

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

**FORM 8-K**

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

**Date of Report (Date of earliest event reported): January 29, 2021**

**Agios Pharmaceuticals, Inc.**

(Exact Name of Registrant as Specified in Charter)

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

**001-36014**  
(Commission  
File Number)

**26-0662915**  
(IRS Employer  
Identification No.)

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

**02139**  
(Zip Code)

**Registrant's telephone number, including area code: (617) 649-8600**

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

**Item 7.01 Regulation FD Disclosure.**

Agios Pharmaceuticals, Inc. (“Agios”) is filing this Current Report on Form 8-K to furnish its historical consolidated financial statements and the notes thereto previously included in its Annual Report on Form 10-K for the fiscal years ended December 31, 2019 and 2018 (the “Prior 10-K”) filed with the Securities and Exchange Commission on February 19, 2020 (such financial statements and notes thereto, the “2018-2019 Financial Statements”). The 2018-2019 Financial Statements, furnished as Exhibit 99.1 to this Current Report, are consistent in all respects with the financial statements for such periods included in the Prior 10-K. This Current Report does not reflect events occurring after February 19, 2020, the filing date of the Prior 10-K, and does not modify or update the disclosures set forth in the Prior 10-K in any way.

Agios expects to incorporate by reference the 2018-2019 Financial Statements in its proxy statement to be filed in connection with its previously announced sale of specified assets related to its oncology business. The 2018-2019 Financial Statements are being furnished solely for such purpose.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#"><u>The consolidated financial statements of Agios Pharmaceuticals, Inc. and its subsidiaries as of December 31, 2019 and 2018, including the consolidated balance sheets and the related consolidated statements of operations, of comprehensive loss, of stockholders’ equity and of cash flows for the years then ended, including the related notes</u></a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AGIOS PHARMACEUTICALS, INC.

Date: January 29, 2021

By: /s/ Jacquelyn A. Fouse  
Jacquelyn A. Fouse, Ph.D.  
Chief Executive Officer

## Agios Pharmaceuticals, Inc.

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## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Agios Pharmaceuticals, Inc.

### ***Opinion on the Financial Statements***

We have audited the accompanying consolidated balance sheets of Agios Pharmaceuticals, Inc. and its subsidiaries (the “Company”) as of December 31, 2019 and 2018, and the related consolidated statements of operations, of comprehensive loss, of stockholders’ equity and of cash flows for the years then ended, including the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

### ***Changes in Accounting Principles***

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019 and the manner in which it accounts for revenue from contracts with customers in 2018.

### ***Basis for Opinion***

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

### ***Critical Audit Matters***

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

#### ***Revenue recognition – Celgene Collaboration Agreement Research and Development Services Recognized Under an Input Method***

As described in Notes 2 and 11 to the consolidated financial statements, the Company recognizes revenue arising from collaboration agreements with Celgene. A significant portion of revenue generated from the Company’s collaboration agreements with Celgene relates to the provision of research and development services whereby revenue is recognized under an input method using the ratio of effort incurred to date compared to the total estimated effort required to complete the performance obligation. The calculation of the total estimated effort includes the total amount of forecasted costs associated with the completion of discovery, pre-clinical or clinical trials, as well as the assumed timing of these activities and estimated patient populations. Such cost estimates include forecasted direct labor and material costs, subcontractor costs, and external contract research organization costs. Research and development services revenue recognized from the collaboration with Celgene were \$36.0 million during the year-ended December 31, 2019.

The principal considerations for our determination that performing procedures relating to revenue recognition—Celgene collaboration agreement research and development services recognized under an input method—is a critical audit matter are there was significant judgment and estimation by management in determining the total estimated effort required to complete the performance obligation,

specifically the estimation of forecasted direct labor and material costs, and external contract research organization costs. This in turn led to a high degree of auditor judgment, effort and subjectivity in performing procedures and in evaluating audit evidence relating to the cost estimates made by management.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the revenue recognition process, including controls over the revenue recognized for research and development services, controls over the costs incurred to date for each performance obligation, and controls over the inputs and assumptions used to estimate the total effort required to complete each performance obligation. These procedures also included, among others, testing the actual costs incurred to date for each identified performance obligation, and evaluating and testing management's process for estimating total costs to complete each performance obligation which included evaluating the reasonableness of management's estimates of total forecasted direct labor and materials costs and total external contract research organization costs. Evaluating the reasonableness of the assumptions used involved evaluating the appropriateness of changes to management's estimates of total costs to complete and performing a comparison of management's prior period cost estimates to actual costs incurred.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts  
February 19, 2020

We have served as the Company's auditor since 2017.

Agius Pharmaceuticals, Inc.  
Consolidated Balance Sheets

(In thousands) December 31:

	2019	2018
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 80,931	\$ 70,502
Marketable securities	483,946	514,800
Accounts receivable, net	8,952	5,076
Collaboration receivable – related party	1,539	2,462
Collaboration receivable – other	1,928	670
Royalty receivable – related party	2,900	2,234
Inventory	7,331	869
Prepaid expenses and other current assets	24,177	17,167
Total current assets	611,704	613,780
Marketable securities	152,929	220,119
Operating lease assets	93,643	—
Property and equipment, net	31,472	24,320
Financing lease assets	993	—
Other non-current assets	—	238
Total assets	<u>\$ 890,741</u>	<u>\$ 858,457</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 21,896	\$ 17,880
Accrued expenses	53,142	42,147
Deferred revenue – related party	10,933	32,710
Operating lease liabilities	6,642	—
Deferred rent	—	766
Financing lease liabilities	273	—
Total current liabilities	92,886	93,503
Deferred revenue, net of current portion – related party	50,580	59,809
Operating lease liabilities, net of current portion	106,074	—
Deferred rent, net of current portion	—	17,608
Financing lease liabilities, net of current portion	673	—
Total liabilities	250,213	170,920
Commitments and contingent liabilities (Note 9)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 25,000,000 shares authorized, no shares issued and outstanding at December 31, 2019 and 2018	—	—
Common stock, \$0.001 par value; 125,000,000 shares authorized and 68,401,105 and 58,218,653 shares issued and outstanding at December 31, 2019 and 2018, respectively	68	58
Additional paid-in capital	2,156,363	1,794,283
Accumulated other comprehensive income (loss)	202	(2,171)
Accumulated deficit	(1,516,105)	(1,104,633)
Total stockholders' equity	640,528	687,537
Total liabilities and stockholders' equity	<u>\$ 890,741</u>	<u>\$ 858,457</u>

*See accompanying Notes to Consolidated Financial Statements.*

Agios Pharmaceuticals, Inc.  
Consolidated Statements of Operations

(In thousands, except share and per share data) Years Ended December 31:

	2019	2018
<b>Revenues:</b>		
Product revenue, net	\$ 59,851	\$ 13,841
Collaboration revenue – related party	39,257	60,661
Collaboration revenue – other	8,262	12,670
Royalty revenue – related party	10,542	7,215
Total revenue	<u>117,912</u>	<u>94,387</u>
<b>Cost and expenses:</b>		
Cost of sales	1,317	1,397
Research and development	410,894	341,324
Selling, general and administrative	132,034	114,145
Total cost and expenses	<u>544,245</u>	<u>456,866</u>
Loss from operations	(426,333)	(362,479)
Interest income, net	14,861	16,451
Net loss	<u>\$ (411,472)</u>	<u>\$ (346,028)</u>
Net loss per share – basic and diluted	<u>\$ (6.86)</u>	<u>\$ (6.03)</u>
Weighted-average number of common shares used in computing net loss per share – basic and diluted	59,994,539	57,418,300

*See accompanying Notes to Consolidated Financial Statements.*



Agius Pharmaceuticals, Inc.  
Consolidated Statements of Comprehensive Loss

<u>(In thousands) Years Ended December 31:</u>	<u>2019</u>	<u>2018</u>
Net loss	\$(411,472)	\$(346,028)
Other comprehensive income (loss):		
Unrealized gain (loss) on available-for-sale securities	2,373	(782)
Comprehensive loss	<u>\$(409,099)</u>	<u>\$(346,810)</u>

*See accompanying Notes to Consolidated Financial Statements.*

Agius Pharmaceuticals, Inc.  
Consolidated Statements of Stockholders' Equity

(In thousands, except share amounts)	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
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	—	—	—	(782)	—	(782)
Net loss	—	—	—	—	(346,028)	(346,028)
Adjustment to beginning accumulated deficit resulting from adoption of ASC 606	—	—	—	—	39,456	39,456
Stock-based compensation expense	—	—	73,357	—	—	73,357
Issuance of common stock under stock incentive and employee stock purchase plans	1,239,514	1	30,215	—	—	30,216
Issuance of common stock for follow-on offering	8,152,986	8	516,198	—	—	516,206
Other	—	—	(391)	—	—	(391)
Balance at December 31, 2018	58,218,653	\$ 58	\$1,794,283	\$ (2,171)	\$(1,104,633)	\$ 687,537
Unrealized gain on available-for-sale securities	—	—	—	2,373	—	2,373
Net loss	—	—	—	—	(411,472)	(411,472)
Stock-based compensation expense	—	—	72,373	—	—	72,373
Issuance of common stock under stock incentive and employee stock purchase plans	694,952	1	12,515	—	—	12,516
Issuance of common stock for follow-on offering	9,487,500	9	277,192	—	—	277,201
Other	—	—	—	—	—	—
Balance at December 31, 2019	68,401,105	\$ 68	\$2,156,363	\$ 202	\$(1,516,105)	\$ 640,528

