AGIOS PHARMACEUTICALS INC
Form 10-Q
May 04, 2018
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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 March 31, 2018
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	26-0662915
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

88 Sidney Street, Cambridge, Massachusetts	02139
(Address of Principal Executive Offices)	(Zip Code)

(617) 649-8600
(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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth 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
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.
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 April 30, 2018: 57,605,621

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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)

	March 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$364,469	$102,724
Marketable securities	417,981	321,212
Collaboration receivable – related party	3,512	2,448
Royalty receivable – related party	1,417	1,222
Prepaid expenses and other current assets	15,614	17,655
Total current assets	802,993	445,261
Marketable securities	212,297	143,814
Property and equipment, net	23,732	24,431
Other non-current assets	1,104	891
Total assets	$1,040,126	$614,397
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$17,932	$22,767
Accrued expenses	17,005	34,031
Deferred revenue – related party	39,212	37,842
Deferred rent	550	301
Total current liabilities	74,699	94,941
Deferred revenue, net of current portion – related party	81,831	125,798
Deferred rent, net of current portion	18,002	18,155
Total liabilities	174,532	238,894
Stockholders' equity:		
Preferred stock, $0.001 par value; 25,000,000 shares authorized; no shares issued or outstanding at March 31, 2018 and December 31, 2017	—	—
Common stock, $0.001 par value; 125,000,000 shares authorized; 57,541,613 and 48,826,153 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	58	49
Additional paid-in capital	1,717,609	1,174,904
Accumulated other comprehensive loss	(2,643)	(1,389)
Accumulated deficit	(849,430)	(798,061)
Total stockholders' equity	865,594	375,503
Total liabilities and stockholders' equity	$1,040,126	$614,397

See accompanying Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended March 31,	
	2018	2017
Collaboration revenue – related party	$7,345	$10,508
Royalty revenue – related party	1,417	—
Total revenue	8,762	10,508
Operating expenses:		
Research and development (net of $2,776 of cost reimbursement from related party for the three months ended March 31, 2017)	78,224	62,732
General and administrative	24,550	14,823
Total operating expenses	102,774	77,555
Loss from operations	(94,012)	(67,047)
Interest income	3,187	881
Net loss	$(90,825)	$(66,166)
Net loss per share – basic and diluted	$(1.63)	$(1.56)
Weighted-average number of common shares used in computing net loss per share – basic and diluted	55,694,603	42,280,525

See accompanying Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended March 31,	
	2018	2017
Net loss	$(90,825)	$(66,166)
Other comprehensive (loss) income		
Unrealized (loss) gain on available-for-sale securities	(1,254)	101
Comprehensive loss	$(92,079)	$(66,065)

See accompanying Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended March 31,	
	2018	2017
Operating activities		
Net loss	$(90,825)	$(66,166)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,725	1,591
Stock-based compensation expense	14,522	10,734
Net amortization of premium and discounts on investments	(406)	163
Loss on disposal of property and equipment	—	40
Changes in operating assets and liabilities:		
Collaboration receivable – related party	(1,064)	(6,379)
Royalty receivable – related party	(195)	—
Tenant improvement and other receivables	—	(24)
Prepaid expenses and other current and non-current assets	1,901	(3,425)
Accounts payable	(4,469)	(994)
Accrued expenses	(17,144)	(6,889)
Deferred revenue – related party	(3,141)	(1,924)
Deferred rent	96	(801)
Net cash used in operating activities	(99,000)	(74,074)
Investing activities		
Purchases of marketable securities	(330,971)	(26,740)
Proceeds from maturities and sales of marketable securities	164,871	136,585
Purchases of property and equipment	(1,432)	(293)
Net cash (used in) provided by investing activities	(167,532)	109,552
Financing activities		
Payment of public offering costs, net of reimbursements	(188)	(100)
Proceeds from public offering of common stock, net of commissions	516,206	—
Net proceeds from stock option exercises and employee stock purchase plan	12,259	4,146
Net cash provided by financing activities	528,277	4,046
Net change in cash and cash equivalents	261,745	39,524
Cash and cash equivalents at beginning of the period	102,724	160,754
Cash and cash equivalents at end of the period	$364,469	$200,278
Supplemental disclosure of non-cash investing and financing transactions		
Additions to property and equipment in accounts payable and accrued expenses	$605	$213
Proceeds from stock option exercises in other current assets	$73	$6
Public offering costs in other current assets	$—	$329
Public offering costs in accounts payable and accrued expenses	$158	$—

