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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): January 9, 2017**

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**Agios Pharmaceuticals, Inc.**  
(Exact Name of Registrant as Specified in Charter)

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**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)**

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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))
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**Item 2.02 Results of Operations and Financial Condition.**

Although it has not finalized its full financial results for the fourth quarter and fiscal year ended December 31, 2016, Agios Pharmaceuticals, Inc. (the “Company”) announced on January 9, 2017, that it expects to report that it had approximately \$574 million of cash, cash equivalents and marketable securities as of December 31, 2016.

The information contained in Item 2.02 of this Form 8-K is unaudited and preliminary, and does not present all information necessary for an understanding of the Company’s financial condition as of December 31, 2016 and its results of operations for the three months and year ended December 31, 2016. The audit of the Company’s consolidated financial statements for the year ended December 31, 2016 is ongoing and could result in changes to the information set forth above.

The information in this Item 2.02 shall not be deemed “filed” for 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 in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 7.01 Regulation FD Disclosure.**

On January 9, 2017, the Company intends to make a slide presentation at the 35th Annual J.P. Morgan Healthcare Conference. A form of the slide presentation is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information responsive to Item 7.01 of this Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 8.01 Other Events.**

On January 9, 2017, the Company issued a press release outlining its 2017 milestones for its development programs and research pipeline, which will be discussed at the Company’s presentation at the 35th Annual J.P. Morgan Healthcare Conference on January 9, 2017. The full text of the press release issued in connection with this announcement is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

**Forward Looking Statements**

This Current Report on Form 8-K and the exhibits attached hereto contain forward-looking statements of the Company that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Current Report on Form 8-K and the exhibits attached hereto, are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” “contemplate,” or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about: the Company’s estimates regarding its balance of cash, cash equivalents and marketable securities for the year ended December 31, 2016 and other expectations regarding its business, plans, prospects and strategies. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that the Company makes due to a number of important factors, including those Risk Factors discussed in the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, and other filings that the Company may make with the Securities and Exchange Commission in the future. Any forward-looking statements contained in this Current Report on Form 8-K speak only as of the date hereof, and the Company expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

**Item 9.01 Financial Statements and Exhibits.**

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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Form of Presentation as of January 9, 2017.
99.2	Press release issued by Agios Pharmaceuticals, Inc. on January 9, 2017.

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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: January 9, 2017

By: /s/ David P. Schenkein

David P. Schenkein, M.D.  
President and Chief Executive Officer

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**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
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99.2	Press release issued by Agios Pharmaceuticals, Inc. on January 9, 2017.



## **AgiOS: Delivering Our First Medicines to Patients**

JPMorgan Healthcare Conference

January 9, 2017

David Schenkein, M.D.  
Chief Executive Officer

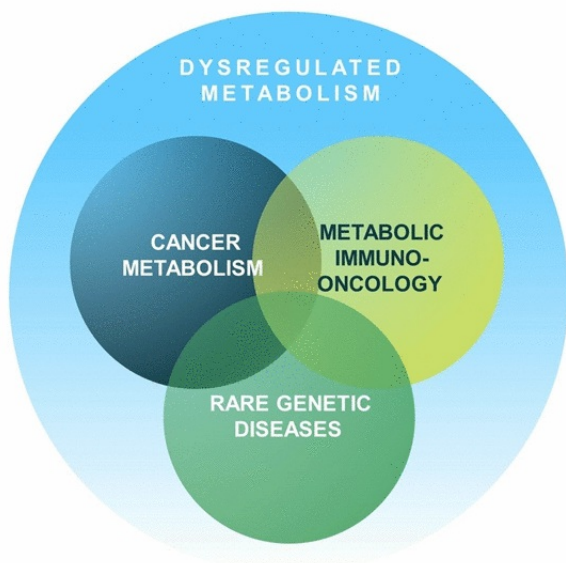


## Forward Looking Statements

This presentation and various remarks we make during this presentation contain forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding the Agios' plans, strategies and expectations for its and its collaborator's preclinical, clinical and commercial advancement of its drug development programs including enasidenib, AG-120, and AG-348; the potential benefits of Agios' product candidates; its key milestones for 2017; its financial guidance regarding the period in which it will have capital available to fund its operations; and the potential benefit of its strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "would," "could," "potential," "possible," "hope," "strategy," "milestone," "will," 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 Agios' current expectations and beliefs. For example, there can be no guarantee that any product candidate Agios or its collaborator, Celgene, 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 presentation and various remarks we make during this presentation 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 quarter ended September 30, 2016, and other filings that Agios may make with the Securities and Exchange Commission in the future. Any forward-looking statements contained in this presentation and various remarks we make during this presentation 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, except as required by law.