*See accompanying Notes to Consolidated Financial Statements.*

Agius Pharmaceuticals, Inc.  
Consolidated Statements of Cash Flows

(In thousands) Years Ended December 31:

	2019	2018
<b>Operating activities</b>		
Net loss	\$(411,472)	\$(346,028)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	8,087	7,172
Stock-based compensation expense	72,373	73,357
Net accretion of discount on marketable securities	(3,195)	(3,837)
Loss on disposal of property and equipment	1,052	20
Non-cash operating lease expense	8,532	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(3,876)	(5,076)
Collaboration receivable – related party	923	(14)
Collaboration receivable – other	(1,258)	(670)
Royalty receivable – related party	(666)	(1,012)
Inventory	(6,462)	(869)
Prepaid expenses and other current and non-current assets	(7,742)	1,148
Accounts payable	3,716	(5,488)
Accrued expenses	7,233	8,623
Deferred revenue – related party	(31,006)	(31,665)
Operating lease liabilities	(6,861)	—
Deferred rent	—	(82)
Net cash used in operating activities	<u>(370,622)</u>	<u>(304,421)</u>
<b>Investing activities</b>		
Purchases of marketable securities	(488,566)	(933,320)
Proceeds from maturities and sales of marketable securities	592,177	666,481
Purchases of property and equipment	(12,171)	(6,986)
Net cash provided by (used in) investing activities	<u>91,440</u>	<u>(273,825)</u>
<b>Financing activities</b>		
Payments on financing lease obligations	(113)	—
Proceeds from public offering of common stock, net of reimbursements	277,201	516,206
Reimbursement (payment) of public offering costs	—	(391)
Net proceeds from stock option exercises and employee stock purchase plan	12,523	30,209
Net cash provided by financing activities	<u>289,611</u>	<u>546,024</u>
Net change in cash and cash equivalents	10,429	(32,222)
Cash and cash equivalents at beginning of the period	70,502	102,724
Cash and cash equivalents at end of the period	<u>\$ 80,931</u>	<u>\$ 70,502</u>
<b>Supplemental disclosure of non-cash investing and financing transactions:</b>		
Additions to property and equipment in accounts payable and accrued expenses	\$ 5,168	\$ 1,106
Proceeds from stock option exercises in other current assets	\$ —	\$ 7
Operating lease liabilities arising from obtaining operating lease assets	\$ 42,322	\$ —
Financing lease liabilities arising from obtaining financing lease assets	\$ 1,052	\$ —

*See accompanying Notes to Consolidated Financial Statements.*

## Note 1. Nature of Business

### References to Agios

Throughout these financial statements as filed on Form 8-K, “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 creating differentiated, small molecule medicines for patients in the areas of hematologic malignancies, solid tumors and rare genetic diseases, or RGDs. To address these focus areas, 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.

Our wholly-owned product, TIBSOVO® (ivosidenib) is an oral targeted inhibitor of the mutated isocitrate dehydrogenase 1, or IDH1 enzyme. TIBSOVO® is the first and only U.S. Food and Drug Administration, or FDA-approved therapy for the treatment of adult patients with (i) relapsed or refractory acute myeloid leukemia, or R/R AML, with a susceptible IDH1 mutation as detected by an FDA-approved test (approved by the FDA in July 2018) and (ii) newly diagnosed AML with a susceptible IDH1 mutation as detected by an FDA-approved test who are at least 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy (approved by the FDA in May 2019). In December 2018, we submitted a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, for TIBSOVO® for the treatment of adult patients with R/R AML with an IDH1 mutation.

Our other marketed product is IDHIFA® (enasidenib), an oral targeted inhibitor of the mutated isocitrate dehydrogenase 2, or IDH2 enzyme and the first and only FDA-approved therapy for patients with R/R AML and an IDH2 mutation. In August 2017, the FDA granted our collaboration partner Celgene approval of IDHIFA® for the treatment of adult patients with R/R AML and an IDH2, mutation as detected by an FDA-approved test. We are eligible to receive royalties at tiered low-double digit to mid-teen percentage rates on any net sales of IDHIFA® and have exercised our rights to provide up to one-third of the field-based commercialization efforts in the United States. In June 2018, Celgene submitted an MAA to the EMA for IDHIFA® for IDH2 mutant-positive AML which it subsequently withdrew in December 2019.

Our pre-commercial clinical cancer product candidates are vorasidenib, AG-270, and AG-636.

Vorasidenib is an orally available, selective brain-penetrant pan-IDH mutant inhibitor. We are developing vorasidenib for the treatment of IDH mutant-positive low grade glioma and are currently evaluating vorasidenib in clinical trials.

AG-270 is an orally available selective potent inhibitor of methionine adenosyltransferase 2a, or MAT2A. We are currently evaluating AG-270 in a phase 1 dose-escalation and expansion trial in multiple tumor types carrying a methylthioadenosine phosphorylase, or MTAP, deletion.

AG-636 is an inhibitor of the metabolic enzyme dihydroorotate dehydrogenase, or DHODH. We are currently evaluating AG-636 in the phase 1 dose-escalation trial in lymphoma.

The lead product candidate in our RGD portfolio, mitapivat, is an activator of both wild-type and mutant pyruvate kinase-R for the potential treatment of hemolytic anemias. We are currently evaluating mitapivat for the treatment of pyruvate kinase, or PK, deficiency, thalassemia and sickle cell disease, or SCD, in clinical trials.

In addition to the aforementioned development programs, we are seeking to advance a number of early-stage discovery programs in our focus areas of malignant hematology, solid tumors and RGDs based on our scientific leadership in the field of cellular metabolism and adjacent areas of biology.

We are subject to risks common to companies in our industry including, but not limited to, uncertainties relating to conducting clinical research and development, the manufacture and supply of products for clinical and commercial use, obtaining and maintaining regulatory approvals and pricing and reimbursement for our products, market acceptance, managing global growth and operating expenses, availability of additional capital, competition, obtaining and enforcing patents, stock price volatility, dependence on collaborative relationships and third-party service providers, dependence on key personnel, potential litigation, product liability claims and government investigations.

## ***Liquidity***

In November 2019, we completed a public offering of 8,250,000 shares of common at an offering price of \$31.00 per share. We received net proceeds from this offering of \$241.0 million, after deducting underwriting discounts and commissions paid by us. In addition, we granted the underwriters the right to purchase up to an additional 1,237,500 shares of common stock, which was exercised in November 2019, resulting in additional net proceeds to us of \$36.2 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 9,487,500 shares, and net proceeds to us totaled \$277.2 million, after underwriting discounts and commissions.

As of December 31, 2019, we had cash, cash equivalents and marketable securities of \$717.8 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 to be sufficient to fund current operations for at least the next twelve months from the issuance of the financial statements. If the Company is unable to raise additional funds through equity or debt financings, the Company may be required to delay, limit, reduce or terminate product development or future commercialization efforts or grant rights to develop and market products or product candidates that the Company would otherwise prefer to develop and market itself.

## **Note 2. Summary of Significant Accounting Policies**

### ***Principles of consolidation***

The consolidated financial statements include our accounts and the accounts of our wholly owned subsidiaries, Agios Securities Corporation, Agios International Sarl, Agios Germany GmbH, Agios Netherlands B.V., and Agios Limited. All intercompany transactions have been eliminated in consolidation. The consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles, or U.S. GAAP.

### ***Use of estimates***

The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. Actual results could differ from those estimates.

### ***Cash and cash equivalents***

We consider highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash equivalents are stated at fair value.

### ***Marketable securities***

Marketable securities at December 31, 2019 and 2018 consisted of investments in certificates of deposit, U.S. Treasuries, government securities and corporate debt securities. We determine the appropriate classification of the securities at the time they are acquired and evaluate the appropriateness of such classifications at each balance sheet date. We classify our marketable securities as available-for-sale pursuant to Accounting Standards Codification, or ASC, 320, *Investments – Debt and Equity Securities*. Marketable securities 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 consolidated statements of comprehensive loss, until realized. Realized gains and losses are included in investment income on a specific-identification basis.

At December 31, 2019 and 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 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.

We review marketable securities for other-than-temporary impairment whenever the fair value of a marketable security is less than the amortized cost and evidence indicates that a marketable security's carrying amount is not recoverable within a reasonable period of time. Other-than-temporary impairments of investments are recognized in the consolidated statements of operations if we experience a credit loss, have the intent to sell the marketable security, or if it is more likely than not that we will be required to sell the marketable security before recovery of the amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, compliance with our investment policy, the severity and the duration of the impairment, and changes in value subsequent to the end of the period.

### ***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, either 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.

Our financial assets, which include cash equivalents and marketable securities, have been initially valued at the transaction price, and subsequently revalued at the end of each reporting period, utilizing third-party pricing services or other observable market 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 December 31, 2019 or 2018. Fair value information for these assets, including their classification in the fair value hierarchy is included in Note 3. *Fair Value Measurements*.

There have been no changes to the valuation methods during the years ended December 31, 2019 and 2018. We evaluate transfers between levels at the end of each reporting period.