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

References to Agios

Throughout this Quarterly Report on Form 10-Q, "we," "us," and "our," and similar expressions, except where the context requires otherwise, refer to Agios Pharmaceuticals, Inc. and its consolidated subsidiaries, and "our Board of Directors" refers to the board of directors of Agios Pharmaceuticals, Inc.

Overview

We are a biopharmaceutical company committed to the fundamental transformation of patients' lives through scientific leadership in the field of cellular metabolism, with the goal of making transformative, first- or best-in-class medicines. Our therapeutic areas of focus are cancer and rare genetic diseases, or RGDs, which are diseases that are directly caused by changes in genes or chromosomes, often passed from one generation to the next. Most RGDs are often associated with severe or life-threatening features. The incidence of a single RGD can vary widely but is generally very infrequent, usually equal to or less than one per 100,000 births. In both areas of cancer and RGDs, we are seeking to unlock the biology of cellular metabolism as a platform to create transformative therapies. We are located in Cambridge, Massachusetts.

Basis of presentation

The condensed consolidated balance sheet as of March 31, 2018, and the condensed consolidated statements of operations, comprehensive loss, and cash flows for the three months ended March 31, 2018 and 2017 are unaudited. The unaudited condensed consolidated financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of our management, reflect all adjustments, which include only normal recurring adjustments, necessary to fairly state our financial position as of March 31, 2018, and our results of operations and cash flows for the three months ended March 31, 2018 and 2017. The financial data and the other financial information disclosed in these notes to the condensed consolidated financial statements related to the three-month period are also unaudited. The results of operations for the three months ended March 31, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018 or for any other future annual or interim period. The year-end condensed consolidated balance sheet data was derived from our audited financial statements, but does not include all disclosures required by U.S. generally accepted accounting principles, or U.S. GAAP. Accordingly, the condensed consolidated interim financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2017 that was filed with the Securities and Exchange Commission, or the SEC, on February 14, 2018.

Our consolidated financial statements include our accounts and the accounts of our wholly owned subsidiaries, Agios Securities Corporation, Agios International Sarl, and Agios Limited. All intercompany transactions have been eliminated in consolidation. The consolidated financial statements have been prepared in conformity with U.S. GAAP.

Liquidity

In January 2018, we completed a public offering of 7,089,553 shares of common stock at an offering price of $67.00 per share. We received net proceeds from this offering of $448.9 million, after deducting underwriting discounts and commissions paid by us. In addition, we granted the underwriters the right to purchase up to an additional 1,063,433 shares of common stock, which was exercised in January 2018, resulting in additional net proceeds to us of $67.3 million, after underwriting discounts and commissions. After giving effect to the full exercise of the over-allotment option, the number of shares sold by us in the public offering totaled 8,152,986 shares, and net proceeds to us totaled $516.2 million, after underwriting discounts and commissions.

As of March 31, 2018, we had cash, cash equivalents and marketable securities of $994.7 million. Although we have incurred recurring losses and expect to continue to incur losses for the foreseeable future, we expect our cash, cash equivalents and marketable securities will be sufficient to fund current operations for at least the next twelve months from the issuance date of these financial statements.

2. Summary of Significant Accounting Policies and Recent Accounting Pronouncements

Significant accounting policies

Revenue from Contracts with Customers

In May 2014, the Financial Accounting Standards Board, or FASB, issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), or ASU 2014-09. ASU 2014-09 was codified as Accounting Standards Codification, or ASC, 606,