## We Are Driven By a Clear Vision and Values



*AgiOS is passionately committed to applying our scientific leadership in the field of cellular metabolism to transform the lives of patients with cancer and rare genetic diseases.*

**Building a Global, Commercial-Stage Biopharmaceutical Company**



**January 2009**





2009



Team



Science



Discovery



January 9, 2017



Delivering Our First  
Medicines to Patients



Team



Science



Discovery



## 2017 Key Priorities & Expected Milestones

### IDH

- Secure approval and co-commercialize enasidenib for R/R AML in the U.S.
- Submit NDA for wholly owned AG-120 in R/R AML by YE 2017
- Initiate Phase 3 combining AG-120 and VIDAZA® in frontline AML in 1H 2017

### PKR

- Continue to demonstrate leadership in PK deficiency
- Prepare for 1H 2018 pivotal trial initiation for wholly owned AG-348 in PK deficiency

### RESEARCH

- Advance next wave of research in three areas of expertise: cancer metabolism, rare genetic diseases and metabolic immuno-oncology
- File IND application for MTAP pathway development candidate by YE 2017



## 2017 – 2018

### Commercial Stage Biopharmaceutical Company



2

approved  
precision  
medicines in AML



4+

clinical-  
stage  
molecules



3+

pivotal trials  
(IDH, PKR)



3

areas of  
research  
expertise



450+

employees



100%

committed  
to helping  
patients



### Delivering Our First Medicines to Patients



Team



Science



Discovery



**IDH**

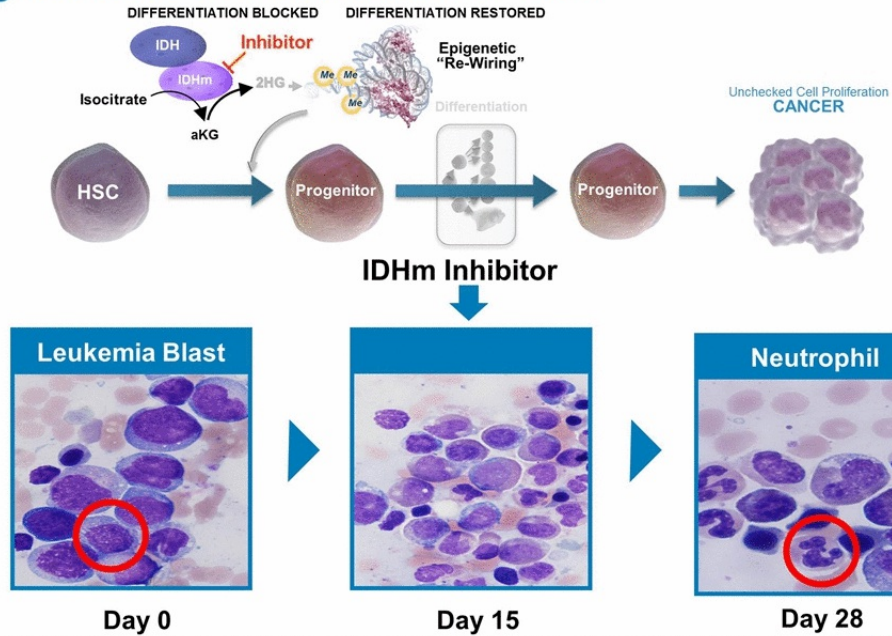
**PKR**

**RESEARCH**





# Repairing an IDH Mutant Cancer Cell

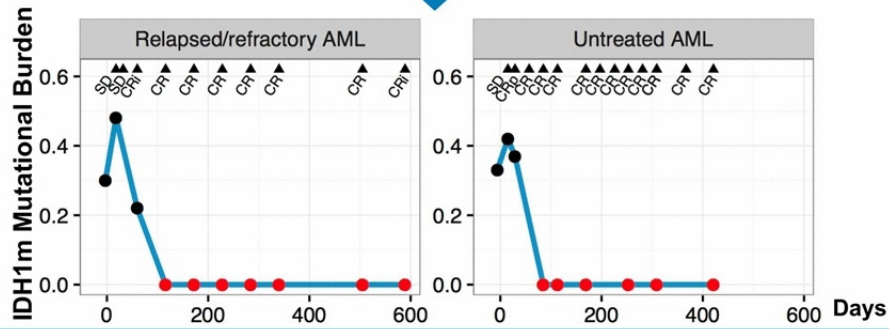
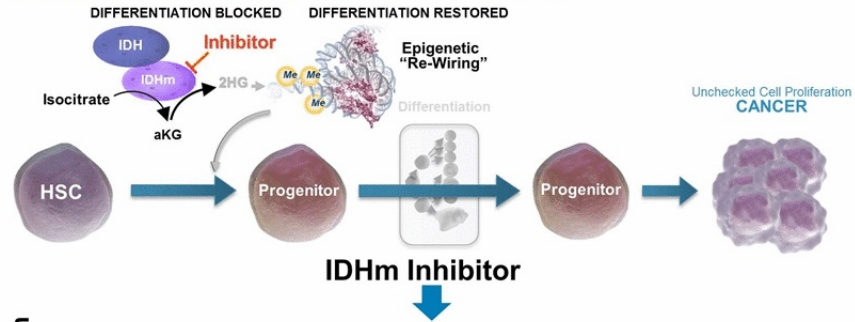