The carrying amounts of collaboration receivable – related party, collaboration receivable – other, royalty receivable – related party, accounts receivable, prepaid expenses and other current assets, accounts payable, and accrued expenses approximate their fair values due to their short-term maturities.

### ***Accounts receivable, net***

Our trade accounts receivable arise from product sales and represent amounts due from specialty distributors and specialty pharmacy providers in the U.S. We monitor the financial performance and creditworthiness of our customers so that we can properly assess and respond to changes in their credit profile. We reserve against these receivables for estimated losses that may arise from a customer's inability to pay. Amounts determined to be uncollectible are charged or written-off against the reserve.

### ***Concentrations of credit risk***

Financial instruments which potentially subject us to credit risk consist primarily of cash, cash equivalents, and marketable securities. We hold these investments in highly rated financial institutions, and, by policy, limit the amounts of credit exposure to any one financial institution. These amounts at times may exceed federally insured limits. We have not experienced any credit losses in such accounts and do not believe we are exposed to any significant credit risk on these funds. We have no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts, or other hedging arrangements.

We are also subject to credit risk on our receivables, including trade receivables from our customers and collaboration and royalty receivables from Celgene and CStone Pharmaceuticals, or CStone. Concentrations of credit risk with respect to receivables, which are typically unsecured, are somewhat mitigated due to the number of customers using our products. Our trade receivables arise from product sales in the U.S. and have standard payment terms that generally require payment within 30 to 60 days. We have evaluated the creditworthiness of our customers, including Celgene, and determined them to be creditworthy. To date we have not experienced any losses with respect to our receivables.

### ***Inventory***

Inventory is stated at the lower of cost or estimated net realizable value on a first-in, first-out basis. Prior to the regulatory approval of our product candidates, we incur expenses for the manufacture of drug product that could potentially be available to support the commercial launch of those products. Until the date at which regulatory approval has been received or is otherwise considered probable, we record all such costs as research and development expenses. Upon approval of our wholly owned product, TIBSOVO®, by the FDA on July 20, 2018 for the treatment of adult patients with R/R AML with susceptible IDH1 mutation as detected by an FDA-approved test, we began to capitalize inventories of TIBSOVO®.

We perform an assessment of the recoverability of capitalized inventory during each reporting period and write down any excess and obsolete inventory to its estimated net realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded as a component of cost of sales in the consolidated statements of operations. The determination of whether inventory costs will be realizable requires the use of estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required.

### ***Property and equipment***

Property and equipment consist of laboratory equipment, computer equipment and software, leasehold improvements, furniture and fixtures, and office equipment. Costs of major additions and betterment are capitalized; maintenance and repairs, which do not improve or extend the life of the respective assets, are charged to expense as incurred. Upon retirement or sale, the cost of the disposed asset and the related accumulated depreciation are removed from the accounts and the resulting gain or loss is recognized.

Property and equipment is stated at cost, and depreciated using the straight-line method over the estimated useful lives of the respective assets:

	<b>Years</b>
Laboratory equipment	5
Computer equipment and software	3
Furniture and fixtures	5
Office equipment	5

Leasehold improvements are amortized over the lesser of the remaining lease term or the estimated useful life of the improvement.

### ***Impairment of long-lived assets***

We periodically evaluate our long-lived assets for potential impairment in accordance with ASC 360, *Property, Plant and Equipment*. Potential impairment is assessed when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recovered. Recoverability of these assets is assessed based on the undiscounted expected future cash flows from the assets, considering a number of factors, including past operating results, budgets and economic projections, market trends and product development cycles. If impairments are identified, assets are written down to their estimated fair value. We did not recognize any impairment charges through December 31, 2019.

### ***Leases***

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 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.

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

### ***Revenue from contracts with customers***

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 the consideration received under the Collaboration Agreements under ASC 605-25, *Multiple Element Arrangements*.

In adopting ASC 606, we applied the practical expedient that permits aggregating the effect of all contract 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 with Celgene.

Revenue is recognized when the customer obtains control of promised goods or services, in an amount that reflects the consideration that we expect to receive in exchange for those goods or services. To determine revenue recognition for

arrangements that we determined to be within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We will then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

#### *Product revenue*

We generate product revenue from sales of 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.

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.

*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.

Chargebacks 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.

#### *Collaboration revenue*

We apply the provisions of ASC 808, *Collaborative Arrangements*, when accounting for our collaboration agreements. We evaluate the presentation of amounts due from our collaborative partners associated with activities in the collaborative arrangement based on the nature of each activity. For transactions with customers, we have reported revenues and costs in accordance with ASC 606, *Revenue from Contracts with Customers*, ASC 606-10-55-36 through 55-40, *Principal versus Agent Considerations*. We recognize revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration that we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that have been determined to be within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract based on the relative standalone selling prices of the goods or services provided; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer.



Once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We will then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The transaction price for each collaboration agreement is determined based on the amount of consideration we expect to be entitled to for satisfying all performance obligations within the agreement. Significant judgment may be required in determining the amount of variable consideration to be included in the transaction price. We use the expected value methods to determine variable consideration and will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

As part of the initial accounting for these arrangements, we must develop assumptions that require judgment to determine the standalone selling price, or SSP, for each performance obligation identified in the contract. We use these 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.

We recognize the transaction price allocated to upfront license payments as revenue upon delivery of the license to the customer and resulting ability of the customer to use and benefit from the license, if the license is determined to be distinct from the other performance obligations identified in the contract. If the license is considered to not be distinct from other performance obligations, we exercise judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied (i) at a point in time, but only for licenses determined to be distinct from other performance obligations in the contract, or (ii) over time; and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from license payments. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

A significant portion of revenue generated from our collaboration agreements with Celgene relates to the provision of research and development services whereby revenue is recognized under an input method using the ratio of effort incurred to date compared to the total estimated effort required to complete the performance obligation. The calculation of the total estimated effort includes the total amount of forecasted costs associated with the completion of discovery, pre-clinical or clinical trials, as well as the assumed timing of these activities and estimated patient populations. Such cost estimates include forecasted direct labor and material costs, subcontractor costs, and external contract research organization, or CRO, costs.

#### *Milestone revenue*

Many of our collaboration agreements also entitle us to additional payments upon the achievement of performance-based milestones. These milestones are generally categorized into three types: development milestones, which are generally based on the initiation of clinical trials; regulatory milestones, which are generally based on the submission, filing or approval of regulatory applications such as a new drug application, or NDA, in the U.S.; and sales-based milestones, which are generally based on meeting specific thresholds of sales in certain geographic areas during a specified period. Upfront and ongoing development milestones per our collaboration agreements are not subject to refund if the development activities are not successful.

For each collaboration that includes development milestone payments, we evaluate whether it is probable that the consideration associated with each milestone will not be subject to a significant reversal in the cumulative amount of revenue recognized. Amounts that meet this threshold are included in the transaction price using the most likely amount method, whereas amounts that do not meet this threshold are considered constrained and excluded from the transaction price until they meet this threshold. Milestones tied to regulatory approval, and therefore not within our control, are considered constrained until such approval is received. At the end of each subsequent reporting period, we re-evaluate the probability of a significant reversal of the cumulative revenue recognized for our milestones, and, if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues from collaborators and loss in the period of adjustment. For arrangements that include sales-based milestone or royalty payments based on the level of sales, and in which the license is deemed to be the predominant item to which the sales-based milestone or royalties relate to, we recognize revenue in the period in which the sales-based milestone is achieved and in the period in which the sales associated with the royalty occur.

#### *Adoption of ASC 606*

We adopted ASC 606 using the modified retrospective method. Under this method, we recognized the cumulative effect of the change in the opening balance of accumulated deficit in the December 31, 2018 consolidated balance sheet.

In adopting ASC 606, we applied the practical expedient that permits aggregating the effect of all contract modifications that occurred prior to January 1, 2018. No other practical expedients were used.

The impact of the cumulative effect of the accounting changes upon the adoption of the standard is as follows:

(In thousands)	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 consolidated financial statements:

#### Consolidated Balance Sheets

(In thousands)	December 31, 2018		
	Under Topic 606	Under Topic 605	Effect of Change
Accounts receivable, net	\$ 5,076	\$ 5,076	\$ —
Collaboration receivable – related party	2,462	2,462	—
Collaboration receivable – other	670	230	440
Total current assets	613,780	613,340	440
Total assets	858,457	858,017	440
Deferred revenue – related party	32,710	29,133	3,577
Total current liabilities	93,503	89,926	3,577
Deferred revenue, net of current portion – related party	59,809	101,180	(41,371)
Total liabilities	170,920	208,714	(37,794)
Accumulated deficit	(1,104,633)	(1,142,867)	38,234
Total stockholders' equity	687,537	649,303	38,234
Total liabilities and stockholders' equity	858,457	858,017	440

#### Consolidated Statements of Operations

(In thousands, except per share data)	Year ended December 31, 2018		
	Under Topic 606	Under Topic 605	Effect of Change
Product revenue, net	\$ 13,841	\$ 13,841	\$ —
Collaboration revenue – related party	60,661	58,994	1,667
Collaboration revenue – other	12,670	12,230	440
Total revenue	94,387	92,280	2,107
Research and development expense	341,324	337,995	3,329
Total cost and expenses	456,866	453,537	3,329
Loss from operations	(362,479)	(361,257)	(1,222)
Net loss	(346,028)	(344,806)	(1,222)
Net loss per share – basic and diluted	(6.03)	(6.01)	(0.02)

