

AGIOS PHARMACEUTICALS INC

Form 10-Q

August 07, 2014

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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, DC 20549**

**FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the quarterly period ended June 30, 2014**

**OR**

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**Commission file number 001-36014**

**AGIOS PHARMACEUTICALS, INC.**

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

**Delaware**  
**(State or Other Jurisdiction of**  
**Incorporation or Organization)**

**26-0662915**  
**(I.R.S. Employer**  
**Identification No.)**

**38 Sidney Street, 2<sup>nd</sup> Floor, Cambridge, Massachusetts**  
**(Address of Principal Executive Offices)**  
**(617) 649-8600**

**02139**  
**(Zip Code)**

**(Registrant's Telephone Number, Including Area Code)**

**(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)**

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

Number of shares of the registrant's Common Stock, \$0.001 par value, outstanding on August 6, 2014: 34,458,016

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**AGIOS PHARMACEUTICALS, INC.**

**FORM 10-Q**

**FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2014**

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**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements (Unaudited).****AGIOS PHARMACEUTICALS, INC.****Condensed Consolidated Balance Sheets****(in thousands, except share and per share data)***(Unaudited)*

	<b>June 30, 2014</b>	<b>December 31, 2013</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 108,247	\$ 71,560
Marketable securities	130,233	95,209
Unbilled collaboration receivable related party		476
Prepaid expenses and other current assets	2,842	2,502
Refundable income taxes	3,841	
Total current assets	245,163	169,747
Marketable securities	22,631	27,125
Property and equipment, net	3,210	3,758
Restricted cash	571	571
Other assets	455	4
Total assets	\$ 272,030	\$ 201,205
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 5,388	\$ 3,678
Accrued expenses	5,456	6,586
Income taxes payable		1,462
Deferred revenue related party	33,644	25,072
Deferred rent	142	123
Other current liabilities	8	9
Total current liabilities	44,638	36,930
Deferred revenue, net of current portion related party	26,697	32,567
Deferred rent, net of current portion	145	220
Other non-current liabilities	2	6
Commitments and contingencies		
Stockholders equity:		

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Preferred stock, \$0.001 par value; 25,000,000 shares authorized; no shares issued and outstanding

Common stock, \$0.001 par value; 125,000,000 shares authorized; 34,424,415 and 31,202,542 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively

	34	31
Additional paid-in capital	344,490	244,881
Accumulated other comprehensive income	12	14
Accumulated deficit	(143,988)	(113,444)
<b>Total stockholders' equity</b>	<b>200,548</b>	<b>131,482</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 272,030</b>	<b>\$ 201,205</b>

*See accompanying notes to condensed consolidated financial statements.*

Table of Contents**AGIOS PHARMACEUTICALS, INC.****Condensed Consolidated Statements of Operations****(in thousands, except share and per share data)***(Unaudited)*

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Collaboration revenue related party	\$ 8,411	\$ 6,268	\$ 16,822	\$ 12,536
Operating expenses:				
Research and development	22,576	12,958	39,982	24,420
General and administrative	4,165	1,836	7,454	3,688
Total operating expenses	26,741	14,794	47,436	28,108
Loss from operations	(18,330)	(8,526)	(30,614)	(15,572)
Interest income	34	5	70	13
Loss before provision for income taxes	(18,296)	(8,521)	(30,544)	(15,559)
Provision for income taxes		(99)		(289)
Net loss	(18,296)	(8,620)	(30,544)	(15,848)
Cumulative preferred stock dividends		(1,798)		(3,595)
Net loss applicable to common stockholders	\$ (18,296)	\$ (10,418)	\$ (30,544)	\$ (19,443)
Net loss per share applicable to common stockholders basic and diluted	\$ (0.54)	\$ (2.80)	\$ (0.94)	\$ (5.27)
Weighted-average number of common shares used in net loss per share applicable to common stockholders basic and diluted	33,602,472	3,722,963	32,506,739	3,690,669

*See accompanying notes to condensed consolidated financial statements.*

Table of Contents**AGIOS PHARMACEUTICALS, INC.****Condensed Consolidated Statements of Comprehensive Loss****(in thousands)***(Unaudited)*