Mutation occurs early and persists throughout illness

AG-120, EORTC, 2014



# Repairing an IDH Mutant Cancer Cell



Mutation occurs early and persists throughout illness

AG-120, ASH, 2016



# Our Vision for IDHm Inhibitors

A Roadmap for Speed and Breadth



**All IDHm patients  
screened and treated  
with an IDHm inhibitor  
for the entire course of  
their disease**

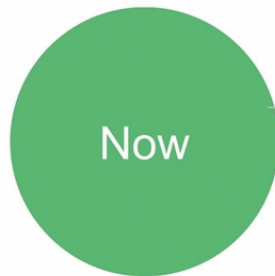




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## Our Vision for IDHm Inhibitors

A Roadmap for Speed and Breadth



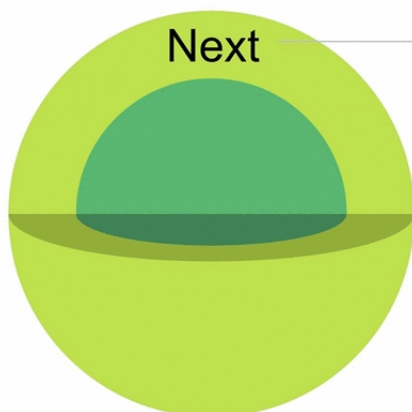
### Relapsed/Refractory AML

- ✓ Enasidenib NDA submission 2016
- AG-120 NDA submission by YE 2017



# Our Vision for IDHm Inhibitors

A Roadmap for Speed and Breadth



## Frontline AML

- AG-120 + Vidaza® Phase 3
- Enasidenib / AG-120 + (7+3) with maintenance

## Relapsed/Refractory AML

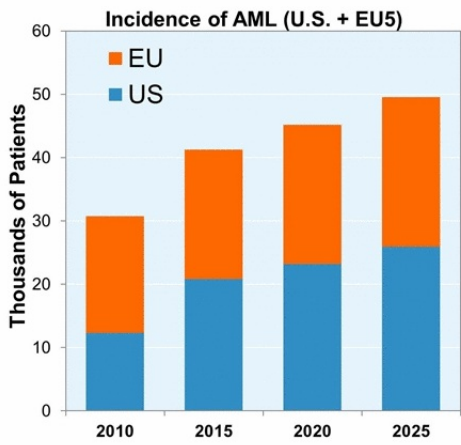
- Novel-novel combination Phase 1 studies

## Solid Tumors

- AG-120 Phase 3 cholangiocarcinoma
- AG-120 and AG-881 Phase 1 glioma expansion
- Glioma development strategy



# Incidence of AML Rising in U.S. and EU5 with Aging Population



- Worldwide incidence of AML is growing in step with an aging population
- ~65% of incident patients in the U.S. and EU are 65 years of age or older
- It is estimated that ~15-23% of patients with AML will have an IDH mutation

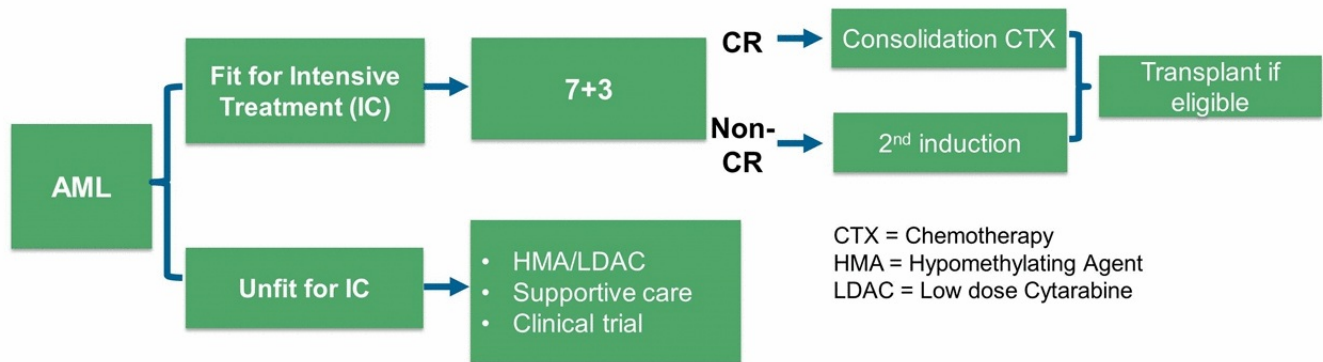
Acute Myeloid Leukemia (AML)		
IDH1m frequency	IDH2m frequency	5-year overall survival
6-10%	9-13%	20-25%

