AGIOS PHARMACEUTICALS INC
Form 10-Q
May 02, 2019
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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, 2019
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 every Interactive Data File required to be submitted 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 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.

Large accelerated filer	Accelerated filer
Non-accelerated filer	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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, Par Value $0.001 per share	AGIO	Nasdaq Global Select Market

Number of shares of the registrant's Common Stock, $0.001 par value, outstanding on April 26, 2019: 58,711,333

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FOR THE THREE MONTHS ENDED MARCH 31, 2019
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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, 2019		December 31, 2018	
Assets				
Current assets:				
Cash and cash equivalents	$	103,443	$	70,502
Marketable securities	421,114		514,800	
Accounts receivable, net	4,355		5,076	
Collaboration receivable – related party	2,319		2,462	
Collaboration receivable – other	1,640		670	
Royalty receivable – related party	2,200		2,234	
Inventory	2,328		869	
Prepaid expenses and other current assets	19,696		17,167	
Total current assets	557,095		613,780	
Marketable securities	183,234		220,119	
Operating lease assets	57,768		—	
Property and equipment, net	23,974		24,320	
Other non-current assets	60		238	
Total assets	$	822,131	$	858,457
Liabilities and stockholders' equity				
Current liabilities:				

Accounts payable	$	12,413	$	17,880
Accrued expenses	37,199		42,147	
Deferred revenue – related party	22,167		32,710	
Operating lease liabilities	9,128		—	
Deferred rent	—		766	
Total current liabilities	80,907		93,503	
Deferred revenue, net of current portion – related party	54,961		59,809	
Operating lease liabilities, net of current portion	66,006		—	
Deferred rent, net of current portion	—		17,608	
Total liabilities	201,874		170,920	
Stockholders' equity:				
Preferred stock, $0.001 par value; 25,000,000 shares authorized; no shares issued or outstanding at March 31, 2019 and December 31, 2018	—		—	
Common stock, $0.001 par value; 125,000,000 shares authorized; 58,659,821 and 58,218,653 shares issued and outstanding at March 31, 2019 and December	59		58	

31, 2018, respectively				
Additional paid-in capital	1,818,393		1,794,283	
Accumulated other comprehensive loss	(484)		(2,171)	
Accumulated deficit	(1,197,711)		(1,104,633)	
Total stockholders' equity	620,257		687,537	
Total liabilities and stockholders' equity	$	822,131	$	858,457

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,	
	2019	**2018**
Revenues:		
Product revenue, net	$ 9,138	$ —
Collaboration revenue – related party	17,919	7,345
Collaboration revenue – other	970	—
Royalty revenue – related party	2,200	1,417
Total revenue	30,227	8,762
Cost and expenses:		
Cost of sales	334	—
Research and development	95,585	78,224
Selling, general and administrative	31,791	24,550
Total cost and expenses	127,710	102,774
Loss from operations	(97,483)	(94,012)
Interest income	4,405	3,187
Net loss	$ (93,078)	$ (90,825)
Net loss per share – basic and diluted	$ (1.59)	$ (1.63)
Weighted-average number of common shares used in computing net loss per share – basic and diluted	58,453,918	55,694,603

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,	
	2019	**2018**
Net loss	$ (93,078)	$ (90,825)
Other comprehensive income (loss)		
Unrealized gain (loss) on available-for-sale securities	1,687	(1,254)
Comprehensive loss	$ (91,391)	$ (92,079)

See accompanying Notes to Condensed Consolidated Financial Statements.