	<b>Three Months Ended June 30</b>		<b>Six Months Ended June 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Net loss	\$ (18,296)	\$ (8,620)	\$ (30,544)	\$ (15,848)
Other comprehensive loss:				
Unrealized loss on available-for-sale securities	(21)	(3)	(2)	(2)
Comprehensive loss	\$ (18,317)	\$ (8,623)	\$ (30,546)	\$ (15,850)

*See accompanying notes to condensed consolidated financial statements.*

Table of Contents**AGIOS PHARMACEUTICALS, INC.****Condensed Consolidated Statements of Cash Flows****(in thousands)***(Unaudited)*

	<b>Six Months Ended June 30,</b>	
	<b>2014</b>	<b>2013</b>
<b>Operating activities</b>		
Net loss	\$ (30,544)	\$ (15,848)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	659	723
Stock-based compensation expense	3,886	753
Net amortization (accretion) of premium (discount) on investments	305	(9)
Changes in operating assets and liabilities:		
Unbilled collaboration receivable related party	476	
Prepaid expenses and other assets	(791)	(2,690)
Accounts payable	1,684	(271)
Accrued expenses and other liabilities	(1,130)	1,845
Deferred rent	(55)	(36)
Refundable income taxes and income taxes payable	(5,303)	266
Deferred revenue related party	2,702	(12,536)
Net cash used in operating activities	(28,111)	(27,803)
<b>Investing activities</b>		
Purchases of marketable securities	(126,338)	(23,195)
Proceeds from maturities and sales of marketable securities	95,501	38,086
Purchases of property and equipment	(99)	(976)
Net cash (used in) provided by investing activities	(30,936)	13,915
<b>Financing activities</b>		
Proceeds from public offering of common stock, net of commissions and offering costs	94,698	
Net proceeds from stock option exercises and issuance of common stock	1,036	72
Net cash provided by financing activities	95,734	72
Net increase (decrease) in cash and cash equivalents	36,687	(13,816)
Cash and cash equivalents at beginning of the period	71,560	91,297
Cash and cash equivalents at end of the period	\$ 108,247	\$ 77,481
<b>Supplemental disclosure of non-cash investing and financing transactions</b>		
Additions to property, plant and equipment included in accounts payable	\$ 12	\$



Vesting of restricted stock	\$	(6)	\$
Public offering costs included in accounts payable	\$	13	\$
<b>Supplemental cash flow information</b>			
Cash paid for income taxes	\$	5,958	\$

*See accompanying notes to condensed consolidated financial statements.*

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**Agios Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements**

*(Unaudited)*

**1. Overview and Basis of Presentation**

Agios Pharmaceuticals, Inc. ( Agios or the Company ) is a biopharmaceutical company committed to the fundamental transformation of patients' lives through scientific leadership in the field of cancer metabolism and inborn errors of metabolism. The Company has built a unique set of core capabilities in the field of cellular metabolism, with the goal of making transformative, first or best in class medicines. The Company's therapeutic areas of focus are cancer and inborn errors of metabolism, which are a broad group of more than 600 rare genetic diseases caused by mutations, or defects, of single metabolic genes. In both of these areas, the Company is seeking to unlock the biology of cellular metabolism to create transformative therapies. The Company is located in Cambridge, Massachusetts.

The condensed consolidated interim balance sheet as of June 30, 2014, the condensed consolidated interim statements of operations and comprehensive loss for the three and six months ended June 30, 2014 and 2013 and the statements of cash flows for the six months ended June 30, 2014 and 2013, are unaudited. The unaudited condensed consolidated interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's condensed consolidated financial position as of June 30, 2014, and its results of operations for the three and six months ended June 30, 2014 and 2013 and cash flows for the six months ended June 30, 2014 and 2013. The financial data and the other financial information disclosed in these notes to the condensed consolidated interim financial statements related to the three and six month periods are also unaudited. The results of operations for the three and six months ended June 30, 2014 are not necessarily indicative of the results to be expected for the year ending December 31, 2014 or for any other future annual or interim period. The condensed consolidated interim financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2013 that was filed with the Securities and Exchange Commission (the SEC ) on March 18, 2014.

