Clovis Oncology, Inc.
Form 10-Q
November 01, 2018
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2018.

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

For the transition period from to .

Commission file number: 001-35347

Clovis Oncology, Inc.

(Exact name of Registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	90-0475355 (I.R.S. Employer Identification No.)
5500 Flatiron Parkway, Suite 100 Boulder, Colorado (Address of principal executive offices)	80301 (Zip Code)

(303) 625-5000

(Registrant's telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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

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

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

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

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

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

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of October 26, 2018 was 52,711,827.

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CLOVIS ONCOLOGY, INC.

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PART I. FINANCIAL INFORMATION

ITEM 1.FINANCIAL STATEMENTS

CLOVIS ONCOLOGY, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

(In thousands, except per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
	(in thousands, except per share amounts)		(in thousands, except per share amounts)	
Revenues:				
Product revenue	$ 22,757	$ 16,806	$ 65,037	$ 38,471
Operating expenses:				
Cost of sales - product	4,766	3,026	13,262	6,920
Cost of sales - intangible asset amortization	771	372	1,851	1,115
Research and development	63,887	38,924	160,138	104,479
Selling, general and administrative	42,495	35,011	126,634	100,384
Total expenses	111,919	77,333	301,885	212,898
Operating loss	(89,162)	(60,527)	(236,848)	(174,427)
Other income (expense):				
Interest expense	(3,376)	(2,618)	(9,592)	(7,796)
Foreign currency gain (loss)	151	(44)	(34)	(127)
Legal settlement loss	—	—	(7,975)	(117,000)
SEC settlement costs	—	—	(20,000)	—
Other income	2,536	1,291	5,419	2,237
Other expense, net	(689)	(1,371)	(32,182)	(122,686)
Loss before income taxes	(89,851)	(61,898)	(269,030)	(297,113)
Income tax (expense) benefit	(13)	1,234	280	2,599
Net loss	$ (89,864)	$ (60,664)	$ (268,750)	$ (294,514)
Other comprehensive income (loss):				
Foreign currency translation adjustments, net of tax	(495)	1,595	(2,448)	4,874
Net unrealized (loss) gain on available-for-sale securities, net of tax	(10)	10	71	5
Other comprehensive (loss) income:	(505)	1,605	(2,377)	4,879
Comprehensive loss	$ (90,369)	$ (59,059)	$ (271,127)	$ (289,635)

Loss per basic and diluted common share:				
Basic and diluted net loss per common share	$ (1.71)	$ (1.24)	$ (5.18)	$ (6.39)
Basic and diluted weighted average common shares outstanding	52,669	48,917	51,844	46,062

See accompanying Notes to Unaudited Consolidated Financial Statements.

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CLOVIS ONCOLOGY, INC.

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except for share amounts)

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 290,853	$ 464,198
Accounts receivable, net	14,495	6,181
Inventories	43,682	27,508
Available-for-sale securities	313,525	99,533
Prepaid research and development expenses	2,907	1,559
Deposit on inventory	13,514	20,461
Other current assets	11,780	7,500
Total current assets	690,756	626,940
Inventories	20,005	—
Deposit on inventory	31,119	—
Property and equipment, net	11,035	4,007
Intangible assets, net	52,709	19,561
Goodwill	63,074	65,217
Other assets	22,766	19,505
Total assets	$ 891,464	$ 735,230
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 30,501	$ 15,147
Accrued research and development expenses	21,259	18,465
Milestone liability	—	22,022
Other accrued expenses	24,732	25,883
Total current liabilities	76,492	81,517
Convertible senior notes	574,828	282,406
Deferred rent, long-term	6,478	3,671
Total liabilities	657,798	367,594
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Preferred stock, par value $0.001 per share; 10,000,000 shares authorized, no shares issued and outstanding at September 30, 2018 and December 31, 2017	—	—
Common stock, $0.001 par value per share, 100,000,000 shares authorized at September 30, 2018 and December 31, 2017; 52,708,767 and 50,565,119 shares issued and outstanding at September 30, 2018 and December 31, 2017 respectively	53	51

Additional paid-in capital	2,021,997	1,887,198
Accumulated other comprehensive loss	(44,550)	(42,173)
Accumulated deficit	(1,743,834)	(1,477,440)
Total stockholders' equity	233,666	367,636
Total liabilities and stockholders' equity	$ 891,464	$ 735,230

See accompanying Notes to Unaudited Consolidated Financial Statements.