Multiple sources including market research SEER

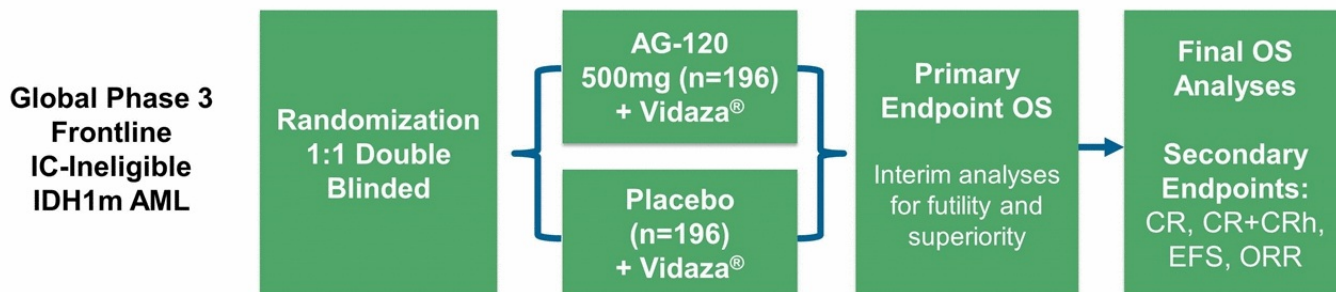
Sources:  
 1) American Cancer Society: Cancer Facts and Figures  
 2) Visser et. Al. Incidence, survival and prevalence of myeloid malignancies in Europe. Eur J Cancer. 2012 Nov;48(17):3257-66  
 3) Epiphany Partners Epic Oncology  
 4) Decision Resources



# Shifting the Treatment Paradigm for AML with Precision Medicine



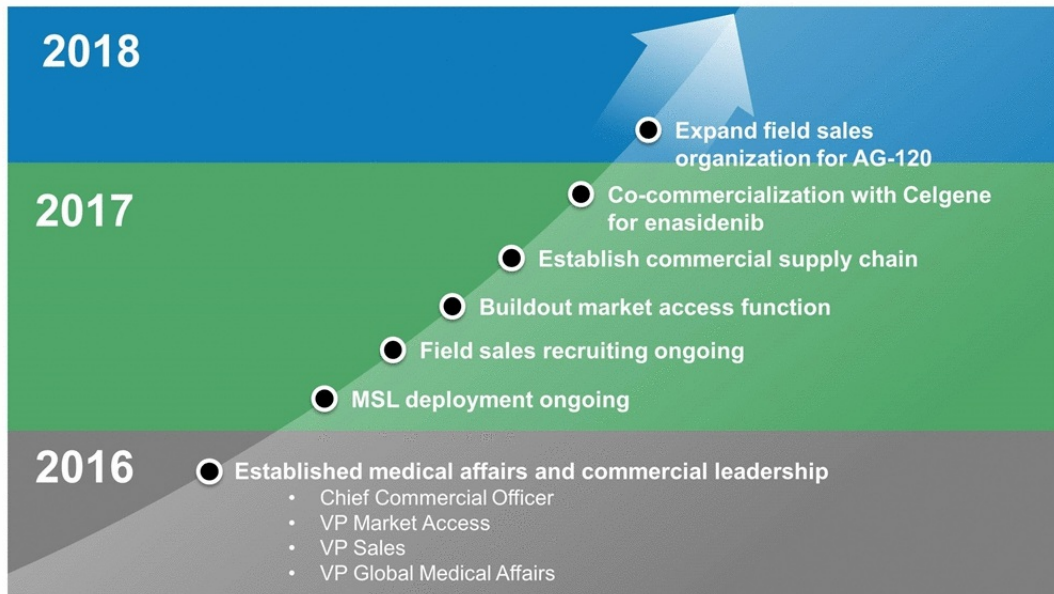
# Advancing AG-120 into Frontline Setting



IC = intensive chemotherapy  
Vidaza® is a registered trademark of Celgene Corporation

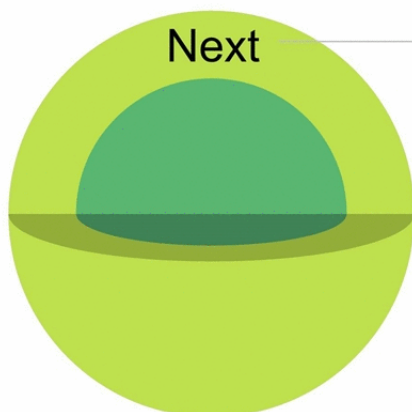


# Building World-Class Commercial Capabilities for IDH Launches



# Our Vision for IDHm Inhibitors

## A Roadmap for Speed and Breadth



### Frontline AML

- AG-120 + Vidaza® Phase 3
- Enasidenib / AG-120 + (7+3) with maintenance

### Relapsed/Refractory AML

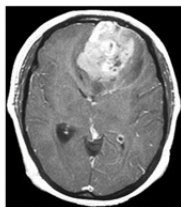
- Novel-novel combination Phase 1 studies

### Solid Tumors

- AG-120 Phase 3 cholangiocarcinoma
- AG-120 and AG-881 Phase 1 glioma expansion
- Glioma development strategy



## Treating Solid Tumors with an IDH1m Inhibitor



	<b>Glioma</b>	<b>Intrahepatic Cholangiocarcinoma (IHCC)</b>	<b>Chondrosarcoma</b>
	Low grade and 2 <sup>ary</sup> GBM	Bile ducts	Cartilage
Incidence (cases/year U.S.)	5K	2K – 4K	700 – 1000
IDH1m frequency	68-74%	11-24%	40-52%
Treatment options	Surgery, XRT Chemotherapy	Surgery, Chemotherapy Liver transplantation	Surgery, XRT Chemotherapy
5-year OS	~32-68%*	~9%	~10-90%

Other solid tumor types include colon, melanoma, lung, ovarian.