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AGIOS PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)
(Unaudited)

	Common Stock Shares	Amount		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' (Deficit) Equity
Balance at December 31, 2018	58,213,653	$	58	$ 1,794,283	$ (2,171)	$ (1,104,633)	$ 687,537
Unrealized gain on available-for-sale securities	—	—		—	1,687	—	1,687
Net loss	—	—		—	—	(93,078)	(93,078)
Stock-based compensation expense	—	—		18,108	—	—	18,108
Issuance of common stock under stock incentive and employee stock purchase plans	441,168			6,002	—	—	6,003
Balance at March 31, 2019	58,654,821	$	59	$ 1,818,393	$ (484)	$ (1,197,711)	$ 620,257

	Common Stock Shares	Amount		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' (Deficit) Equity
Balance at Balance at December 31, 2017	48,826,153	$	49	$ 1,174,904	$ (1,389)	$ (798,061)	$ 375,503
Unrealized loss on available-for-sale securities	—	—		—	(1,254)	—	(1,254)
Net loss	—	—		—	—	(90,825)	(90,825)
Adjustment to beginning accumulated deficit resulting from adoption of ASC 606	—	—		—	—	39,456	39,456

Stock-based compensation expense	—	—		14,522		—		—		14,522		
Issuance of common stock under stock incentive and employee stock purchase plans	562,4	174		12,331		—		—		12,332		
Issuance of common stock for follow-on offering	8,152	8986		516,198		—		—		516,206		
Other	—	—		(346)		—		—		(346)		
Balance at Balance at March 31, 2018	57,54	1,613	58	$	1,717,609	$	(2,643)	$	(849,430)	$	865,594	

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,	
	2019	**2018**
Operating activities		
Net loss	$ (93,078)	$ (90,825)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2,005	1,725
Stock-based compensation expense	18,108	14,522
Net amortization of premium and discounts on investments	(1,131)	(406)
Non-cash operating lease expense	2,085	—
Changes in operating assets and liabilities:		
Accounts receivable, net	721	—
Collaboration receivable – related party	143	(1,064)
Collaboration receivable – other	(970)	—
Royalty receivable – related party	34	(195)
Inventory	(1,459)	—
Prepaid expenses and other current and non-current assets	(2,173)	1,901
Accounts payable	(4,939)	(4,469)
Accrued expenses	(5,097)	(17,144)

Deferred revenue – related party	(15,391)	(3,141)
Operating lease liabilities	(2,129)	—
Deferred rent	—	96
Net cash used in operating activities	(103,271)	(99,000)
Investing activities		
Purchases of marketable securities	(77,421)	(330,971)
Proceeds from maturities and sales of marketable securities	210,811	164,871
Purchases of property and equipment	(2,038)	(1,432)
Net cash provided by (used in) investing activities	131,352	(167,532)
Financing activities		
Payment of public offering costs, net of reimbursements	—	(188)
Proceeds from public offering of common stock, net of commissions	—	516,206
Net proceeds from stock option exercises and employee stock purchase plan	4,860	12,259
Net cash provided by financing activities	4,860	528,277
Net change in cash and cash equivalents	32,941	261,745

Cash and cash equivalents at beginning of the period	70,502	102,724
Cash and cash equivalents at end of the period	$ 103,443	$ 364,469
Supplemental disclosure of non-cash investing and financing transactions		
Additions to property and equipment in accounts payable and accrued expenses	$ 727	$ 605
Proceeds from stock option exercises in other current assets	$ 1,149	$ 73
Public offering costs in other current assets, net of amounts 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 and adjacent areas of biology, with the goal of making transformative, first- or best-in-class medicines for the treatment of cancer and rare genetic diseases, or RGDs. To address both cancer and RGDs, we take a systems biology approach to deeply understand disease states, drive the discovery and validation of novel therapeutic targets, and define patient selection strategies, thereby increasing the probability that our experimental medicines will have the desired therapeutic effect. We are located in Cambridge, Massachusetts.

Basis of presentation

The condensed consolidated balance sheet as of March 31, 2019, the condensed consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for the three months ended March 31, 2019 and 2018 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, 2019, our results of operations and stockholders' equity for the three months ended March 31, 2019 and 2018, and cash flows for the three months ended March 31, 2019 and 2018. 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, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019 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, 2018 that was filed with the Securities and Exchange Commission, or the SEC, on February 14, 2019.