#### Consolidated Statements of Comprehensive Loss

(In thousands)	Year ended December 31, 2018		
	Under Topic 606	Under Topic 605	Effect of Change
Net loss	\$ (346,028)	\$ (344,806)	\$ (1,222)
Comprehensive loss	(346,810)	(345,588)	(1,222)

## Consolidated Statements of Cash Flows

(In thousands)	Year ended December 31, 2018		
	Under Topic 606	Under Topic 605	Effect of Change
Net loss	\$(346,028)	\$(344,806)	\$(1,222)
Adjustments to reconcile net loss to net cash used in operating activities:			
Accounts receivable, net	(5,076)	(5,076)	—
Collaboration receivable – related party	(14)	(14)	—
Collaboration receivable – other	(670)	(230)	(440)
Deferred revenue – related party	(31,665)	(33,327)	1,662

### Cost of Sales

Cost of sales consists primarily of manufacturing costs of TIBSOVO®. Based on our policy to expense costs associated with the manufacturing of our products prior to regulatory approval, certain of the manufacturing costs associated with product shipments of TIBSOVO® recorded during the years ended December 31, 2019 and December 31, 2018 were expensed prior to July 20, 2018 and, therefore, are not included in costs of sales during the years ended December 31, 2019 or 2018.

### Research and development costs

Research and development costs, including those accrued as of each balance sheet date, are expensed as incurred. These costs include salaries and personnel-related costs, consulting fees, fees paid for contract research services, fees paid to contract CROs, and other third parties in connection with clinical trials and preclinical development activities, fees paid to investigative sites in connection with clinical studies, the costs associated with the product manufacturing, development, and distribution of clinical supplies, the costs of laboratory equipment and facilities, and other external costs.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. Additionally, there may be instances in which payments made to our vendors will exceed the level of services provided, and result in a prepayment of the research and development expense. The capitalized amounts are expensed as the related goods are delivered or the services are performed. We estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly.

### Stock-based compensation

We account for stock-based compensation awards in accordance with ASC 718, *Compensation – Stock Compensation*, or ASC 718. For stock-based awards granted to employees and to members of the board of directors for their services and for participation in our employee stock purchase plan, we primarily estimate the grant date fair value of each option award using the Black-Scholes option-pricing model. The use of the Black-Scholes option-pricing model requires us to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock. For awards subject to service-based vesting conditions, we recognize stock-based compensation expense equal to the grant date fair value of stock options on a straight-line basis over the requisite service period. For awards subject to both performance and service-based vesting conditions, we recognize stock-based compensation expense over the remaining service period if the performance condition is considered probable of achievement using management's best estimates.

### Income taxes

Income taxes are recorded in accordance with ASC 740, *Accounting for Income Taxes*, or ASC 740, which provides for deferred taxes using an asset and liability approach. We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in our financial statements or tax returns. We determine our deferred tax assets and liabilities based on differences between the financial reporting and tax bases of assets and liabilities, which are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We also account for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, we recognize the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances.

### ***Comprehensive income (loss)***

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions, and other events and circumstances, and currently consists of net loss and unrealized gains and losses on available-for-sale securities. Accumulated other comprehensive loss consists entirely of unrealized gains and losses from available-for-sale securities as of December 31, 2019 and 2018.

### ***Net loss per share***

Basic net loss per share is calculated by dividing net loss by the weighted-average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted-average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the dilutive net loss per share calculation, stock options, restricted stock units, performance-based stock units and market-based stock units for which the performance vesting conditions have been met, and employee stock purchase plan shares are considered to be common stock equivalents but are excluded from the calculation of diluted net loss per share as their effect would be anti-dilutive.

### ***Segment and geographic information***

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions on how to allocate resources and assess performance. Our chief operating decision maker is the chief executive officer. Our chief operating decision maker and we view our operations and manage our business as one operating segment.

### ***Recent accounting pronouncements***

#### ***Leases***

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which was codified as ASC 842, *Leases*, and amended through subsequent ASUs. We adopted ASC 842 effective January 1, 2019 using the optional transition method provided for under ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, whereby we applied the new lease requirements through a cumulative-effect adjustment, which after completing our implementation analysis, resulted in no material adjustment to our January 1, 2019 beginning accumulated deficit balance. We also elected the package of practical expedients provided for under ASU 2018-11, which 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, for our building leases, we chose not to separate the non-lease components from the lease components and, instead, accounted for each non-lease component and lease component as a single component.

We completed our assessment over the impact of the standard and determined that the only material leases that we hold are our building leases. Upon adoption of the standard on January 1, 2019, we recorded operating right of use assets of \$59.9 million and operating lease liabilities of \$77.3 million on our consolidated balance sheets. Prior periods are presented in accordance with ASC 840, *Leases*.

#### ***Other recent accounting pronouncements***

In June 2018, the FASB issued Accounting Standards Update No. 2018-07 – *Compensation-Stock Compensation (Topic 718)-Improvements to Nonemployee Share-Based Payment Accounting*. ASU 2018-07 simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018. The Company adopted the new standard as of January 1, 2019. There was no material impact to the Company's consolidated financial position, results of operation, or cash flows.

In December 2019, the FASB issued Accounting Standards Update No. 2019-12 – *Income Taxes (Topic 740) Simplifying the Accounting for Income Taxes*, as part of its initiative to reduce complexity in the accounting standards. The amendments in ASU 2019-12 eliminate certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. ASU 2019-12 also clarifies and simplifies other aspects of the accounting for income taxes. The amendments in ASU 2019-12 are effective for the fiscal years beginning after December 15, 2020. Early adoption is permitted, including adoption in any interim period. The Company has early adopted this amendment as of January 1, 2019. There was no material impact to the Company's consolidated financial position, results of operation, or cash flows.

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.

### Subsequent events

We considered events or transactions occurring after the balance sheet date, but prior to the issuance of the consolidated financial statements, for potential recognition or disclosure in our consolidated financial statements. All significant subsequent events have been properly disclosed in the consolidated financial statements.

### Note 3. Fair Value Measurements

The following table summarizes our cash equivalents and marketable securities measured at fair value and by level (as described in Note 2. *Summary of Significant Accounting Policies*) on a recurring basis as of December 31, 2019:

(In thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents	\$ 12,568	\$ 36,299	\$ —	\$ 48,867
Total cash equivalents	12,568	36,299	—	48,867
Marketable securities:				
Certificates of deposit	—	—	—	—
U.S. Treasuries	—	214,027	—	214,027
Government securities	—	97,820	—	97,820
Corporate debt securities	—	325,028	—	325,028
Total marketable securities	—	636,875	—	636,875
Total cash equivalents and marketable securities	\$ 12,568	\$ 673,174	\$ —	\$ 685,742

There were no transfers between Level 1 and Level 2 and we had no financial assets or liabilities that were classified as Level 3 at any point during the year ended December 31, 2019.

### Note 4. Marketable Securities

Marketable securities at December 31, 2019 consisted of the following:

(In thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Current:				
Certificates of deposit	\$ —	\$ —	\$ —	\$ —
U.S. Treasuries	178,721	58	(38)	178,741
Government securities	80,228	17	(16)	80,229
Corporate debt securities	224,928	139	(91)	224,976
Total Current	483,877	214	(145)	483,946
Non-current:				
U.S. Treasuries	35,296	3	(13)	35,286
Government securities	17,587	14	(10)	17,591
Corporate debt securities	99,913	239	(100)	100,052
Total Non-current	152,796	256	(123)	152,929
Total marketable securities	\$ 636,673	\$ 470	\$ (268)	\$ 636,875

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
Total Current	515,629	7	(836)	514,800
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 Non-current	221,461	26	(1,368)	220,119
Total marketable securities	<u>\$737,090</u>	<u>\$ 33</u>	<u>\$ (2,204)</u>	<u>\$734,919</u>

There were no material realized gains or losses on marketable securities for the years ended December 31, 2019 and 2018.

At December 31, 2019 and 2018, we held 113 and 242 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 December 31, 2019 and 2018 was \$345.7 million and \$639.3 million, respectively. There were no individual securities that were in a significant unrealized loss position as of December 31, 2019 and 2018. Given our intent and ability to hold such securities until recovery, and the lack of material change in the credit risk of these investments, we do not consider these marketable securities to be other-than-temporarily impaired as of December 31, 2019 and 2018.

#### Note 5. Property and Equipment, net

Property and equipment, net consisted of the following at December 31:

(In thousands)	2019	2018
Laboratory equipment	\$ 23,418	\$ 20,165
Computer equipment and software	6,415	5,449
Leasehold improvements	23,879	22,084
Furniture and fixtures	2,101	1,065
Office equipment	589	407
Construction in progress	7,182	1,302
Total property and equipment	63,584	50,472
Less: accumulated depreciation	(32,112)	(26,152)
Total property and equipment, net	<u>\$ 31,472</u>	<u>\$ 24,320</u>

Depreciation expense for the years ended December 31, 2019 and 2018 was \$8.0 million and \$7.2 million, respectively.