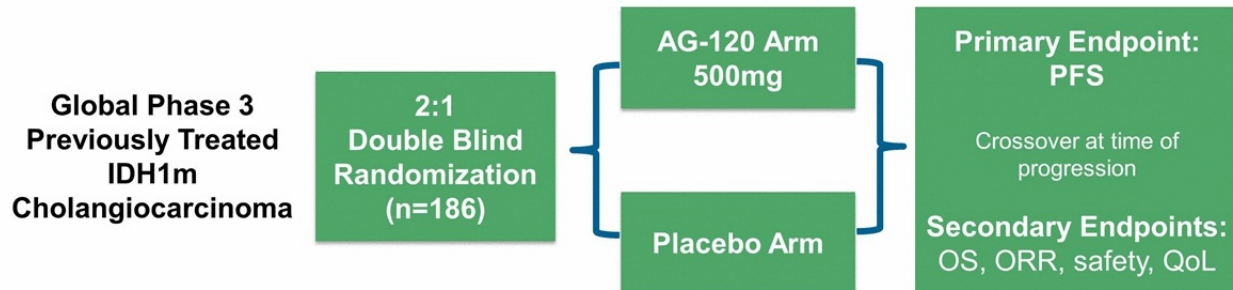
Multiple sources, including market research and SEER. Estimates will continue to evolve with additional future data

\*excludes primary GBM





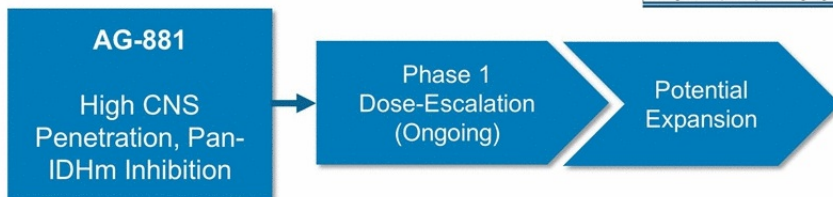
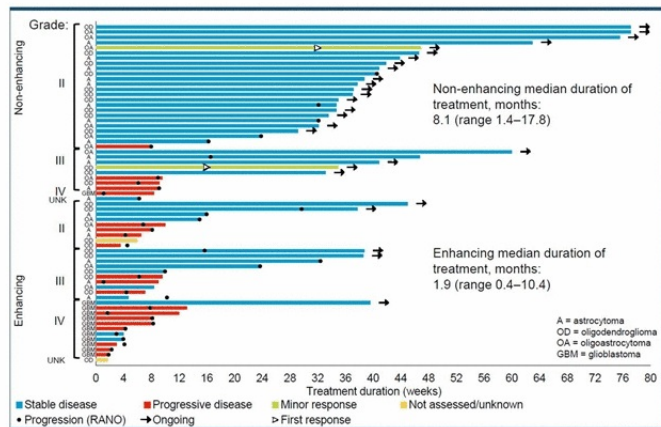
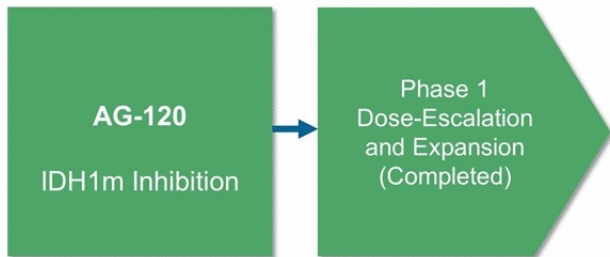
# Registration-Enabling Phase 3 Cholangiocarcinoma Study



