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

88 Sidney Street, Cambridge, MA (Address of Principal Executive Offices) 02139 (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))

D 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 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-toexpire 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 or license agreement for such program for an uncured material breach by the other party terminate the 2016 Collaboration Agreement. Following the exercise of an option for a program, either party may terminate the 2016 Collaboration Agreement. Following the exercise of an option for a program, either party may terminate the 2016 Collaboration Agreement or license agreement for such program for an uncured material breach by the other party terminate the 2016 Collaboration Agreement or license agreement for such program for an uncured material breach by the other party may terminate the row of the other party terminate the 2016 Collaboration Agreement or license agreement or a uncured material breach by the other party terminate the 2016 Collaboration Agreement or license agreement or a uncured material breach by the other party agreement of such program for an uncured material breach by the other party agreement for such program for an uncured material breach by the other party agreement or license

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.

Date: May 23, 2016

AGIOS PHARMACEUTICALS, INC.

By: <u>/s/ David P. Schenkein</u> David P. Schenkein, M.D.

Chief Executive Officer

# EXHIBIT INDEX

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.



#### Agios and Celgene Establish New Collaboration in Metabolic Immuno-Oncology and Amend Certain Rights from 2010 Agreement

- New Collaboration Builds on Agios Research Platform and Leverages Celgene Capabilities; Agios to Receive \$200 Million Upfront Payment -

- AG-120 Rights Outside the United States Transferred to Agios -

**CAMBRIDGE, MA and SUMMIT, NJ, May 17, 2016** — Agios Pharmaceuticals, Inc. (NASDAQ: AGIO) and Celgene Corporation (NASDAQ: CELG) today announced an agreement creating a new global strategic collaboration focused on metabolic immuno-oncology, an emerging field of cancer research focused on altering the metabolic state of immune cells to enhance the body's immune response to cancer. The goal of the collaboration is to discover, develop and commercialize novel therapies based on Agios' innovative cellular metabolism research platform. Agios will receive an upfront cash payment of \$200 million plus the potential for additional payments if certain development and regulatory milestones are achieved. Agios will host a conference call for investors today at 5 p.m. ET.

"The immune system's ability to attack tumors is highly regulated by cellular metabolism. This emerging discipline of metabolic immuno-oncology has great potential to provide novel insights and targets for cancer immunotherapy in solid and hematologic malignancies," said Rob Hershberg, M.D., Ph.D., chief scientific officer at Celgene. "This strategic agreement combines Agios' scientific leadership in cellular metabolism with Celgene's expertise and growing efforts in immuno-oncology and builds upon the extremely productive partnership and working relationship that exist between our two companies."

"Metabolic immuno-oncology is an exciting new area of research for Agios that holds tremendous promise for patients and builds on our strength in cellular metabolism," said David Schenkein, M.D., chief executive officer at Agios. "Following our successful cancer metabolism partnership, we look forward to continuing our work with Celgene in this new field. This strategic alliance will allow Agios to quickly expand our existing research platform into a third core area while leveraging Celgene's capabilities and broad portfolio of immuno-oncology assets."

Also announced today, the companies modified certain rights from their 2010 collaboration (the "2010 Agreement"). First, Agios, which previously held U.S. rights for AG-120, gained global development and commercialization rights to the program from Celgene. As of August 15, 2016, neither party will have financial or other obligations to each other related to AG-120. There are no other changes to the existing IDH partnership between Agios and Celgene. Second, the companies agreed that rights to two cancer metabolism programs discovered under the 2010 Agreement, including a program focused on MTAP (methylthioadenosine phosphorylase) deleted



cancers, will advance under the structure of the new research collaboration outlined below. Following the expiration of the discovery phase of the 2010 Agreement on April 14, 2016, all other cancer metabolism programs discovered at Agios will remain wholly owned by Agios.

#### New Metabolic Immuno-Oncology Collaboration

Metabolic immuno-oncology is a rapidly evolving scientific area focused on altering the metabolic state of immune cells, or the tumor microenvironment, to enhance the body's immune response to cancer. There is increasing evidence that metabolism plays an important role in the regulation of immune cells and their response to tumors. The collaboration aims to discover novel metabolic pathways and their modulators that affect the metabolic state of immune cells, which may serve as potent anticancer therapies. In addition, Agios will focus on discovering molecular markers in order to identify patients who are most likely to respond to therapies.