## Note 6. Inventory

Inventory consisted of the following at December 31:

(In thousands)	2019	2018
Raw materials	\$ 180	\$ —
Work-in-process	6,808	788
Finished goods	343	81
Total Inventory	<u>\$ 7,331</u>	<u>\$ 869</u>

Inventory is related to our approved product, TIBSOVO®. There were no write downs for excess and obsolete inventory during the years ended December 31, 2019 or 2018.

## Note 7. Leases

Our building leases are comprised of office and laboratory space under non-cancelable operating leases. These lease agreements have remaining lease terms of eight 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 option is not reasonably certain of being exercised. The lease agreements do not contain residual value guarantees. Operating lease costs for the year ended December 31, 2019 were \$15.1 million, and cash paid for amounts included in the measurement of operating lease liabilities for the year ended December 31, 2019 was \$12.8 million.

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 commenced on May 1, 2019 and expires 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 continue as set forth in the existing leases for those buildings.

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

In arriving at the operating lease liabilities as of December 31, 2019, we applied the weighted-average incremental borrowing rate of 5.7% over a weighted-average remaining lease term of 8.2 years.

As of December 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)	
2020	\$ 13,242
2021	14,380
2022	16,773
2023	18,126
2024	18,660
Thereafter	63,891
Undiscounted minimum rental commitments	<u>145,072</u>
Interest	<u>(32,356)</u>
Total operating lease liabilities	<u>\$ 112,716</u>

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:

<u>(In thousands)</u>	
2019	\$12,759
2020	13,135
2021	13,473
2022	15,552
2023	17,145
Thereafter	19,223
<b>Total minimum rental commitments</b>	<b><u>\$91,287</u></b>

Rental expense under these leases, net of tenant improvement reimbursements, amounted to \$11.4 million for the year ended December 31, 2018. In addition to rent, the leases may require us to pay additional amounts for taxes, insurance, maintenance and other operating expenses.

We provided our landlord a standby letter of credit of \$2.9 million as security for our leases. We are not required to maintain any cash collateral for the standby letter of credit.

#### **Note 8. Accrued Expenses**

Accrued expenses and other current liabilities consisted of the following at December 31:

<u>(In thousands)</u>	<u>2019</u>	<u>2018</u>
Accrued compensation	\$18,982	\$20,843
Accrued research and development costs	21,777	14,777
Accrued professional fees	8,335	5,441
Accrued other	4,048	1,086
<b>Total accrued expenses</b>	<b><u>\$53,142</u></b>	<b><u>\$42,147</u></b>

#### **Note 9. Commitments and Contingent Liabilities**

##### *Manufacturing Commitments*

We are party to various agreements with contract manufacturing organizations that we are not contractually able to terminate for convenience and avoid any and all future obligations to the vendors. Under such agreements, we are obligated to make certain minimum payments, with the exact amounts in the event of termination to be based on the timing of the termination and the exact terms of the agreement.

##### *Legal Contingencies*

From time to time, we may be involved in disputes and legal proceedings in the ordinary course of business. These proceedings may include allegations of infringement of intellectual property, employment or other matters. We do not have any ongoing legal proceedings that, based on our estimates, could have a material effect on our consolidated financial statements.

#### **Note 10. Product Revenue**

Our wholly owned product, TIBSOVO®, received approval from the FDA on July 20, 2018 for the treatment of adult patients with R/R AML with a susceptible IDH1 mutation. Upon FDA approval of TIBSOVO® in the U.S., we began generating product revenue from U.S. sales of TIBSOVO®.

<u>(In thousands)</u>	<u>2019</u>	<u>2018</u>
Product revenue, net	<u>\$59,851</u>	<u>\$13,841</u>



The following table summarizes balances and activity in each of the product revenue allowance and reserve categories for the year ended December 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	7,899	2,387	1,464	11,750
Adjustments relating to prior years	8	(41)	—	(33)
Payments/returns relating to sales in the current year	(7,027)	(1,286)	—	(8,313)
Payments/returns relating to sales in the prior years	(598)	(261)	—	(859)
Balance at December 31, 2019	<u>\$ 874</u>	<u>\$ 1,124</u>	<u>\$ 1,798</u>	<u>\$ 3,796</u>

The following table summarizes balances and activity in each of the product revenue allowance and reserve categories for the year ended December 31, 2018:

(In thousands)	Contractual Adjustments	Government Rebates	Returns	Total
Balance at December 31, 2017	\$ —	\$ —	\$ —	\$ —
Current provisions relating to sales in the current year	1,777	422	334	2,533
Adjustments relating to prior years	—	—	—	—
Payments/returns relating to sales in the current year	(1,185)	(97)	—	(1,282)
Payments/returns relating to sales in the prior years	—	—	—	—
Balance at December 31, 2018	<u>\$ 592</u>	<u>\$ 325</u>	<u>\$ 334</u>	<u>\$ 1,251</u>

Total revenue-related reserves for the years ended December 31, 2019 and 2018 above, included in our consolidated balance sheets, are summarized as follows:

(In thousands)	December 31, 2019	December 31, 2018
Reduction of accounts receivable	\$ 540	\$ 326
Component of accrued expenses	3,256	925
Total revenue-related reserves	<u>\$ 3,796</u>	<u>\$ 1,251</u>

The following table presents changes in our contract assets and liabilities during the year ended December 31, 2019:

(In thousands)	December 31, 2018	Additions	Deductions	December 31, 2019
Contract assets				
Accounts receivable, net <sup>(1)</sup>	<u>\$ 5,076</u>	<u>\$ 71,542</u>	<u>\$ (67,666)</u>	<u>\$ 8,952</u>

(1) Additions to accounts receivable, net relate to amounts billed to Customers for product sales and deductions primarily relate to collection of receivables during the reporting period.

The following table presents changes in our contract assets and liabilities during the year ended December 31, 2018:

(In thousands)	December 31, 2017	Additions	Deductions	December 31, 2018
Contract assets				
Accounts receivable, net <sup>(1)</sup>	<u>\$ —</u>	<u>\$ 16,374</u>	<u>\$ (11,298)</u>	<u>\$ 5,076</u>

(1) Additions to accounts receivable, net relate to amounts billed to Customers for product sales and deductions primarily relate to collection of receivables during the reporting period.

## **Note 11. Collaboration and License 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 vorasidenib products. The AG-881 Agreements were terminated effective September 4, 2018. 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, 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, 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.

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 year ended December 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.

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, of the applicable licensed products.

### 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.

#### *Ivosidenib Letter Agreement*

On May 17, 2016, we entered into a letter agreement with Celgene regarding ivosidenib, or the Ivosidenib Letter Agreement. Under the Ivosidenib Letter Agreement, the parties agreed to terminate the 2010 Agreement, effective as of August 15, 2016, as to the program directed to the IDH1 target, for which 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 Ivosidenib Letter Agreement, we obtained global rights to ivosidenib and the IDH1 program. Neither party will have any further financial obligation, including royalties or milestone payments, to the other concerning ivosidenib or the IDH1 program. Under the terms of the Ivosidenib Letter Agreement, the parties also agreed to conduct specified transitional activities in connection with the termination. In addition, pursuant to the Ivosidenib Letter Agreement, the parties are released from their exclusivity obligations under the 2010 Agreement with respect to the IDH1 program. The Ivosidenib Letter Agreement does not affect the AG-881 Agreements, which were directed to both the IDH1 target and the IDH2 target, and were subsequently terminated in September 2018 as discussed below.

#### *Termination of AG-881 Agreements*

We and Celgene terminated the AG-881 Agreements, effective as of September 4, 2018. From and after September 4, 2018, we obtained sole global rights to vorasidenib. Neither we nor Celgene will have any further financial obligation under the AG-881 Agreements, including milestones, royalties or other payments, except that (a) Celgene is eligible to receive royalties from us at a low single-digit percentage rate on worldwide net sales of products containing vorasidenib and (b) we and Celgene agreed to split certain agreed-upon worldwide development costs for vorasidenib until December 31, 2018. In addition, for a specified period and subject to specified exceptions, Celgene and its affiliates are prohibited from developing, manufacturing or commercializing any product that inhibits IDH1 at specified levels of binding for any indication and we are prohibited from developing, manufacturing or commercializing vorasidenib in hematologic indications.

#### *2010 Agreement*

The 2010 Agreement, which was entered into in April 2010, 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 ivosidenib is the lead development candidate, the sole program remaining under the 2010 Agreement is IDHIFA<sup>®</sup>, 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<sup>®</sup> in accordance with the applicable commercialization plan. On August 1, 2017, the FDA granted Celgene approval of IDHIFA<sup>®</sup> for the treatment of adult patients with 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 \$80.0 million in potential milestone payments for the IDHIFA<sup>®</sup> 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, of which \$35.0 million relates to the first regulatory approval in any of China, Japan or a major European country, and (ii) a \$25.0 million milestone payment upon achievement of a specified commercial milestone event.

Under the 2010 Agreement, we receive royalties at tiered, low-double digit to mid-teen percentage rates on net sales of IDHIFA<sup>®</sup>.

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.

### **Collaboration revenue**

#### *Performance obligations identified*

Upon the adoption of ASC 606 on January 1, 2018, we applied the practical expedient that permits aggregating the effect of all contract 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 satisfied each performance obligation.