**Trial Initiated in December 2016**



# Encouraging Data with AG-120 Supports Clinical Development of IDH1m Inhibitor in Glioma



IDH

PKR

RESEARCH

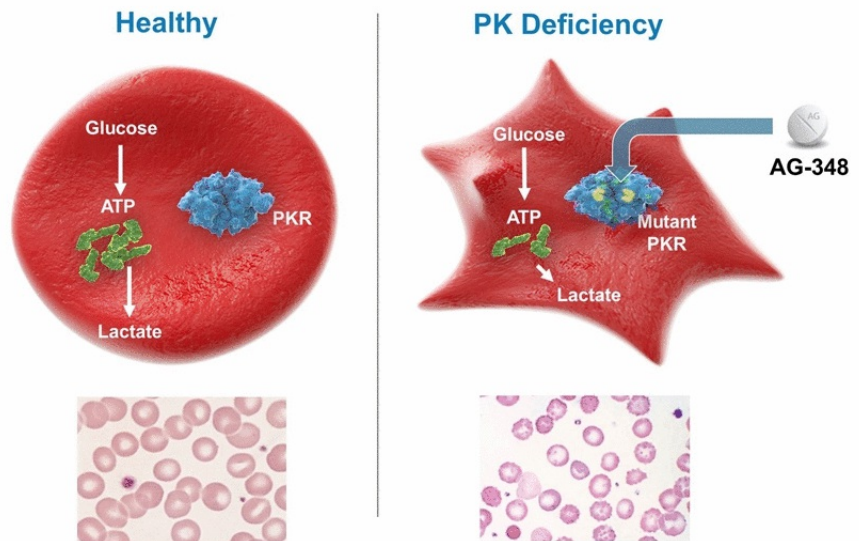


# PK Deficiency Is a Rare Genetic Disease that Affects Red Blood Cells

## Rare genetic disease of erythrocyte pyruvate kinase

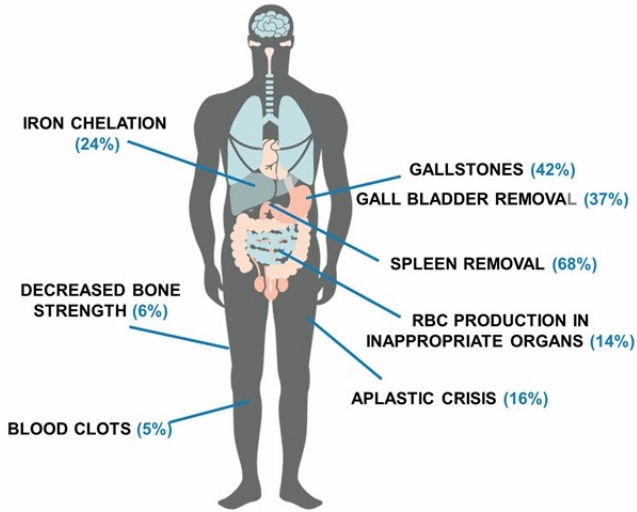
- PK deficiency often presents at birth with jaundice and can cause lifelong hemolytic anemia and associated morbidities
- Estimated prevalence ranges from ~1:20K to ~1:485K<sup>1-4</sup>

PKR regulates a crucial step in red blood cell metabolism and when mutated causes premature death of these cells



# PK Deficiency Is a Lifelong Disease with Only Supportive Treatments

## Disease Burden



	Supportive Treatments	Complications
INFANT	<ul style="list-style-type: none"> <li>Phototherapy</li> <li>Blood transfusions</li> </ul>	
CHILD	<ul style="list-style-type: none"> <li>Removal of spleen</li> <li>Removal of gall bladder</li> <li>Blood transfusions</li> </ul>	<ul style="list-style-type: none"> <li>Infection risk → lifelong prophylactic antibiotics</li> <li>Thrombosis risk</li> </ul>
ADULT	<ul style="list-style-type: none"> <li>Blood transfusions</li> </ul>	<ul style="list-style-type: none"> <li>Iron overload → iron chelation therapy</li> </ul>



## Quality of Life Impact Weighs Heavily for Both Patients & Families

*"If I say I'm tired, people think I need more sleep... I have fatigue so intense that it wakes me up at night. How do you get someone to understand that?!"*

*"Think of a day when you are sick with a cold. That is me on my best day."\**

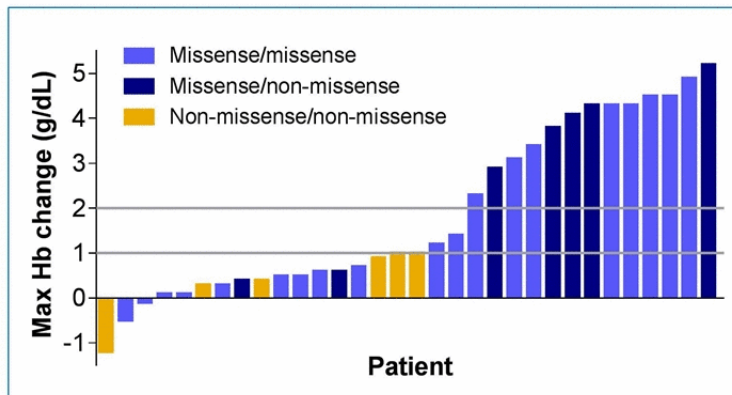


## Agios Leadership in PK Deficiency





# Compelling Proof-of-Concept for AG-348, the First Disease Modifying Therapy for PK Deficiency



**52 patients enrolled;  
17 completed first 24 weeks, 15 in extension**

## DRIVE PK Learnings

Robust hemoglobin increases in 15 / 32 patients; 15 / 26 patients with 1 or more missense mutation