Our condensed 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 condensed consolidated financial statements have been prepared in conformity with U.S. GAAP.

Liquidity

As of March 31, 2019, we had cash, cash equivalents and marketable securities of $707.8 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

Leases

In February 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2016-02, *Leases (Topic 842)*, which was codified as Accounting Standards Codification, or ASC, 842, *Leases*, and amended through subsequent ASUs. We adopted ASC 842 effective January 1, 2019 using the modified retrospective transition approach and elected the package of practical expedients, both provided for under ASU 2018-11, *Leases (Topic 842): Targeted Improvements*. The package of practical expedients allows us not to reassess whether contracts are or contain leases, lease classification, and whether initial direct costs qualify for capitalization. Additionally, as an accounting policy, we chose not to separate the non-lease components from the lease components for our building leases and, instead, accounted for each non-lease component and lease component as a single

component.

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Impact of Adoption of ASC 842

Upon adoption of ASC 842 on January 1, 2019, we recorded operating lease assets of $59.9 million and operating lease liabilities of $77.3 million. The adoption of ASC 842 did not have a material impact on our condensed consolidated statements of operations. Prior periods are presented in accordance with ASC 840, *Leases*.

Leases Accounting Policy

We determine if an arrangement is a lease at inception. An arrangement is determined to contain a lease if the contract conveys the right to control the use of an identified property, plant, or equipment for a period of time in exchange for consideration. If we can benefit from the various underlying assets of a lease on their own or together with other resources that are readily available, or if the various underlying assets are neither highly dependent on nor highly interrelated with other underlying assets in the arrangement, they are considered to be a separate lease component. In the event multiple underlying assets are identified, the lease consideration is allocated to the various components based on each of the component's relative fair value.

Operating lease assets represent our right to use an underlying asset for the lease term and operating lease liabilities represent our obligation to make lease payments arising from the leasing arrangement. Operating lease assets and operating lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most of our leases do not provide an implicit rate, in determining the operating lease liabilities we use an estimate of our incremental borrowing rate. The incremental borrowing rate is determined using two alternative credit scoring models to estimate our credit rating, adjusted for collateralization. The calculation of the operating lease assets includes any lease payments made and excludes any lease incentives. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option.

For operating leases, we record operating lease assets and lease liabilities in our consolidated balance sheets. Lease expense for lease payments is recognized on a straight-line basis over the lease term. Short-term leases, or leases that have a lease term of 12 months or less at commencement date, are excluded from this treatment and are recognized on a straight-line basis over the term of the lease.

Recent accounting pronouncements

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.

The following table summarizes our cash equivalents and marketable securities measured at fair value on a recurring basis as of March 31, 2019 (in thousands):

	Level 1	Level 2	Level 3	Total
Cash equivalents	$ 20,276	$ 38,170	$ —	$ 58,446
Marketable securities:				
Certificates of deposit	—	479	—	479
U.S. Treasuries	—	183,760	—	183,760

Government securities	—		115,630		—		115,630	
Corporate debt securities	—		304,479		—		304,479	
Total cash equivalents and marketable securities	$	20,276	$	642,518	$	—	$	662,794

Cash equivalents and marketable securities have been initially valued at the transaction price and subsequently, at the end of each reporting period, valued utilizing third-party pricing services or other market observable data. The pricing services utilize

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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, 2019.

There have been no changes to the valuation methods during the three months ended March 31, 2019. 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, 2019. We have no financial assets or liabilities that were classified as Level 3 at any point during the three months ended March 31, 2019.

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 material realized gains or losses on marketable securities for the three months ended March 31, 2019 and 2018.