The transaction price is calculated as the total amount of consideration to which the Company expects to be entitled to in exchange of transferring the promised goods and services to Celgene, and excludes any amounts of variable consideration that have been constrained (being contingency based development, regulatory and sales based milestones for which the Company cannot assert it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the milestone is subsequently resolved). The transaction price upon the adoption of ASC 606 was comprised of all consideration received to date under the agreements, as well as the estimated amount of research and development cost reimbursements that will be received under the agreement.

The transaction price was subsequently allocated to the individual performance obligations based on their relative standalone selling prices. We developed 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 adoption of ASC 606, 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 were as follows:

<b>Performance Obligations</b>	<b>SSP</b>	<b>No. of Performance Obligations</b>	<b>Recognition Method</b>
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)	\$350.7 million	10	Fully satisfied; recognized upon adoption of ASC 606
Partially satisfied at time of adoption			
Research and development services (2)	\$266.6 million	6	Proportionally as services are delivered over the performance period, expected to be through September 2023 (3)

(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 performance obligations. 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 and using internal full time equivalent costs to support the development services.

(3)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.

### Remaining performance obligations

As of December 31, 2019, the remaining performance obligations under the Celgene agreements, 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 Remaining Performance Obligations	Recognition Method
Research and development services	\$175.4 million	2	Proportionally as services are delivered over the performance period

A significant portion of revenue generated from our collaboration agreements with Celgene relates to the provision of research and development services whereby revenue is recognized under an input method using the ratio of effort incurred to date compared to the total estimated effort required to complete the performance obligation. The calculation of the total estimated effort includes the total amount of forecasted costs associated with the completion of discovery, pre-clinical or clinical trials, as well as the assumed timing of these activities and estimated patient populations. Such cost estimates include forecasted direct labor and material costs, subcontractor costs, and external contract research organization costs.

As of December 31, 2019, the aggregate amount of the transaction price allocated to performance obligations that are partially unsatisfied was \$70.0 million. This amount is expected to be recognized as performance obligations are satisfied through September 2023.

### Revenue recognition

During the years ended December 31, we recognized the following collaboration revenue:

(In thousands)	2019	2018
<i>Services performed that were considered performance obligations upon the adoption of ASC 606</i>		
Licenses	\$ —	\$ 15,000
On-going research and development services	35,954	40,575
<i>Services performed that were not considered performance obligations as of the adoption of ASC 606</i>		
Development activities	—	1,342
Commercialization Activities	3,303	3,744
<b>Total collaboration revenue—related party</b>	<b>39,257</b>	<b>60,661</b>

The following table presents changes in our contract assets and liabilities during the year ended December 31, 2019:

(In thousands)	December 31, 2018	Additions	Deductions	December 31, 2019
<b>Contract assets</b>				
Collaboration receivable – related party (1)	\$ 2,462	\$ 8,253	\$ (9,176)	\$ 1,539
Royalty receivable – related party (2)	2,234	10,542	(9,876)	2,900
<b>Contract liabilities</b>				
Deferred revenue – related party, current and non-current portions (3)	92,519	4,948	(35,954)	61,513

(1) Additions to collaboration receivables—related party relate to amounts billed to Celgene for reimbursable costs incurred by us during the reporting period. Deductions to receivables relate to collection of receivables during the reporting period.

(2) Additions to receivables relate to amounts billed to Celgene during the reporting period. Deductions to receivables relate to collection of receivables during the reporting period.

(3) Additions to deferred revenue relate to consideration from Celgene during the reporting period. Deductions relate to deferred revenue recognized as revenue during the reporting period.

The following table presents changes in our contract assets and liabilities during the year ended December 31, 2018:

<u>(In thousands)</u>	<u>December 31, 2017</u>	<u>Additions</u>	<u>Deductions</u>	<u>December 31, 2018</u>
<b>Contract assets</b>				
Collaboration receivable – related party (1)	\$ 2,448	\$ 28,695	\$ (28,681)	\$ 2,462
Royalty receivable – related party (2)	1,222	7,087	(6,075)	2,234
<b>Contract liabilities</b>				
Deferred revenue – related party, current and non-current portions (3)	<u>163,640</u>	<u>9,237</u>	<u>(80,358)</u>	<u>92,519</u>

- (1) Additions to collaboration receivables—related party relate to amounts billed to Celgene for reimbursable costs incurred by us during the reporting period. Deductions to receivables relate to collection of receivables during the reporting period.
- (2) Additions to receivables relate to amounts billed to Celgene during the reporting period. Deductions to receivables relate to collection of receivables during the reporting period.
- (3) Additions to deferred revenue relate to consideration from Celgene during the reporting period. Deductions relate to deferred revenue recognized as revenue during the reporting period and the cumulative catch-up adjustment recognized upon adoption of ASC 606 on January 1, 2018.

During the years ended December 31, 2019 and 2018, we recognized the following as revenue due to changes in the contract liability balances:

<u>(In thousands)</u>	<u>2019</u>	<u>2018</u>
Amounts included in the contract liability at the beginning of the period	\$ 31,605	\$ 37,590
Performance obligations satisfied in previous periods	—	469

### ***Royalty revenue***

During the years ended December 31, 2019 and 2018, we recognized the following as royalty revenue:

<u>(In thousands)</u>	<u>2019</u>	<u>2018</u>
Royalty revenue – related party	\$ 10,542	\$ 7,215

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.

### ***Milestone revenue (variable consideration)***

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.

During the year ended December 31, 2019, we did not receive any milestone payments related to our Celgene Agreements, and all variable consideration relating to the remaining development, regulatory and sales-based milestones that can be earned under the terms of the agreement remain fully constrained.

During the year ended December 31, 2018, Celgene submitted an MAA to the EMA for IDHIFA® for IDH2 mutant-positive R/R AML. As a result of the filing, we determined that a \$15.0 million milestone payment for the filing of a first new drug application equivalent in an ex-U.S. country was considered probable of being reached and that a significant reversal of revenue would not occur in future periods. As the underlying performance obligation, or delivery of the license to IDHIFA®, had been satisfied as of June 2014, the milestone payment was recognized in full as collaboration revenue.

The next potential milestone expected to be achieved under our collaboration agreements with Celgene is the first regulatory approval in any of China, Japan or a major European country. Achievement of this event will result in a milestone payment of \$35.0 million under the 2010 Agreement.

### **CStone Pharmaceuticals**

In June 2018, we entered into an exclusive license agreement with CStone, 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. 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.

Under the terms of 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 \$407.0 million in milestone payments upon the achievement of certain development, regulatory and sales milestone events. Approximately one third of the milestone payments are related to development and regulatory milestones, half of which are related to ivosidenib in AML and cholangiocarcinoma and the other half are related to brain cancer indications, including glioma. We will also be entitled to receive tiered royalties, ranging from 15% to 19% percent, on annual net sales, if any, of ivosidenib.

CStone is responsible for all costs it incurs in developing, obtaining regulatory approval of, and commercializing ivosidenib in mainland China, Hong Kong, Macau, and Taiwan, as well as certain costs incurred by us.

During the term of the CStone Agreement, each party and its affiliates are prohibited from developing or commercializing any other compound or product that inhibits IDH1 mutations at specified levels of binding, in the case of CStone, anywhere in the world, and in our case, in mainland China, Hong Kong, Macau, and Taiwan.

#### *Termination*

Unless earlier terminated, the CStone Agreement will expire upon the expiration of the last royalty term for the last licensed product within the scope of the CStone Agreement. At any time after CStone has obtained regulatory approval in mainland China in R/R AML and the last patient has been enrolled in a specified clinical trial (or, if earlier, at any time that CStone acquires or is acquired by an entity with a competing or restricted product), CStone may terminate the CStone Agreement in its entirety by providing us with prior written notice. Either party may, subject to specified cure periods, terminate the CStone Agreement in the event of the other party's uncured material breach. Either party may terminate the CStone Agreement under specified circumstances relating to the other party's insolvency. We have the right to terminate the CStone Agreement immediately if CStone or its affiliates or sublicensees or subcontractors challenges the validity, patentability, or enforceability of certain patent rights that relate to ivosidenib and are owned by or licensed to us or our affiliates.

#### **Collaboration revenue**

##### *Performance obligations identified*

We developed assumptions that require judgment to determine the 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, discount rates and probabilities of technical and regulatory success.

The satisfied and unsatisfied performance obligations, 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:

<b>Performance Obligations</b>	<b>SSP</b>	<b>No. of Performance Obligation(s)</b>	<b>Recognition Method</b>
Licenses (1)	\$ 16.4 million	1	Fully satisfied; recognized upon delivery of license
Other services (2)	\$ 1.7 million	1	As services are delivered, expected to be through September 2021



- (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 costs 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 this performance obligation. 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.

As of December 31, 2019, the aggregate amount of the transaction price allocated to performance obligations that are partially unsatisfied was \$0.4 million. This amount is expected to be recognized as performance obligations are satisfied through September 2021.

