the AG-120 Letter Agreement. The full text of the press release announcing the Company s updated cash guidance is attached as Exhibit 99.2 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 by Agios Pharmaceuticals, Inc. on May 17, 2016.
99.2	Press release issued by Agios Pharmaceuticals, Inc. on May 17, 2016.

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 23, 2016

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

Chief Executive Officer

EXHIBIT INDEX

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