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Revenue from Contracts with Customers, or ASC 606. Subsequently, the FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606), which adjusted the effective date of ASU 2014-09; ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net), which amends the principal-versus-agent implementation guidance and illustrations in ASU 2014-09; ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies identifying performance obligations and licensing implementation guidance and illustrations in ASU 2014-09; ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients, which addresses implementation issues and is intended to reduce the cost and complexity of applying the new revenue standard in ASU 2014-09; ASU No. 2017-13, Revenue Recognition (Topic 605), Revenue from Contracts with Customers (Topic 606), Leases (Topic 840), and Leases (Topic 842): Amendments to SEC Paragraphs Pursuant to the Staff Announcement at the July 20, 2017 EITF Meeting and Rescission of Prior SEC Staff Announcements and Observer Comments (SEC Update), which codifies recent announcements by the SEC staff; and ASU No. 2017-14, Income Statement—Reporting Comprehensive Income (Topic 220), Revenue Recognition (Topic 605), and Revenue from Contracts with Customers (Topic 606) (SEC Update), which codifies SEC Release 33-10403, or collectively with ASU 2014-09, the Revenue ASUs.

We were required to adopt the Revenue ASUs effective January 1, 2018. The guidance permits two methods of adoption: retrospectively to each prior reporting period presented (the full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the modified retrospective method). We adopted the new standard under the modified retrospective method.

In adopting the Revenue ASUs, we applied the practical expedient that permits aggregating the effect of all modifications that occurred prior to January 1, 2018. No other practical expedients were used.

Upon finalization of our assessment, which resulted in changes to our estimates as of December 31, 2017, the impact of the cumulative effect of the accounting changes upon the adoption of the standard (in thousands) is as follows:

	December 31, 2017	Cumulative Effect	January 1, 2018
Deferred revenue – related party, current and net of current portions	$163,640	$(39,456)	$124,184
Accumulated deficit	(798,061)	39,456	(758,605)

The following tables summarize the effects of adopting ASC 606 on our unaudited condensed consolidated financial statements for the three months ended March 31, 2018 (in thousands, except per share data):

Condensed Consolidated Balance Sheets

	March 31, 2018		
	Under Topic 606	Under Topic 605	Effect of Change
Deferred revenue – related party	$39,212	$35,396	$3,816
Deferred revenue, net of current portion – related party	81,831	122,060	(40,229)
Accumulated deficit	(849,430)	(885,843)	36,413

Condensed Consolidated Statements of Operations

	Three Months Ended March 31, 2018		
	Under Topic 606	Under Topic 605	Effect of Change
Collaboration revenue – related party	$7,345	$9,977	$(2,632)
Research and development expense	78,224	77,813	411
Total operating expenses	102,774	102,363	411
Loss from operations	(94,012)	(90,969)	(3,043)
Net loss	(90,825)	(87,782)	(3,043)
Net loss per share – basic and diluted	(1.63)	(1.58)	(0.05)

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Condensed Consolidated Statements of Comprehensive Loss

	Three Months Ended March 31, 2018		
	Under Topic 606	Under Topic 605	Effect of Change
Net loss	$(90,825)	$(87,782)	$(3,043)
Comprehensive loss	(92,079)	(89,036)	(3,043)

Condensed Consolidated Statements of Cash Flows

	Three Months Ended March 31, 2018		
	Under Topic 606	Under Topic 605	Effect of Change
Net loss	$(90,825)	$(87,782)	$(3,043)
Adjustments to reconcile net loss to net cash used in operating activities:			
Deferred revenue – related party	(3,141)	(6,184)	3,043

Recent accounting pronouncements

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), or ASU 2016-02, which establishes principles that lessees and lessors shall apply to report useful information to users of financial statements about the amount, timing and uncertainty of cash flows arising from a lease. ASU 2016-02 was codified as ASC 842, Leases. Subsequently, the FASB issued ASU 2017-13, Revenue Recognition (Topic 605), Revenue from Contracts with Customers (Topic 606), Leases (Topic 840), and Leases (Topic 842): Amendments to SEC Paragraphs Pursuant to the Staff Announcement at the July 20, 2017 EITF Meeting and Rescission of Prior SEC Staff Announcements and Observer Comments (SEC Update), which codifies recent announcements by the SEC staff; and ASU 2018-01, Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842, which provides a transition practical expedient for existing or expired land easements, or collectively with ASU 2016-02, the Leases ASUs.