#### Revenue recognition

During the years ended December 31, we recognized the following collaboration revenue:

<i>(In thousands)</i>	<b>2019</b>	<b>2018</b>
Services performed that were considered performance obligations upon contract inception		
Licenses	\$ 5,000	\$ 12,440
Other services	235	—
Services performed that were not considered performance obligations upon contract inception		
Other services	3,027	230
Total collaboration revenue—other	<u>\$ 8,262</u>	<u>\$ 12,670</u>

The following table presents changes in our contract assets during the year ended December 31, 2019:

<i>(In thousands)</i>	<b>December 31, 2018</b>	<b>Additions</b>	<b>Deductions</b>	<b>December 31 2019</b>
Contract assets				
Collaboration receivable – other (1)	\$ 670	\$ 8,262	\$ (7,004)	\$ 1,928

- (1) Additions to contract assets relate to receivables from CStone and deductions to contract assets relate to collection of receivables during the reporting period.

The following table presents changes in our contract assets during the year ended December 31, 2018:

<i>(In thousands)</i>	<b>December 31, 2017</b>	<b>Additions</b>	<b>Deductions</b>	<b>December 31 2018</b>
Contract assets				
Collaboration receivable – other (1)	\$ —	\$ 12,670	\$ (12,000)	\$ 670

- (1) Additions to contract assets relate to receivables from CStone and deductions to contract assets relate to collection of receivables during the reporting period.

#### 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 (variable consideration)

During the year ended December 31, 2019, upon the dosing of the first patient in a local study in a hematological indication in mainland China, we earned and received a milestone payment of \$5.0 million, which was recognized as collaboration revenue.

#### Aurigene Discovery Technologies Limited

In April 2017, we entered into a global license agreement with Aurigene Discovery Technologies Limited, or Aurigene, to research, develop and commercialize small molecule inhibitors for DHODH, or the Aurigene Agreement.

Under the terms of the Aurigene Agreement, Aurigene will provide us exclusive rights to its portfolio of novel small molecules for DHODH. Financial terms of the Aurigene Agreement include a \$3.0 million upfront payment and potential future milestone payments of up to \$15.0 million if we achieve certain development and regulatory milestones.

Aurigene is also eligible to receive low single-digit royalties on net product sales, if any. We will conduct preclinical studies and, if successful, fund further global research and development, as well as regulatory and commercial activities.

The term of the Aurigene Agreement will continue until the earlier of: (a) termination for convenience at our sole discretion upon 90 days prior written notice, (b) termination by either party for material breach, or (c) the expiration of the last-to-expire of all payment obligations hereunder with respect to all licensed products under the Aurigene Agreement.

#### **Initial payment**

The \$3.0 million upfront payment was incurred in the year ended December 31, 2017 and recorded as research and development expense. Costs incurred and milestone payments due to Aurigene prior to regulatory approval are recognized as expenses in the period incurred. Payments due to Aurigene upon or subsequent to regulatory approval will be capitalized and amortized over the shorter of the remaining license or product patent life.

#### **Milestone payments**

During the year ended December 31, 2019, we achieved the milestone relating to the initiation of the first phase 1 clinical trial for DHODH, and we made a payment of \$2.0 million.

#### **Note 12. Common Stock**

We are authorized to issue 125,000,000 shares of our common stock. Holders of common stock are entitled to one vote per share. Additionally, holders of common stock are entitled to receive dividends, if and when declared by our board of directors, and to share ratably in our assets legally available for distribution to our shareholders in the event of liquidation.

#### **Note 13. Share-Based Payments**

##### **Stock incentive plans**

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, and other stock-based awards to employees, non-employees and non-employee directors. 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 remain outstanding and effective. As of December 31, 2019, the total number of shares reserved under the 2007 Plan and the 2013 Plan are 9,356,754, and we had 2,127,478 shares available for future issuance under the 2013 Plan.

The 2013 Plan provides for an annual increase, to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2014 and continuing until the expiration of the 2013 Plan, equal to the lesser of (i) 2,000,000 shares of common stock, (ii) 4% of the outstanding shares of common stock on such date or (iii) an amount determined by our Board of Directors. On January 1, 2020, the annual increase for the 2013 Plan resulted in an additional 2,000,000 shares authorized for issuance.

##### **Stock options**

The following table summarizes the stock option activity of all stock incentive plans for the year ended December 31, 2019:

	Number of Stock Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2018	5,416,069	\$ 60.10	7.30	\$ 27,941
Granted	1,772,485	53.79		
Exercised	(283,200)	32.69		
Forfeited/Expired	(703,869)	68.36		
Outstanding at December 31, 2019	<u>6,201,485</u>	<u>\$ 58.61</u>	<u>7.09</u>	<u>\$ 28,528</u>
Exercisable at December 31, 2019	3,541,821	\$ 58.90	5.89	\$ 25,258
Vested and expected to vest at December 31, 2019	<u>6,201,485</u>	<u>\$ 58.61</u>	<u>7.09</u>	<u>\$ 28,528</u>

The weighted-average grant date fair value of options granted was \$36.44 and \$53.22 during the years ended December 31, 2019 and 2018, respectively. The total intrinsic value of options exercised was \$6.4 million and \$65.1 million during the years ended December 31, 2019 and 2018, respectively.

At December 31, 2019, the total unrecognized compensation expense related to unvested stock option awards was \$92.3 million, which we expect to recognize over a weighted-average period of approximately 2.54 years.

#### *Restricted stock units*

Upon vesting, each RSU entitles the holder to receive a specified number of shares of our common stock. The following table presents RSU activity for the year ended December 31, 2019:

	Number of Stock Units	Weighted-Average Grant Date Fair Value
Unvested shares at December 31, 2018	532,144	\$ 75.45
Granted	505,362	54.44
Vested	(166,740)	69.58
Forfeited	(103,813)	71.34
Unvested shares at December 31, 2019	<u>766,953</u>	<u>\$ 63.44</u>

As of December 31, 2019, there was approximately \$28.1 million of total unrecognized compensation expense related to RSUs, which we expect to be recognized over a weighted-average period of 1.71 years.

#### *Performance-based stock units*

At the achievement of the performance-based and service-based vesting criteria, each PSU entitles the holder to receive a specified number of shares of our common stock. The following table presents PSU activity for the year ended December 31, 2019:

	Number of Stock Units	Weighted-Average Grant Date Fair Value
Unvested shares at December 31, 2018	169,031	\$ 52.67
Granted	216,143	55.43
Vested	(167,031)	52.36
Forfeited	—	—
Unvested shares at December 31, 2019	<u>218,143</u>	<u>\$ 55.64</u>

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. As of December 31, 2019, there was approximately \$1.5 million of total unrecognized compensation expense related to PSUs with performance-based vesting criteria that are considered probable of achievement, which we expect to recognize over a weighted-average period of 0.33 years, and \$8.0 million of total unrecognized compensation expense related to PSUs with performance-based vesting criteria that are considered not probable of achievement.

#### *Market-based stock units*

The Company has issued certain equity awards that contain market based vesting conditions, in which shares of stock are earned at vesting based on stock price performance. The fair value of MSUs are estimated using a Monte Carlo simulation model. Assumptions and estimates utilized in the model include the risk-free interest rate, dividend yield, expected stock volatility and the estimated period to achievement of the market condition. The following table presents MSU activity for the year ended December 31, 2019:

	Number of Stock Units	Weighted-Average Grant Date Fair Value
Unvested shares at December 31, 2018	—	\$ —
Granted	42,695	41.50
Unvested shares at December 31, 2019	<u>42,695</u>	<u>\$ 41.50</u>

As of December 31, 2019, there was approximately \$0.8 million of total unrecognized compensation expense related to MSUs, which we expect to recognize over the remaining derived service period of 0.72 years.

### **2013 Employee Stock Purchase Plan**

In June 2013, our Board of Directors adopted, and in July 2013 our stockholders approved, the 2013 Employee Stock Purchase Plan, or the 2013 ESPP. We issued 77,981 shares and 53,255 shares during the years ended December 31, 2019 and 2018, respectively, under the 2013 ESPP. The 2013 ESPP provides participating employees with the opportunity to purchase up to an aggregate of 327,272 shares of our common stock. As of December 31, 2019, we had 82,555 shares available for future issuance under the 2013 ESPP. On January 1, 2020, the annual increase for the 2013 ESPP resulted in an additional 509,091 shares authorized for issuance.

### **Stock-based compensation expense**

During the years ended December 31, 2019 and 2018, we recorded stock-based compensation expense for employee and non-employee stock options, RSUs, PSUs, ESPP shares and other stock-based awards. Stock-based compensation expense by award type included within the consolidated statements of operations is as follows:

<u>(In thousands)</u>	<u>2019</u>	<u>2018</u>
Stock options	\$ 48,219	\$ 51,460
Restricted stock units	19,079	12,032
Performance-based stock units	2,647	8,717
Employee Stock Purchase Plan	1,437	1,148
Other stock awards	991	—
Total stock-based compensation expense	<u>\$ 72,373</u>	<u>\$ 73,357</u>

Expenses related to equity-based awards were allocated as follows in the consolidated statements of operations:

<u>(In thousands)</u>	<u>2019</u>	<u>2018</u>
Research and development expense	\$ 39,029	\$ 41,982
Selling, general and administrative expense	33,344	31,375
Total stock-based compensation expense	<u>\$ 72,373</u>	<u>\$ 73,357</u>

No related tax benefits were recognized for the years ended December 31, 2019 and 2018.