Responses are rapid and sustained; median time to response of 1.4 weeks

Majority of responders seen at doses  $\leq 50$  mg BID and as low as 5 mg QD

Well-tolerated beyond six months of dosing



## Key Considerations for AG-348 Pivotal Trial Design

Design Element	Considerations	Rationale
<b>Patient Population</b>	<ul style="list-style-type: none"><li>• Transfusion dependent adult (TD)</li><li>• Non-Transfusion dependent adult (NTD)</li></ul>	<ul style="list-style-type: none"><li>• Goal to treat all adult patients</li></ul>
<b>Size</b>	<ul style="list-style-type: none"><li>• ~100 patients</li></ul>	<ul style="list-style-type: none"><li>• Rare disease</li></ul>
<b>Dose</b>	<ul style="list-style-type: none"><li>• Dose titration up to optimal hemoglobin response</li></ul>	<ul style="list-style-type: none"><li>• Majority of responders seen at doses <math>\leq 50</math> mg BID and as low as 5 mg QD</li></ul>
<b>Endpoints</b>	<ul style="list-style-type: none"><li>• Hemoglobin response (NTD)</li><li>• Reduction in transfusion frequency (TD)</li><li>• Patient-reported outcomes (PRO)</li></ul>	<ul style="list-style-type: none"><li>• Establish clinical benefit</li></ul>
<b>Control</b>	<ul style="list-style-type: none"><li>• Placebo controlled</li></ul>	<ul style="list-style-type: none"><li>• Evaluate PRO</li></ul>



Expect to initiate pivotal study in 1H 2018



IDH

PKR

RESEARCH



# Agios' Scientific Research Platform

## DYSREGULATED METABOLISM

### CANCER METABOLISM

- Inhibit key enzymes in cancer cell specific metabolic pathways to disrupt tumor cell proliferation and survival

### RARE GENETIC DISEASES

- Restore defective metabolic pathways in disease cells that cause rare genetic disorders of metabolism

### METABOLIC IMMUNO-ONCOLOGY

- Alter the metabolic state of immune cells to enhance the body's anti-tumor response

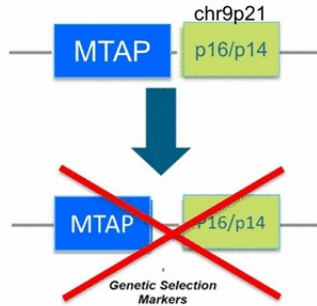
## RESEARCH PLATFORM



# Development Candidate for MTAP Pathway Selected

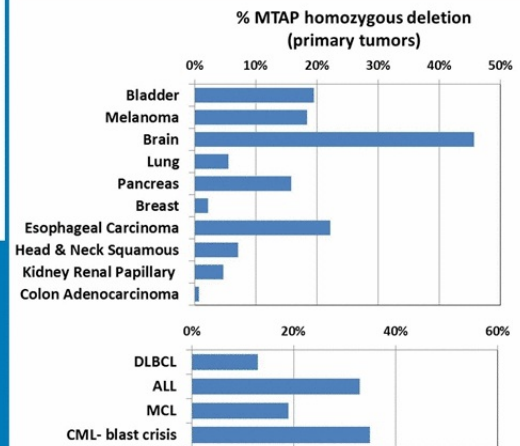
IND Expected by Year-End

## Deletion of metabolic gene adjacent to tumor suppressor p16/p14



- p16/p14 tumor suppressor locus deleted in 15% of all cancers
- Metabolic gene, MTAP, is adjacent to p16/p14 & typically co-deleted

## ~75,000 new patients/year in U.S. with MTAP deletion across many indications



MTAP-deleted tumors constitute a large, genetically defined patient population



## 2017 – 2018

### Commercial Stage Biopharmaceutical Company



2

approved  
precision  
medicines in AML



4+

clinical-  
stage  
molecules



3+

pivotal trials  
(IDH, PKR)



3

areas of  
research  
expertise



450+

employees



100%

committed  
to helping  
patients



### Delivering Our First Medicines to Patients



Team



Science



Discovery





**AgiOS Announces Key Upcoming Milestones to Support Evolution to a Commercial Stage Biopharmaceutical Company in 2017**

*- Enasidenib (AG-221) NDA Submitted for IDH2m Relapsed/Refractory (R/R) Acute Myeloid Leukemia (AML) -*

*- AG-120 NDA Submission for IDH1m R/R AML Planned by Year End 2017 -*

*- AG-348 Advancing to Pivotal Development in PK Deficiency -*

*- Development Candidate for MTAP Pathway Selected; IND Submission Expected by Year End 2017 -*

*- Company Ends 2016 in a Strong Financial Position with \$574M in Cash, Cash Equivalents and Marketable Securities -*

**SAN FRANCISCO, January 9, 2017** — Agios Pharmaceuticals, Inc. (NASDAQ: AGIO), a leader in the fields of cancer metabolism and rare genetic metabolic diseases, today outlined key 2017 milestones in conjunction with its presentation at the 35<sup>th</sup> Annual J.P. Morgan Healthcare Conference in San Francisco. The presentation will outline important milestones as Agios evolves into a commercial stage company, including potential launches for enasidenib and AG-120 in R/R AML, pivotal development for its second wholly owned asset, AG-348 in pyruvate kinase (PK) deficiency, and an investigational new drug (IND) application submission for the company's next development candidate, focused on MTAP deleted cancers. The company will webcast its presentation on Monday, January 9, 2017 at 10:00 a.m. PT (1:00 p.m. ET) at [www.agios.com](http://www.agios.com).