Marketable securities at March 31, 2019 consisted of the following (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Current:				
Certificates of deposit	$ 480	$ —	$ (1)	$ 479
U.S. Treasuries	173,432	59	(125)	173,366
Government securities	69,419	16	(65)	69,370
Corporate debt securities	178,047	53	(201)	177,899
Non-current:				
U.S. Treasuries	10,434	10	(50)	10,394
Government securities	46,377	7	(124)	46,260
Corporate debt securities	126,641	185	(246)	126,580
Total marketable securities	$ 604,830	$ 330	$ (812)	$ 604,348

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

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Current:				
Certificates of deposit	$ 960	$ —	$ (4)	$ 956
U.S. Treasuries	231,101	7	(228)	230,880
Government securities	75,335	—	(121)	75,214

Corporate debt securities	208,233	—	(483)	207,750
Non-current:				
U.S. Treasuries	12,202	4	(125)	12,081
Government securities	70,177	10	(188)	69,999
Corporate debt securities	139,082	12	(1,055)	138,039
Total marketable securities	$ 737,090	$ 33	$ (2,204)	$ 734,919

As of March 31, 2019 and December 31, 2018, 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 greater than one year, and (ii) we do not intend to liquidate within the next twelve months, although these funds are available for use and, therefore, are classified as available-for-sale.

As of March 31, 2019 and December 31, 2018, we held 148 and 242 debt securities, respectively, that were in an unrealized loss position for less than one year. The aggregate fair value of debt securities in an unrealized loss position at March 31, 2019 and December 31, 2018 was $362.6 million and $639.3 million, respectively. There were no individual securities that were in a significant unrealized loss position as of March 31, 2019 and December 31, 2018. Given our intent and ability to hold such

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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, 2019 and December 31, 2018.

5. Inventory

Inventory, which consists of commercial supply of TIBSOVO® (ivosidenib), consists of the following (in thousands):

	March 31, 2019	December 31, 2018
Raw materials	$ —	$ —
Work-in-process	2,267	788
Finished goods	61	81
Total inventory	$ 2,328	$ 869

6. Leases

Our building leases comprise of office and laboratory space under non-cancelable operating leases. These lease agreements have remaining lease terms of six years and contain various clauses for renewal at our option. The renewal options were not included in the calculation of the operating lease assets and the operating lease liabilities as the renewal is not reasonably certain. The lease agreements do not contain residual value guarantees. Operating lease costs for the three months ended March 31, 2019 were $3.1 million and cash paid for amounts included in the measurement of operating lease liabilities for the three months ended March 31, 2019 were $3.1 million.

We have not entered into any material short-term leases or financing leases as of March 31, 2019.

As of March 31, 2019, undiscounted minimum rental commitments under non-cancelable leases, for each of the next five years and total thereafter were as follows (in thousands):

Remaining 2019	$ 8,576
2020	13,096
2021	13,434
2022	15,798
2023	17,040
2024	17,542
Thereafter	2,951
	$ 88,437

In arriving at the operating lease liabilities as of March 31, 2019, we applied the weighted-average incremental borrowing rate of 5.3% over a weighted-average remaining lease term of 5.9 years.

As of March 31, 2019, the following represents the difference between the remaining undiscounted minimum rental commitments under non-cancelable leases and the operating lease liabilities (in thousands):

Undiscounted minimum rental commitments	$ 88,437
Present value adjustment using incremental borrowing rate	(13,303)
Operating lease liabilities	$ 75,134

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As of December 31, 2018, minimum rental commitments under non-cancelable leases, for each of the next five years and total thereafter were as follows (in thousands):

2019	$	12,759
2020	13,135	
2021	13,473	
2022	15,552	
2023	17,145	
Thereafter	19,223	
	$	91,287

New lease arrangements

On April 11, 2019, we entered into an agreement to lease approximately 13,000 square feet of office space located at 38 Sidney Street, Cambridge, Massachusetts, or the 38 Sidney Lease, with Thirty-Eight Sidney Street, LLC. The initial term of the 38 Sidney Lease is expected to commence on May 1, 2019 and expire on February 29, 2028. At the end of the lease term, we have the option to extend the 38 Sidney Lease for two consecutive terms of five years at fair market rent at the time of the extension. The 38 Sidney Lease provides us with the right to lease additional space within the 38 Sidney Street building and also includes rent escalation clauses and a tenant improvement allowance of $1.0 million.