Scope:

- Agios will receive an upfront cash payment of \$200 million for the initial four-year research term. Celgene has the option to extend the research term for up to two years for a pre-specified amount.
- Exploratory research, drug discovery and early development will be led by Agios.
- Generally, collaboration programs may be designated by Celgene when preclinical studies begin, and Celgene will then have an option on each program up through Phase 1 dose escalation for at least a \$30 million fee.

#### Economic Terms on Optioned Programs:

- For metabolic immuno-oncology programs, Celgene and Agios will enter into a global co-development and co-commercialization agreement with a worldwide 50/50 cost and profit share. Agios is eligible for up to \$169 million in clinical and regulatory milestone payments for each program.
- The two cancer metabolism programs from the 2010 Agreement, including a program focused on MTAP deleted cancers, are eligible for the same global co-development, co-commercialization and milestone structure described above.
- Celgene will have a one-time opportunity to select a metabolic immuno-oncology program for which costs and profits will be shared 65 percent by Celgene and 35 percent by Agios. Agios may also receive up to \$209 million in clinical and regulatory milestone payments for this program.
- For any inflammation or autoimmune programs that may result from the collaboration, Celgene has the option to enter into an exclusive worldwide license agreement and lead worldwide development and commercialization. For any such licensed products, Agios may receive up to \$386 million in clinical, regulatory and commercial milestone payments, as well as double-digit tiered royalties on any net sales.



Development and Commercial Rights:

- Agios and Celgene will alternate leadership of all 50/50 programs in the U.S. territory, with Agios making the first program selection.
- Celgene will lead ex-U.S. development and commercialization for all programs. Celgene will lead worldwide development and commercialization for the 65/35 program.

#### Global Rights for AG-120 Transferred to Agios

Agios now has full global development and commercial rights for AG-120, a first-in-class, oral, potent inhibitor of mutant isocitrate dehydrogenase 1 (IDH1). Agios is studying AG-120 in AML in multiple clinical trials, including as a single agent in the relapsed/refractory setting as well as in combination with standard chemotherapy regimens in the frontline setting. Additionally, Agios plans to initiate pivotal trials in AML and is exploring the use of AG-120 in several solid tumors, including cholangiocarcinoma and glioma.

"We are excited to consolidate the full worldwide rights for AG-120, providing us with another wholly owned investigational therapy discovered by Agios scientists to develop and commercialize along with our rare genetic disorders programs," said Dr. Schenkein. "We know that people with AML have limited treatment options today, and we are committed to bringing AG-120 through pivotal development as quickly as possible."

#### AGIOS CONFERENCE CALL INFORMATION

Agios will host a conference call and live webcast with slides for investors today at 5 p.m. ET. To participate in the conference call, please dial (877) 377-7098 (domestic) or (631) 291-4547 (international) and refer to conference ID 15115720. The live webcast can be accessed under "Events & Presentations" in the Investors & Media section of the company's website at www.agios.com. The archived webcast will be available on the company's website beginning approximately two hours after the event.

#### About the Agios-Celgene IDH Program

AG-221 and AG-881 remain part of Agios' global strategic collaboration with Celgene Corporation, and there are no changes to these programs. Under the terms of the 2010 Agreement, Celgene has worldwide development and commercialization rights for AG-221 (CC-90007). Agios continues to conduct clinical development activities within the AG-221 development program and is eligible to receive up to \$95 million in payments on achievement of certain milestones and royalties on any net sales. For AG-881, the companies have a joint worldwide development and 50/50 profit share collaboration, and Agios is eligible to receive regulatory milestone payments of up to \$70 million.

#### **About Agios**

Agios is focused on discovering and developing novel investigational medicines to treat cancer and rare genetic metabolic disorders through scientific leadership in the field of cellular metabolism. In addition to an active research and discovery pipeline across both therapeutic areas, Agios has multiple first-in-class investigational medicines in clinical and/or preclinical



development. All Agios programs focus on genetically identified patient populations, leveraging our knowledge of metabolism, biology and genomics. For more information, please visit the company's website at <u>www.agios.com</u>.

#### About Celgene

Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation. For more information, please visit <u>www.celgene.com</u>. Follow Celgene on Social Media: <u>@Celgene, Pinterest, LinkedIn, FaceBook</u> and <u>YouTube</u>.