“This is the year Agios will evolve into a commercial-stage organization with the anticipated launch of enasidenib for patients with R/R AML, followed by the NDA submission of AG-120 and AG-348 preparing to enter a pivotal trial in PK deficiency,” said David Schenkein, M.D., chief executive officer of Agios. “We believe these milestones will enable us to achieve our vision of delivering important medicines with the potential to transform patients’ lives. Additionally, our robust research engine continues to be highly productive with an IND submission for the company’s sixth development candidate in eight years anticipated by the end of 2017.”

The company expects to achieve the following key milestones by the end of 2017:

- Potential approval of enasidenib in the United States for IDH2m positive R/R AML in collaboration with Celgene.
- Submit a new drug application (NDA) to the U.S. FDA for AG-120 by the end of 2017. AG-120 is a wholly owned, first-in-class, oral, selective, potent inhibitor of IDH1m, in IDH1m positive R/R AML.





- Initiate a global, registration-enabling Phase 3 study combining AG-120 and VIDAZA® in frontline AML patients with an IDH1 mutation ineligible for intensive chemotherapy in the first half of 2017.
- Finalize design and operational activities for a global pivotal trial of AG-348 to initiate in the first half of 2018. AG-348 is a wholly owned, first-in-class, oral activator of both wild-type (normal) and mutated pyruvate kinase-R (PKR) enzymes, in PK deficiency.
- File an IND application for the MTAP pathway development candidate by the end of 2017.

The company also provided an update on the following 2016 milestones achieved in December:

- Supported Celgene's submission of an NDA for enasidenib in IDH2m positive R/R AML.
- Initiated a global, registration-enabling randomized Phase 3 trial for AG-120 in IDH1m positive cholangiocarcinoma. The FDA also granted AG-120 Fast Track Designation for the treatment of patients with previously treated, unresectable or metastatic cholangiocarcinoma with an IDH1 mutation.
- Selected a development candidate focused on the MTAP pathway to enter IND-enabling studies.

#### **2016 Year-End Cash and Guidance**

AgiOS ended 2016 with approximately \$574 million of cash, cash equivalents and marketable securities. Based on its current operating plans, the company expects that its existing cash, cash equivalents and marketable securities as of December 31, 2016, together with anticipated interest income, and anticipated expense reimbursements under its collaboration agreements with Celgene, but excluding any additional program-specific milestone payments from Celgene, will enable the company to fund its anticipated operating expenses and capital expenditure requirements through at least the end of 2018.

#### **Presentation at 35<sup>th</sup> Annual J.P. Morgan Healthcare Conference**

AgiOS will webcast its corporate presentation from the 35<sup>th</sup> Annual J.P. Morgan Healthcare Conference in San Francisco on Monday, January 9, 2017 at 10:00 a.m. PT (1:00 p.m. ET). A live webcast of the presentation can be accessed under "Events & Presentations" in the Investors and Media section of the company's website at [agios.com](http://agios.com). A replay of the webcast will be archived on the Agios website for at least two weeks following the presentation.

#### **About Agios**

AgiOS is focused on discovering and developing novel investigational medicines to treat cancer and rare genetic metabolic diseases 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 the company's knowledge of metabolism, biology and genomics. For more information, please visit the company's website at [www.agios.com](http://www.agios.com).

#### **About Agios/Celgene Collaboration**

Enasidenib and AG-881 are part of Agios' global strategic collaboration with Celgene Corporation focused on cancer metabolism. Under the terms of the 2010 collaboration, Celgene has worldwide development and commercialization rights for enasidenib. Agios continues to conduct clinical development activities within the enasidenib development program and is eligible to receive up to \$120 million in payments assuming achievement of certain milestones and royalties on net sales. Additionally, Agios and Celgene intend to co-commercialize enasidenib in the U.S. 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. The program focused on MTAP (methylthioadenosine phosphorylase) deleted cancers is part of a 2016 global co-development and co-commercialization agreement with Celgene focused on metabolic immuno-oncology with a worldwide 50/50 cost and profit share between Agios and Celgene, under which Agios is eligible for up to \$169 million in clinical and regulatory milestone payments for the program.

Vidaza® is a registered trademark of Celgene Corporation.

#### **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 Agios' plans, strategies and expectations for its and its collaborator's preclinical, clinical and commercial advancement of its drug development programs including enasidenib, AG-120, and AG-348; the potential benefits of Agios' product candidates; its key milestones for 2017; its financial guidance regarding the period in which it will have capital available to fund its operations; and the potential benefit of its strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "would," "could," "potential," "possible," "hope," "strategy," "milestone," "will," 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 Agios' current expectations and beliefs. For example, there can be no guarantee that any product candidate Agios or its collaborator, Celgene, 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 quarter ended September 30, 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, except as required by law.

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