The Company's condensed consolidated financial statements include the Company's accounts and the accounts of the Company's wholly-owned subsidiary, Agios Securities Corporation. All intercompany transactions have been eliminated in consolidation. The condensed consolidated interim financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ( GAAP ).

On July 29, 2013, the Company closed an initial public offering ( IPO ) of its common stock, which resulted in the sale of 6,772,221 shares of its common stock at a public offering price of \$18.00 per share, before underwriting commissions and discounts, including 883,333 shares of common stock issued upon the exercise in full by the underwriters of their option to purchase additional shares at the public offering price to cover over-allotments. The Company received net proceeds from the IPO of \$111.0 million, after deducting underwriting discounts, commissions, and expenses payable by the Company. Additionally, an affiliate of Celgene Corporation ( Celgene ), the Company's cancer metabolism strategic alliance partner, purchased 708,333 shares of common stock in a separate private placement concurrent with the completion of the IPO at a purchase price of \$18.00 per share for aggregate proceeds of \$12.8 million.

In connection with preparing for the IPO, the Company's Board of Directors and stockholders approved a 1-for-2.75 reverse stock split of the Company's common stock. The reverse stock split became effective on July 11, 2013. All

share and per share amounts in the condensed consolidated interim financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this reverse stock split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital. In connection with the closing of the IPO, all of the Company's outstanding convertible preferred stock automatically converted to common stock as of July 29, 2013, resulting in an additional 19,731,564 shares of common stock of the Company becoming outstanding. The significant increase in common stock outstanding in July 2013 impacts the period-over-period comparability of the Company's net loss per share calculations.

In April 2014, the Company completed a public offering of 2,000,000 shares of its common stock at a public offering price of \$44.00 per share, before underwriting commissions and discounts. The Company received net proceeds from this offering of \$82.3 million, after deducting underwriting discounts, commissions and expenses payable by the Company. Celgene purchased 294,800 shares of the Company's common stock in the offering. In addition, the Company granted the underwriters the right to purchase up to an additional 300,000 shares of its common stock which was exercised in May 2014 resulting in additional net proceeds to the Company of \$12.4 million, after underwriting discounts and commissions paid by the Company.

**Table of Contents****2. Summary of Significant Accounting Policies and Recent Accounting Pronouncements**

There have been no material changes to the significant accounting policies previously disclosed in the Annual Report on Form 10-K for the year ended December 31, 2013.

In June 2014, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update ( ASU ) 2014-12, *Compensation - Stock Compensation (Topic 718)*. The ASU clarifies how entities should treat performance targets that can be achieved after the requisite service period of a share-based payment award. The accounting standard is effective for interim and annual periods beginning after December 15, 2015. The Company is currently in the process of evaluating the impact of the guidance on its financial position, results of operation, and cash flows.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The ASU provides for a single comprehensive model for use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance. The accounting standard is effective for interim and annual periods beginning after December 15, 2016 with no early adoption permitted. The Company is currently in the process of evaluating the impact of the guidance on its financial position, results of operation, and cash flows.

Accounting standards that have been issued by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company's financial statements upon adoption.

**3. Fair Value Measurements**

The Company records cash equivalents and marketable securities at fair value. Accounting Standards Codification ( ASC ) Topic 820, *Fair Value Measurements and Disclosures*, established a fair value hierarchy for those instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). The hierarchy consists of three levels:

*Level 1* Unadjusted quoted prices in active markets for identical assets or liabilities.

*Level 2* Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.

*Level 3* Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

The following table summarizes the cash equivalents and marketable securities measured at fair value on a recurring basis as of June 30, 2014 (in thousands):

	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Cash equivalents	\$ 105,084	\$ 480	\$	\$ 105,564
Marketable securities:				
Certificates of deposit		12,835		12,835
U.S. Treasuries	140,029			140,029

	\$ 245,113	\$ 13,315	\$	\$ 258,428
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The following table summarizes the cash equivalents and marketable securities measured at fair value on a recurring basis as of December 31, 2013 (in thousands):

	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Cash equivalents	\$ 68,792	\$	\$	\$ 68,792
Marketable securities:				
Certificates of deposit		6,915		6,915
U.S. Treasuries	115,419			115,419
	\$ 184,211	\$ 6,915	\$	\$ 191,126