In connection with the 38 Sidney Lease, we also amended our existing building leases at 88 Sidney Street, Cambridge, Massachusetts and at 64 Sidney Street, Cambridge, Massachusetts to extend the initial terms of those leases by approximately three years through February 29, 2028. The amendments also provide us with the right to lease additional space at the 64 Sidney Street building. Our existing extension options for the 88 Sidney Street building and 64 Sidney Street building will continue as set forth in the existing leases for those buildings.

7. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	March 31, 2019		**December 31, 2018**	
Accrued compensation	$	5,201	$	20,843
Accrued research and development costs	23,588		14,777	
Accrued professional fees	6,774		5,441	
Accrued other	1,636		1,086	
Total accrued expenses	$	37,199	$	42,147

8. Product Revenue

Our wholly owned product, TIBSOVO®, received approval from the U.S. Food and Drug Administration, or FDA, on July 20, 2018 for the treatment of adult patients with relapsed and refractory, or R/R, acute myeloid leukemia, or AML, with a susceptible isocitrate dehydrogenase 1, or IDH1, mutation. Upon FDA approval of TIBSOVO® in the U.S., we began generating product revenue from sales of TIBSOVO®. We sell TIBSOVO® to a limited number of specialty distributors and specialty pharmacy providers in the U.S., or collectively, the Customers. The Customers subsequently resell TIBSOVO® to pharmacies or dispense directly to patients. In addition to distribution agreements with Customers, we enter into arrangements with healthcare providers and payors that provide for

government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of TIBSOVO®.

The performance obligation related to the sale of TIBSOVO® is satisfied and revenue is recognized when the Customer obtains control of the product, which occurs at a point in time, typically upon delivery to the Customer.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price, or transaction price, which includes estimates of variable consideration for which reserves are established and result from contractual adjustments, government rebates, returns and other allowances that are offered within the contracts with our Customers, healthcare providers, payors and other indirect customers relating to the sale of our products.

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Contractual Adjustments

We generally provide Customers with discounts, including prompt pay discounts, and allowances that are explicitly stated in the contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, we receive sales order management, data and distribution services from certain Customers. Chargebacks for fees and discounts represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from us. Customers charge us for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are estimated using the expected value method, based upon a range of possible outcomes that are probability-weighted for the estimated channel mix and are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue.

Government Rebates

Government rebates consist of Medicare, TriCare, and Medicaid rebates, which we estimate using the expected value method, based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue. For Medicare, we also estimate the number of patients in the prescription drug coverage gap for whom we will owe an additional liability under the Medicare Part D program.

Returns

We estimate the amount of product sales that may be returned by Customers and record this estimate as a reduction of revenue in the period the related product revenue is recognized. We currently estimate product return liabilities using the expected value method, based on available industry data, including our visibility into the inventory remaining in the distribution channel.

Total net product revenue from U.S. sales of TIBSOVO®, which is our only source of product revenue, was $9.1 million for the three months ended March 31, 2019. The following table summarizes balances and activity in each of the product revenue allowance and reserve categories for the three months ended March 31, 2019 (in thousands):

	Contractual Adjustments	Government Rebates	Returns	Total
Balance at December 31, 2018	$ 592	$ 325	$ 334	$ 1,251
Current provisions relating to sales in the current year	1,265	421	215	1,901
Adjustments relating to prior years	8	—	—	8
Payments/returns relating to sales in the current year	(756)	—	—	(756)
Payments/returns relating to sales in the prior years	(598)	(150)	—	(748)
Balance at March 31, 2019	$ 511	$ 596	$ 549	$ 1,656