We will adopt ASC 842 effective January 1, 2019. We are currently in the process of evaluating the impact of the guidance on our consolidated financial statements.

Other 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 our financial statements upon adoption.

3. Fair Value Measurements

We record cash equivalents and marketable securities at fair value. ASC 820, Fair Value Measurements and Disclosures, establishes a fair value hierarchy for those instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and our 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, directly or indirectly, for substantially the full term of the asset or liability.

Level 3 – Unobservable inputs that reflect our 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.

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The following table summarizes our cash equivalents and marketable securities measured at fair value on a recurring basis as of March 31, 2018 (in thousands):

	Level 1	Level 2	Level 3	Total
Cash equivalents	$262,897	$84,827	$ —	$347,724
Marketable securities:				
Certificates of deposit	—	5,226	—	5,226
U.S. Treasuries	—	179,580	—	179,580
Government securities	—	128,968	—	128,968
Corporate debt securities	—	316,504	—	316,504
Total cash equivalents and marketable securities	$262,897	$715,105	$ —	$978,002

Cash equivalents and marketable securities have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third-party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based approaches, and observable market inputs to determine value. After completing our validation procedures, we did not adjust or override any fair value measurements provided by the pricing services as of March 31, 2018.

There have been no changes to the valuation methods during the three months ended March 31, 2018. We evaluate transfers between levels at the end of each reporting period. There were no transfers between Level 1 and Level 2 during the three months ended March 31, 2018. We have no financial assets or liabilities that were classified as Level 3 at any point during the three months ended March 31, 2018.

4. Marketable Securities

Our marketable securities are classified as available-for-sale pursuant to ASC 320, Investments – Debt and Equity Securities, and are recorded at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive loss in stockholders' equity and a component of total comprehensive loss in the condensed consolidated statements of comprehensive loss, until realized. Realized gains and losses are included in investment income on a specific-identification basis. There were no realized gains or losses on marketable securities for the three months ended March 31, 2018 and 2017 and, as a result, there were no reclassifications of any amounts out of accumulated other comprehensive loss for those periods.

Marketable securities at March 31, 2018 consisted of the following (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Current:				
Certificates of deposit	$4,760	$ —	$ (8)	$4,752
U.S Treasuries	144,849	—	(209)	144,640
Government securities	71,773	—	(141)	71,632
Corporate debt securities	197,334	—	(377)	196,957
Non-current:				
Certificates of deposit	480	—	(6)	474
U.S Treasuries	35,318	—	(378)	34,940
Government securities	57,646	—	(310)	57,336
Corporate debt securities	120,752	—	(1,205)	119,547
Total marketable securities	$632,912	$ —	$ (2,634)	$630,278

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Marketable securities at December 31, 2017 consisted of the following (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Current:				
Certificates of deposit	$ 8,081	$ —	$ (11)	$ 8,070
U.S. Treasuries	113,852	—	(119)	113,733
Government securities	44,421	—	(57)	44,364
Corporate debt securities	155,222	—	(177)	155,045
Non-current:				
Certificates of deposit	960	—	(8)	952
U.S. Treasuries	36,165	—	(311)	35,854
Government securities	23,992	—	(182)	23,810
Corporate debt securities	83,722	—	(524)	83,198
Total marketable securities	$ 466,415	$ —	$ (1,389)	$ 465,026

At March 31, 2018 and December 31, 2017, we held both current and non-current investments. Investments classified as current have maturities of less than one year. Investments classified as non-current are those that: (i) have a maturity of one to two years, and (ii) we do not intend to liquidate within the next twelve months, although these funds are available for use and therefore classified as available-for-sale.

At March 31, 2018 and December 31, 2017, we held 257 and 240 debt securities that were in an unrealized loss position for less than one year, respectively. The aggregate fair value of debt securities in an unrealized loss position at March 31, 2018 and December 31, 2017 was $572.7 million and $439.4 million, respectively. There were no individual securities that were in a significant unrealized loss position as of March 31, 2018 and December 31, 2017. Given our intent and ability to hold such securities until recovery, and the lack of material of change in the credit risk of these investments, we do not consider these marketable securities to be other-than-temporarily impaired as of March 31, 2018 and December 31, 2017.