The fair value of each stock option granted to employees and nonemployees is estimated on the date of grant using the Black-Scholes option-pricing model. The following table summarizes the weighted average assumptions used in calculating the grant date fair value of the awards:

	<u>2019</u>	<u>2018</u>
Risk-free interest rate	2.32%	2.71%
Expected dividend yield	—	—
Expected term (in years)	6.06	6.06
Expected volatility	76.19%	76.62%

### **Expected term**

We use the “simplified method” as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share Based Payments*, to estimate the expected term of stock option grants. Under this approach, the weighted-average expected life is presumed to be the average of the contractual term of ten years and the weighted-average vesting term of the stock options, taking into consideration multiple vesting tranches. We utilize this method due to lack of historical data and the plain-vanilla nature of our share-based awards.

### **Volatility**

We use a weighted-average of expected volatility based on the volatilities of a representative group of publicly traded biopharmaceutical companies, including ourselves. The expected volatility has been determined using a weighted-average of the historical volatilities of the representative group of companies for a period equal to the expected term of the option grant.

**Risk-free rate**

The risk-free rate is based on the yield curve of U.S. Treasury securities with periods commensurate with the expected term of the options being valued.

**Dividends**

We have never paid, and do not anticipate paying, any cash dividends in the foreseeable future, and, therefore, use an expected dividend yield of zero in the option-pricing model.

**Forfeitures**

We account for forfeitures as they occur and, therefore, do not estimate forfeitures.

**Note 14. Income Taxes**

The domestic and foreign components of loss before income taxes are as follows:

<i>(In thousands)</i>	<b>2019</b>	<b>2018</b>
Domestic	\$(432,535)	\$(311,159)
Foreign	21,063	(34,869)
<b>Total</b>	<b><u>\$(411,472)</u></b>	<b><u>\$(346,028)</u></b>

We did not have any provision for income taxes for the years ended December 31, 2019 and 2018.

A reconciliation of the expected income tax benefit (expense) computed using the federal statutory income tax rate to our effective income tax rate is as follows for the years ended December 31, 2019 and 2018:

	<b>2019</b>	<b>2018</b>
Income tax benefit computed at federal statutory tax rate	21.0%	21.0%
State taxes, net of federal benefit	2.8%	0.8%
Change in valuation allowance	(27.2)%	(28.4)%
General business credits and other credits	5.0%	5.7%
Permanent differences and other adjustments	(1.3)%	(0.7)%
Incentive stock options	(0.6)%	2.2%
Foreign rate differential	0.3%	(0.6)%
<b>Total</b>	<b><u>—%</u></b>	<b><u>—%</u></b>

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets and liabilities for the years ended December 31, 2019 and 2018 are as follows:

(In thousands)	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	\$ 294,614	\$ 211,563
Deferred revenue	14,372	21,956
Tax credit carryforwards	141,219	120,605
Purchased intangible assets	14,479	3,204
Stock-based compensation	30,861	27,636
Operating lease liability	27,173	—
Deferred rent	—	4,458
Non-deductible accruals and reserves, including inventory	4,729	4,900
Total deferred tax assets	527,447	394,322
Depreciation and amortization	(2,613)	(3,569)
Operating lease right of use asset	(22,625)	—
Less: valuation allowance	(502,209)	(390,753)
Net deferred taxes	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2019, we had net operating loss carryforwards, or NOLs, available to reduce federal, state and foreign income taxes of approximately \$1,133.0 million, \$877.9 million and \$61.9 million, respectively. If not utilized, these NOLs begin to expire in 2033 (for pre-2018 NOLs), 2032 and 2023, respectively. Approximately \$669.6 million of federal NOLs can be carried forward indefinitely. At December 31, 2019, we also had available research and development tax credits for federal and state income tax purposes of approximately \$31.2 million and \$15.0 million, respectively. If not utilized, the credits begin to expire in 2027 and 2020 for federal and state income tax purposes, respectively. We engaged in clinical testing activities and incurred expenses that qualify for the federal orphan drug tax credit. At December 31, 2019, we had available orphan drug tax credits for federal purposes only of approximately \$98.1 million. If not utilized, the orphan drug credits begin to expire in 2035.

As provided by Section 382 of the Internal Revenue Code of 1986, or Section 382, and similar state provisions, utilization of NOLs and tax credit carryforwards may be subject to substantial annual limitations due to ownership change limitations that have previously occurred or that could occur in the future. Ownership changes may limit the amount of NOLs and tax credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions that increase the ownership of five percent stockholders in the stock of a corporation by more than 50 percent in the aggregate over a three year period. We completed a review of our changes in ownership through December 31, 2019 and determined that transactions have resulted in no ownership changes during the year ended December 31, 2019, as defined by Section 382. The impact of the historical ownership changes has been reflected in our deferred tax assets in the table above. There could be additional ownership changes after December 31, 2019 that could further limit the amount of NOLs and tax credit carryforwards that we can utilize.

As required by ASC 740, we have evaluated the positive and negative evidence bearing upon the realizability of our deferred tax assets. Based on the weight of available evidence, both positive and negative, we recorded a valuation allowance of \$502.2 million and \$390.8 million as of December 31, 2019 and December 31, 2018, respectively, because we have determined that it is more likely than not that these assets will not be fully realized. The valuation allowance increased by \$111.4 million and \$88.8 million for the years ended December 31, 2019 and, 2018, respectively.

In December 2019, the FASB issued Accounting Standards Update No. 2019-12 – *Income Taxes (Topic 740) Simplifying the Accounting for Income Taxes*, as part of its initiative to reduce complexity in the accounting standards. The amendments in ASU 2019-12 eliminate certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. ASU 2019-12 also clarifies and simplifies other aspects of the accounting for income taxes. The amendments in ASU 2019-12 are effective for the fiscal years beginning after December 15, 2020. Early adoption is permitted, including adoption in any interim period. The Company has early adopted this amendment as of January 1, 2019. There was no material impact to the Company's consolidated financial position, results of operation, or cash flows.

We apply the accounting guidance in ASC 740 related to accounting for uncertainty in income taxes. Our reserves related to taxes are based on a determination of whether, and how much of, a tax benefit taken by us in our tax filings or positions is more likely than not to be realized following resolution of any potential contingencies present related to the tax benefit.

The following table presents our unrecognized tax benefits activity for the years ended December 31, 2019 and 2018:

(In thousands)	2019	2018
Unrecognized tax benefits at the beginning of the year	\$ 14,288	\$ 11,263
Gross increases—current period tax positions	3,172	3,025
Unrecognized tax benefits at the end of the year	<u>\$ 17,460</u>	<u>\$ 14,288</u>

The uncertain tax position does not impact our effective income tax rate due to the full valuation allowance.

We are subject to taxation in the United States and Switzerland. The statute of limitations for assessment by the IRS and state tax authorities is open for tax years ending December 31, 2019, 2018, 2017, and 2016, although carryforward attributes that were generated for tax years prior to 2016 may still be adjusted upon examination by the IRS or state tax authorities if they either have been, or will be, used in a future period. The statute of limitations for assessment in Switzerland remains open for tax year ending December 31, 2019, 2018, 2017, and 2016. There are currently no federal, state or foreign audits in progress.

#### Note 15. Defined Contribution Benefit Plan

We sponsor a 401(k) retirement plan, in which substantially all of our full-time employees are eligible to participate. Participants may contribute a percentage of their annual compensation to this plan, subject to statutory limitations. We will make matching contributions equal to 100% of the employee's contributions, subject to a maximum of 4% of eligible compensation.

#### Note 16. Net Loss per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting the weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury stock method. For purposes of the dilutive net loss per share calculation, stock options, RSUs, PSUs and MSUs for which the performance and market vesting conditions, respectively, have been deemed probable, and 2013 ESPP shares are considered to be common stock equivalents, while PSUs and MSUs with performance and market vesting conditions, respectively, that were not deemed probable as of December 31, 2019 are not considered to be common stock equivalents.

Since we had a net loss for all periods presented, the effect of all potentially dilutive securities is anti-dilutive. Accordingly, basic and diluted net loss per share was the same for the years ended December 31, 2019 and 2018.

The following common stock equivalents were excluded from the calculation of diluted net loss per share applicable to common stockholders for the years ended December 31, 2019 and 2018 because including them would have had an anti-dilutive effect:

	2019	2018
Stock options	6,201,485	5,416,069
Restricted stock units	766,953	532,144
Performance-based stock units	72,046	169,031
Employee Stock Purchase Plan Shares	49,418	32,304
Total	<u>7,089,902</u>	<u>6,149,548</u>

**Note 17. Selected Quarterly Financial Data (Unaudited)**

The following table contains quarterly financial information for 2019 and 2018:

	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
<u>2019 (in thousands, except per share data)</u>				
Total revenue	\$ 30,227	\$ 26,221	\$ 26,024	\$ 35,440
Loss from operations	(97,483)	(113,861)	(109,060)	(105,929)
Net loss	(93,078)	(109,871)	(106,173)	(102,350)
Net loss per share – basic and diluted	(1.59)	(1.87)	(1.81)	(1.60)
<u>2018 (in thousands, except per share data)</u>				
Total revenue	\$ 8,762	\$ 40,414	\$ 15,198	\$ 30,013
Loss from operations	(94,012)	(72,949)	(99,162)	(96,356)
Net loss	(90,825)	(68,745)	(94,664)	(91,794)
Net loss per share – basic and diluted	(1.63)	(1.19)	(1.63)	(1.58)