Total revenue-related reserves above, included in our condensed consolidated balance sheets, are summarized as follows (in thousands):

March 31, 2019	December 31, 2018
$ 303	$ 326

Reduction of accounts receivable		
Component of accrued expenses	1,353	925
Total revenue-related reserves	$ 1,656	$ 1,251

The following table presents changes in our contract assets during the three months ended March 31, 2019 (in thousands):

	December 31, 2018	Additions	Deductions	March 31, 2019
Contract assets (1)				
Accounts receivable, net	$ 5,076	$ 11,047	$ (11,768)	$ 4,355

(1) Additions to contract assets relate to amounts billed to Customers for product sales during the reporting period. Deductions to contract assets primarily relate to collection of receivables during the reporting period.

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9. Collaboration and License Agreements

Accounting analysis and revenue recognition

Our collaboration and license agreements typically involve us granting licenses of our intellectual property and performing research and development services in exchange of upfront fees, milestone payments and royalty payments. Since December 31, 2018, there have been no material changes to the key terms of our collaboration or license agreements. For further information on the terms and conditions of our existing collaboration and license agreements, please see the notes to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2018.

Collaboration revenue

On January 1, 2018 we adopted ASC 606, *Revenue from Contracts with Customers,* under the modified retrospective method. Prior to January 1, 2018, we accounted for collaboration agreements under ASC 605-25, *Multiple Element Arrangements.* 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 satisfied each performance obligation.

Royalty revenue

For arrangements that include sales-based royalties and sales-based milestones and in which the license is deemed to be the predominant item to which the royalties relate, we recognize royalty revenue upon the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Milestone revenue

At each reporting period we evaluate whether milestones are considered probable of being reached and, to the extent that a significant reversal would not occur in future periods, estimate the amount to be included in the transaction price using the most likely amount method. Milestone payments that are not within our control, such as regulatory approvals, are not considered probable of being achieved and are excluded from the transaction price until those approvals are received.

Celgene Corporation

We have entered into the following collaboration agreements, or collectively, the Collaboration Agreements, with Celgene Corporation, or Celgene, which 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. The discovery phase of the 2010 Agreement expired in April 2016. On August 15, 2016, we terminated the 2010 Agreement as to the program directed to the IDH1 target, for which ivosidenib is the lead development candidate. Accordingly, the sole program remaining under the 2010 Agreement is IDHIFA® (enasidenib), a co-commercialized licensed program for which Celgene leads and funds global development and commercialization activities. Under the remaining terms of the 2010 Agreement, we are eligible to receive up to $80.0 million in potential milestone payments for the enasidenib program. The potential milestone payments are comprised of: (i) up to $55.0 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, as well as royalties at tiered, low-double digit to mid-teen percentage rates on net sales of IDHIFA®.

•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 vorasidenib products. Under the AG-881 Agreements, we and Celgene split all worldwide development costs for vorasidenib, subject to specified exceptions. The AG-881 Agreements were terminated effective September 4, 2018, upon which we received sole global rights to vorasidenib. In connection with the termination of the AG-881 Agreements, Celgene will be eligible to receive royalties from us at a low single-digit percentage rate on worldwide net sales of products containing vorasidenib.

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•In May 2016, we entered into a master research and collaboration agreement with Celgene, or the 2016 Agreement, focused on metabolic immuno-oncology, or MIO. The initial four-year research term of the 2016 Agreement may be extended for up to two, or in specified cases, up to four additional one-year terms by paying a $40.0 million per year extension fee. Celgene has designated AG-270, our methionine adenosyltransferase 2a, or MAT2A, inhibitor, as a development candidate under the 2016 Agreement, and has the option, upon payment of an option exercise fee of at least $30.0 million, to participate in a worldwide 50/50 cost and profit share with us for AG-270, under which we are eligible for up to $169.0 million in potential milestone payments for the program, comprised of: (i) a $20.0 million milestone-based payment upon achievement of a specified clinical development event and (ii) up to $149.0 million in milestone-based payments upon achievement of specified regulatory milestone events. We are also eligible to receive designation, option exercise and milestone and royalty payments for other programs that may be designated for further development under the 2016 Agreement.