5. Collaboration Agreements

Celgene Corporation

To date, our revenue has primarily been generated from our collaboration agreements with Celgene, or collectively, the Collaboration Agreements. Celgene is a related party through ownership of our common stock. In April 2010, we entered into a discovery and development collaboration and license agreement focused on cancer metabolism, or the 2010 Agreement. The 2010 Agreement was amended in October 2011 and July 2014. In April 2015, we entered into a joint worldwide development and profit share collaboration and license agreement with Celgene, and our wholly owned subsidiary, Agios International Sarl, entered into a collaboration and license agreement with Celgene International II Sarl, or collectively, the AG-881 Agreements, to establish a worldwide collaboration focused on the development and commercialization of AG-881 products. In May 2016, we entered into a master research and collaboration agreement with Celgene, or the 2016 Agreement.

2016 Agreement

In May 2016, we entered into the 2016 Agreement focused on metabolic immuno-oncology, or MIO, a developing field which aims to modulate the activity of relevant immune cells by targeting critical metabolic nodes, thereby, enhancing the immune mediated anti-tumor response. In addition to new programs identified under the 2016 Agreement, both parties also agreed that all future development and commercialization of two remaining cancer metabolism programs discovered under the 2010 Agreement, including AG-270, an inhibitor of methionine adenosyltransferase 2a, will now be governed by the 2016 Agreement.

During the research term of the 2016 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, and may be extended for up to two, or in specified cases, up to four additional one-year terms.

For each program under the 2016 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 preclinical and clinical development for such program through the completion of an initial phase 1 dose escalation study.

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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 are referred to as continuation programs. We may conduct further research and preclinical and clinical development activities on any continuation program, at our expense, through the completion of an initial phase 1 dose escalation study.

We granted Celgene the right to obtain exclusive options for 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: (i) the end of a specified period after we have furnished Celgene with specified information about the initial phase 1 dose escalation study for such program, or (ii) January 1, 2030. Research programs that have applications in the inflammation or autoimmune, or I&I, field that may result from the 2016 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 it does not exercise its option.

Under the terms of the 2016 Agreement, following Celgene's exercise of its option with respect to a program, the parties 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-commercialization agreement, the two parties 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, the parties 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.

Co-development and co-commercialization agreements

Under each co-development and co-commercialization agreement entered into under the 2016 Agreement, the parties 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 in the IO field. 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 us having the right to be the lead party for the first such program, and each party will 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.

License agreements

Under each license agreement under the 2016 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 in the I&I field.

Financial terms

Under the terms of the 2016 Agreement, we received an initial upfront payment in the amount of $200.0 million. The 2016 Agreement provides specified rights to extend the research term for up to two, or in specified cases, up to four, additional years by paying a $40.0 million per-year extension fee. Celgene will pay an $8.0 million designation fee for each program that Celgene designates for further development and for each continuation program. During the three months ended March 31, 2017, we received $8.0 million from Celgene upon the designation of AG-270 as a development candidate. For each program as to which Celgene exercises its option to develop and commercialize, subject to antitrust clearance, Celgene will pay an option exercise fee of at least $30.0 million for any designated development program and at least $35.0 million for any continuation programs. In certain cases, Celgene may exercise its option to develop and commercialize two early-stage I&I programs, prior to Celgene designating the program for further development, by paying an option exercise fee of $10.0 million.

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We are eligible to receive the following milestone-based payments associated with the 2016 Agreement:

Program	Milestone	Amount
65/35 program in IO field	Specified clinical development event	$25.0 million
65/35 program in IO field	Specified regulatory milestone events	Up to $183.8 million
50/50 program in IO field	Specified clinical development event	$20.0 million
50/50 program in IO field	Specified regulatory milestone events	Up to $148.8 million
I&I field	Specified clinical development event	$25.0 million
I&I field	Specified regulatory milestone events	Up to $236.3 million
I&I field	Specified commercial milestone events	Up to $125.0 million

Additionally, for each licensed program in the I&I field, we are eligible to receive royalties at tiered, low double-digit percentage rates on Celgene's net sales, if any.