#### **Cautionary Note Regarding Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding the potential benefits of, and plans relating to the collaboration between Agios and Celgene; the potential of IDH1/IDH2 as therapeutic targets; the potential benefits of product candidates targeting IDH1/IDH2 or other genetic mutations, including AG-221, AG-120, and AG-881; and the benefit of each company's strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "would," "could," "potential," "possible," "hope" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from current expectations and beliefs. For example, there can be no guarantee that any product candidate will be successfully developed or complete necessary preclinical and clinical phases, or that development of any of product candidates will successfully continue. There can be no guarantee that any positive developments will result in stock price appreciation. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other important factors, including: results of clinical trials and preclinical studies, including subsequent analysis of existing data and new data received from ongoing and future studies; the content and timing of decisions made by the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; the ability to obtain and maintain requisite regulatory approvals and to enroll patients in its planned clinical trials; unplanned cash requirements and expenditures; competitive factors; the ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates ; the ability to maintain key collaborations; and general economic and market conditions. These and other risks are described in greater detail under the caption "Risk Factors" included in each company's public filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and neither company has any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.



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# CONTACTS

# **Agios Pharmaceuticals:**

Investors: Kendra Adams, 617-844-6407 Senior Director, Investor & Public Relations Kendra.Adams@agios.com

Renee Leck, 617-649-8299 Senior Manager, Investor & Public Relations <u>Renee.Leck@agios.com</u>

Media: Dan Budwick, 973-271-6085 Senior Vice President, Media Relations Pure Communications Inc. dan@purecommunicationsinc.com

## **Celgene Corporation:**

Investors: Patrick E. Flanigan III, 908-673-9969 Corporate Vice President, Investor Relations

Media: Brian P. Gill, 908-673-9530 Vice President, Corporate Communications



#### Agios Updates 2016 Financial Guidance

- \$200 Million Upfront Payment from Celgene for New Metabolic Immuno-Oncology Collaboration -

- Agios Expects 2016 Ending Cash Position of More than \$390 Million -

- Investor Conference Call Today at 5 p.m. ET -

**CAMBRIDGE, MA, May 17, 2016** — Agios Pharmaceuticals, Inc. (NASDAQ: AGIO) today updated financial guidance for the full year 2016 following today's joint announcement that Agios and Celgene have established a new collaboration in metabolic immuno-oncology. As part of this new agreement, Agios will receive an upfront cash payment of \$200 million.

Additionally, Agios and Celgene modified certain rights from their 2010 collaboration (the "2010 Agreement"). First, Agios, which previously held U.S. rights for AG-120, gained global development and commercialization rights to the program from Celgene. Second, the companies allocated rights to two cancer metabolism programs discovered under the 2010 Agreement, which will advance under the structure of the new research collaboration. Agios will host a conference call for investors at 5 p.m. ET today to discuss these announcements.

As a result of the \$200 million upfront payment related to this new collaboration, Agios' pro forma cash balance as of March 31, 2016 was \$556 million. Agios now expects to end 2016 with more than \$390 million of cash, cash equivalents and marketable securities. This revised cash guidance takes into account full ownership of AG-120 as of August 15, 2016. The company expects that its cash, cash equivalents and marketable securities would be sufficient to fund its operating expenses and capital expenditure requirements through mid-2018.

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#### Agios Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding the potential benefits of, and plans relating to, Agios' collaborations with Celgene; the potential of IDH1/IDH2 as therapeutic targets; the potential benefits of Agios' product candidates targeting IDH1/IDH2 or other genetic mutations, including AG-221, AG-120, and AG-881; its financial guidance regarding the amount of cash, cash equivalents and marketable securities that the company will have as of December 31, 2016; and the benefit of Agios' strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "would," "could," "potential," "possible," "hope" and similar expressions are intended to identify forward-looking statements, although not all forwardlooking statements contain these identifying words. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from Agios' current expectations and beliefs. For example, there can be no guarantee that any product candidate Agios is developing will successfully commence or complete necessary preclinical and clinical development phases, or that development of any of Agios' product candidates will successfully continue. There can be no guarantee that any positive developments in Agios' business will result in stock price appreciation. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other important factors, including: Agios' results of clinical trials and preclinical studies, including subsequent analysis of existing data and new data received from ongoing and future studies; the content and timing of decisions made by the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; Agios' ability to obtain and maintain requisite regulatory approvals and to enroll patients in its planned clinical trials; unplanned cash requirements and expenditures; competitive factors; Agios' ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates it is developing; Agios' ability to maintain key collaborations, such as its agreements with Celgene; and general economic and market conditions. These and other risks are described in greater detail under the caption "Risk Factors" included in Agios' Quarterly Report on Form 10-Q for the guarter ended March 31, 2016, and other filings that Agios may make with the Securities and Exchange Commission in the future. Any forward-looking statements contained in this press release speak only as of the date hereof, and Agios expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.



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