Collaboration revenue

During the three months ended March 31, 2019 and 2018, we recognized the following collaboration revenue (in thousands):

	Three Months Ended March 31,	
	2019	**2018**
Services performed that were considered performance obligations as of the modification dates		
On-going research and development services	$ 17,065	$ 6,364
Services performed that were not considered performance obligations as of the modification dates		
Development activities	854	981
Total collaboration revenue - related party	$ 17,919	$ 7,345

The following table presents changes in our contract assets and liabilities during the three months ended March 31, 2019 (in thousands):

December 31, 2018	**Additions**	**Deductions**	**March 31, 2019**

Contract assets (1)				
Collaboration receivable – related party	$ 2,462	$ 2,531	$ (2,674)	$ 2,319
Royalty receivable – related party	2,234	2,200	(2,234)	2,200
Contract liabilities (2)				
Deferred revenue – related party, current and net of current portions	92,519	2,528	(17,919)	77,128

(1) Additions to contract assets relate to amounts billed to Celgene during the reporting period. Deductions to contract assets relate to collection of receivables during the reporting period.
(2) Additions to contract liabilities relate to consideration from Celgene during the reporting period. Deductions to contract liabilities relate to deferred revenue recognized as revenue during the reporting period.

During the three months ended March 31, 2019, we recognized the following as revenue due to changes in the contract liability balances (in thousands):

	Three Months Ended March 31,	
	2019	2018
Amounts included in the contract liability at the beginning of the period	$ 16,410	$ 5,984
Performance obligations satisfied in previous periods	21	323

As of March 31, 2019, the aggregate amount of the transaction price allocated to performance obligations that are partially unsatisfied was $83.8 million. This amount is expected to be recognized as performance obligations are satisfied through March 2023.

Royalty revenue

As the underlying performance obligation, or delivery of the enasidenib license, had been satisfied as of June 2014, royalty revenue is recognized as the related sales occur. During the three months ended March 31, 2019 and 2018, we recognized the following as royalty revenue (in thousands):

	Three Months Ended March 31,	
	2019	2018
Royalty revenue – related party	$ 2,200	$ 1,417

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Milestone revenue

No milestones were achieved during the three months ended March 31, 2019 or 2018. The next potential milestone expected to be achieved under our Collaboration Agreements is the first regulatory approval in any of China, Japan or a major European country. Achievement of this event would result in milestone payment of $35.0 million under the 2010 Agreement.

CStone Pharmaceuticals

In June 2018, we and CStone Pharmaceuticals, or CStone, entered into an exclusive license agreement, or the CStone Agreement, to grant CStone specified intellectual property licenses to enable CStone to develop and commercialize certain products containing ivosidenib in mainland China, Hong Kong, Macau, and Taiwan, or the CStone Territory. We retain development and commercialization rights for the rest of the world. Pursuant to the CStone Agreement, CStone will initially be responsible for the development and commercialization of ivosidenib in AML, cholangiocarcinoma, and, at our discretion, brain cancer indications. CStone is responsible for all costs it incurs in developing, obtaining regulatory approval of, and commercializing ivosidenib in the CStone Territory, as well as certain costs incurred by us. Pursuant to the CStone Agreement, we received an initial upfront payment in the amount of $12.0 million and are entitled to receive up to an additional $412.0 million in milestone payments upon the achievement of certain development, regulatory and sales milestone events. We will also be entitled to receive tiered royalties, ranging from 15% to 19% percent, on annual net sales, if any, of ivosidenib in the CStone Territory.