Opt-out right

Under the 2016 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. Upon opting 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 expense. Further, in lieu of the profit or loss sharing described above, we would be eligible to receive royalties at tiered, low double-digit percentage rates on Celgene's net sales, if any, of the applicable licensed products. However, we would continue to be eligible to receive the developmental and regulatory milestone-based payments described above.

Term

The term of the 2016 Agreement commenced on May 17, 2016 and, if not terminated earlier, will expire upon the 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 Agreement in its entirety for any reason by providing us 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 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 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 Agreement. Following the exercise of an option for a program, either party may terminate the 2016 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.

Exclusivity

While any of Celgene's options remain available under the 2016 Agreement, subject to specified exceptions, we may not directly or indirectly develop, manufacture or commercialize, outside of the 2016 Agreement, any therapeutic modality in the IO or 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.

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TIBSOVO® (ivosidenib) Letter Agreement

In May 2016, we entered into a letter agreement with Celgene regarding TIBSOVO® (ivosidenib), or the TIBSOVO® (ivosidenib) Letter Agreement. Under the TIBSOVO® (ivosidenib) Letter Agreement, the parties agreed to terminate the 2010 Agreement, effective as of August 15, 2016, as to the program directed to the isocitrate dehydrogenase 1, or IDH1, target, for which TIBSOVO® (ivosidenib) is the lead development candidate. Under the 2010 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 termination, we obtained global rights to TIBSOVO® (ivosidenib) and the IDH1 program. Neither party will have any further financial obligation, including royalties or milestone payments, to the other concerning TIBSOVO® (ivosidenib) or the IDH1 program. Under the terms of the termination, the parties also agreed to conduct specified transitional activities in connection with the termination. In addition, pursuant to the TIBSOVO® (ivosidenib) Letter Agreement, the parties are released from their exclusivity obligations under the 2010 Agreement with respect to the IDH1 program. The termination does not affect the AG-881 Agreements, which are directed to both the IDH1 target and the isocitrate dehydrogenase 2, or IDH2, target.

AG-881 Agreements

In April 2015, we entered into the AG-881 Agreements. The AG-881 Agreements establish a joint worldwide collaboration focused on the development and commercialization of AG-881 products. Under the terms of the AG-881 Agreements, we received an initial upfront payment of $10.0 million in May 2015 and are eligible to receive milestone-based payments described below. The parties will split all worldwide development costs equally, subject to specified exceptions, as well as any profits from any net sales of, or commercialization losses related to, licensed AG-881 products. Either party may, at its own expense and with the other party's permission, undertake additional development activities outside of the scope of the development plan agreed upon with the other party.

We are eligible to receive up to $70.0 million in potential milestone payments under the AG-881 Agreements. The potential milestone payments are comprised of: (i) a $15.0 million milestone payment for filing of a first new drug application, or NDA, in a major market, and (ii) up to $55.0 million in milestone payments upon achievement of specified regulatory milestone events. We may also receive royalties at tiered, low-double digit to mid-teen percentage rates on net sales if we elect not to participate in the development and commercialization of AG-881.

Termination

Celgene may terminate the AG-881 Agreements in their entirety for any reason upon ninety days written notice to us. Either party may terminate the AG-881 Agreements for the insolvency of the other party. Either party may terminate the AG-881 Agreements in their entirety or with respect to one of the agreements upon 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 AG-881 Agreements. If one of the AG-881 Agreements terminates, the other will terminate automatically.

2010 Agreement

In April 2010, we entered into the 2010 Agreement, which was amended in October 2011 and July 2014. The goal of the collaboration was to discover, develop and commercialize disease-altering therapies in oncology based on our cancer metabolism research platform. We initially led discovery, preclinical and early clinical development for all cancer metabolism programs under the collaboration. The discovery phase of the 2010 Agreement expired in April 2016.

Upon agreement to terminate the 2010 Agreement, effective as of August 15, 2016, as to the program directed to the IDH1 target, for which TIBSOVO® (ivosidenib) is the lead development candidate, the sole program remaining under the 2010 Agreement is IDHIFA®, a co-commercialized licensed program for which Celgene leads and funds global development and commercialization activities. We have exercised our right to participate in a portion of commercialization activities in the United States for IDHIFA® in accordance with the applicable commercialization plan. On August 1, 2017, the U.S. Food and Drug Administration, or FDA, granted Celgene approval of IDHIFA® for the treatment of adult patients with relapsed or refractory acute myeloid leukemia, or R/R AML, with an IDH2 mutation as detected by an FDA-approved test.

Under the remaining terms of the 2010 Agreement, we are eligible to receive up to $95.0 million in potential milestone payments for the IDHIFA® program. The potential milestone payments are comprised of: (i) up to $70.0 million in milestone payments upon achievement of specified ex-U.S. regulatory milestone events, and (ii) a $25.0

million milestone payment upon achievement of a specified ex-U.S. commercial milestone event.

Under the 2010 Agreement, we may also receive royalties at tiered, low-double digit to mid-teen percentage rates on net sales of IDHIFA®. Assuming all other revenue recognition criteria are met, royalty payments will be recognized as revenue in the period in which they are earned. During the three months ended March 31, 2018, we earned $1.4 million in royalty revenue under the 2010 Agreement.

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Unless terminated earlier by either party, the term of the 2010 Agreement will continue until the expiration of all royalty terms with respect to IDHIFA®. Celgene may terminate this agreement for convenience in its entirety upon ninety days written notice to us. If either party is in material breach and fails to cure such breach within the specified cure period, the other party may terminate the 2010 Agreement in its entirety. Either party may terminate the agreement in the event of specified insolvency events involving the other party.

Accounting analysis and revenue recognition – collaboration revenue

On January 1, 2018 we adopted ASC 606 under the modified retrospective method. Prior to January 1, 2018 we accounted for the Collaboration Agreements under ASC 605-25, Multiple Element Arrangements.

Accounting under ASC 606

In adopting ASC 606, we applied the practical expedient that permits aggregating the effect of all modifications that occurred prior to January 1, 2018. No other practical expedients were used. Similar to the accounting under ASC 605-25, the 2016 Agreement was determined to be a modification of the 2010 Agreement and the AG-881 Agreements. In determining the appropriate amount of revenue to be recognized under ASC 606, we performed the following steps: (i) identified the promised goods or services in the contract; (ii) determined whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measured the transaction price, including the constraint on variable consideration; (iv) allocated the transaction price to the performance obligations; and (v) recognized revenue when (or as) we satisfy each performance obligation.

As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price, or SSP, for each performance obligation identified in the contract. We use key assumptions to determine the SSP, which include forecast of revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

The satisfied and unsatisfied performance obligations at the time of the ASC 606 adoption, each of which are considered by us to be distinct within the context of the contract, their SSP, the method of recognizing the allocated consideration, and the period through which they are expected to be recognized are as follows:

Performance Obligations	SSP	No. of Performance Obligation(s)	Recognition Method
Fully satisfied at time of adoption			
Licenses (1)	$86.7 million	4	Fully satisfied; recognized upon adoption of ASC 606
Research and development services (2) (3)	$350.7 million	10	Fully satisfied; recognized upon adoption of ASC 606
Partially satisfied at time of adoption			
Research and development services (2) (3)	$266.6 million	6	Proportionally as services are delivered over the performance period, expected to be through September 2022 (4)

(1) The SSP was developed by probability weighting multiple cash flow scenarios using the income approach. Our management estimates within the models include the expected, probability-weighted net profits from estimated future sales, an estimate of the direct cost incurred to generate future cash flows, a discount rate and other business forecast factors. There are significant judgments and estimates inherent in the determination of the SSP of these units of accounting. These judgments and estimates include assumptions regarding future operating performance, the timelines of the clinical trials and regulatory approvals, and other factors. If different reasonable assumptions are utilized, the SSP and revenue recognized would vary.

(2) The SSP was developed using our management's best estimate of the cost of obtaining these services at arm's length from a third-party provider.

(3) The SSP was developed using internal full time equivalent costs to support the development services.

(4) We determined that recognizing revenue on a proportional basis using the ratio of effort incurred to date compared to the total estimated effort required to complete the performance obligation best depicts the satisfaction of our obligations under the Collaboration Agreements.

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