Collaboration revenue

During the three months ended March 31, 2019, we recognized $1.0 million as collaboration revenue - other for certain other services provided by us to CStone, that were not considered performance obligations as of the inception date of the CStone Agreement.

The following table presents changes in our contract assets during the three months ended March 31, 2019 (in thousands):

	December 31, 2018	Additions	Deductions	March 31, 2019
Contract assets (1)				
Collaboration receivable - other	$ 670	$ 970	$ —	$ 1,640

(1) Additions to contract assets relate to amounts receivable from CStone. Deductions to contract assets relate to collection of receivables during the reporting period.

As of March 31, 2019, the aggregate amount of the transaction price allocated to performance obligations that are partially unsatisfied was $0.7 million.

Royalty revenue

The license was determined to be the predominant item to which sales-based royalties and sales-based milestones relate. As the license was delivered in June 2018, we will recognize royalty revenue when the related sales occur. To date, no royalties have been received under the CStone Agreement.

Milestone revenue

No milestones were earned during the three months ended March 31, 2019. The next potential milestone expected to be achieved under the CStone Agreement is the dosing of the first patient in a local study in a hematological indication in mainland China. Achievement of this event will result in milestone payments of $5.0 million.

10. Share-Based Payments

2013 Stock Incentive Plan

In June 2013, our Board of Directors adopted and, in July 2013 our stockholders approved, the 2013 Stock Incentive Plan, or the 2013 Plan. The 2013 Plan became effective upon the closing of our initial public offering and provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock awards, restricted stock units, or RSUs, performance-based stock units, or PSUs, market-based stock units, or MSUs, and other stock-based awards. Following the adoption of the 2013 Plan, we granted no further stock options or other awards under the 2007 Stock Incentive Plan, or the 2007 Plan. Any options or awards outstanding under the 2007 Plan

at the time of adoption of the 2013 Plan remained outstanding and effective. As of March 31, 2019, the total number of shares reserved under the 2007 Plan and the 2013 Plan are 9,564,967, and we had 2,328,237 shares available for future issuance under the 2013 Plan.

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Stock options

The following table presents stock option activity for the three months ended March 31, 2019:

	Number of Stock Options	Weighted-Average Exercise Price
Outstanding at December 31, 2018	5,416,069	$ 60.10
Granted	1,357,189	57.47
Exercised	(106,859)	39.45
Forfeited/Expired	(183,526)	64.12
Outstanding at March 31, 2019	6,482,873	$ 59.77
Exercisable at March 31, 2019	3,269,079	$ 57.85
Vested and expected to vest at March 31, 2019	6,482,873	$ 59.77

At March 31, 2019, the total unrecognized compensation expense related to unvested stock option awards was $128.9 million, which we expect to recognize over a weighted-average period of approximately 3.0 years.

Restricted stock units

The following table presents RSU activity for the three months ended March 31, 2019:

	Number of Stock Units	Weighted-Average Grant Date Fair Value
Unvested shares at December 31, 2018	532,144	$ 75.45
Granted	334,827	58.76
Vested	(134,868)	66.98
Forfeited	(22,941)	74.33
Unvested shares at March 31, 2019	709,162	$ 69.22

As of March 31, 2019, there was approximately $40.6 million of total unrecognized compensation expense related to RSUs, which we expect to recognize over a weighted-average period of approximately 2.1 years.

Performance-based stock units

The following table presents PSU activity for the three months ended March 31, 2019:

	Number of Stock Units	Weighted-Average Grant Date Fair Value
Unvested shares at December 31, 2018	169,031	$ 52.67
Vested	(167,031)	52.36

Unvested shares at March 31, 2019	2,000	$	79.05

Stock-based compensation expense associated with these PSUs is recognized if the underlying performance condition is considered probable of achievement using our management's best estimates. Performance-based vesting criteria primarily relate to events specific to our corporate goals.