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CLOVIS ONCOLOGY, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Nine months ended September 30,	
	2018	2017
Operating activities		
Net loss	$ (268,750)	$ (294,514)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	37,715	32,201
Depreciation and amortization	2,497	1,911
Amortization of premiums and discounts on available-for-sale securities	1,079	6
Amortization of debt issuance costs	1,536	956
Legal settlement loss	—	117,000
Deferred income taxes	—	(2,403)
Changes in operating assets and liabilities:		
Accounts receivable	(4,978)	121
Inventory	(25,540)	(5,345)
Prepaid and accrued research and development expenses	1,390	(16,284)
Deposit on inventory	(24,173)	(31,818)
Other operating assets	(7,507)	(4,156)
Accounts payable	4,765	5,050
Other accrued expenses	(1,304)	1,949
Net cash used in operating activities	(283,270)	(195,326)
Investing activities		
Purchases of property and equipment	(7,763)	(416)
Deposits for purchases of property and equipment	—	(2,515)
Purchases of available-for-sale securities	(320,000)	(180,000)
Sales of available-for-sale securities	105,000	213,500
Acquired in-process research and development - milestone payment	(55,000)	(1,100)
Net cash used in investing activities	(277,763)	29,469
Financing activities		
Proceeds from the sale of common stock, net of issuance costs	93,890	545,838
Proceeds from the issuance of convertible senior notes, net of issuance costs	290,887	—
Proceeds from the exercise of stock options and employee stock purchases	3,197	14,419
Net cash provided by financing activities	387,974	560,257
Effect of exchange rate changes on cash and cash equivalents	(286)	886
(Decrease) increase in cash and cash equivalents	(173,345)	395,286
Cash and cash equivalents at beginning of period	464,198	216,186
Cash and cash equivalents at end of period	$ 290,853	$ 611,472

Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 9,188	$ 7,188
Non-cash investing and financing activities:		
Vesting of restricted stock units	$ 10,130	$ 9,449

See accompanying Notes to Unaudited Consolidated Financial Statements.

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CLOVIS ONCOLOGY, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Basis of Presentation

Clovis Oncology, Inc. (together with its consolidated subsidiaries, the “Company”, “Clovis”, “we”, “our”, “us”) is a biopharmaceutical company focused on acquiring, developing and commercializing innovative anti-cancer agents in the United States, Europe and additional international markets. We target our development programs for the treatment of specific subsets of cancer populations, and simultaneously develop, with partners, diagnostic tools intended to direct a compound in development to the population that is most likely to benefit from its use. We have and intend to continue to license or acquire rights to oncology compounds in all stages of clinical development. In exchange for the right to develop and commercialize these compounds, we generally expect to provide the licensor with a combination of upfront payments, milestone payments and royalties on future sales. In addition, we generally expect to assume the responsibility for future drug development and commercialization costs. We currently operate in one segment. Since inception, our operations have consisted primarily of developing in-licensed compounds, evaluating new product acquisition candidates and general corporate activities and since 2016 we have also marketed and sold products.

Our marketed product Rubraca® (rucaparib) is approved in the United States by the Food and Drug Administration (“FDA”) for two indications, encompassing two settings for the treatment of recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer. The initial treatment indication received in December 2016 covers the treatment of adult patients with deleterious BRCA (human genes associated with the repair of damaged DNA) mutation (germline and/or somatic) epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies, and selected for therapy based on an FDA-approved companion diagnostic for Rubraca. In April 2018, the FDA also approved Rubraca for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. The FDA granted regular approval for Rubraca in this second, broader and earlier-line indication on a priority review timeline based on positive data from the phase 3 ARIEL3 clinical trial. Diagnostic testing is not required for patients to be prescribed Rubraca in this maintenance treatment indication.

In May 2018, the European Commission granted a conditional marketing authorization for Rubraca as monotherapy treatment of adult patients with platinum sensitive, relapsed or progressive, BRCA mutated (germline and/or somatic), high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have been treated with two or more prior lines of platinum based chemotherapy, and who are unable to tolerate further platinum based chemotherapy. As this is a conditional approval, it will be necessary to complete confirmatory post marketing commitments, including ensuring that sufficient partially platinum sensitive patients are enrolled in our ARIEL4 confirmatory trial to support the indication. This may require enrollment of additional patients into the study, increasing its overall size and extending the time for enrollment. In June 2018, we submitted to the European Union’s European Medicines Agency (“EMA”) a variation to the marketing authorization for the maintenance treatment of adult patients with recurrent

epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy, for which we received EMA validation for this application in July 2018. We anticipate an opinion on this application from the Committee for Medicinal Products for Human Use ("CHMP") of the EMA by the end of 2018, with a potential formal European Commission approval in early 2019.

Beyond our initial labeled indication, we have a robust Rubraca clinical development program underway in a variety of solid tumor types, also including prostate and bladder cancers, and in July 2017, we entered into a broad clinical collaboration with Bristol-Myers Squibb Company to evaluate the combination of their immunotherapy OPDIVO® (nivolumab) with Rubraca in several tumor types. We hold worldwide rights for Rubraca.

In October 2018, the FDA granted breakthrough therapy designation for Rubraca as a monotherapy treatment of adult patients with BRCA1/2-mutated metastatic castration resistant prostate cancer (mCRPC) who have received at least one prior androgen receptor (AR)-directed therapy and taxane-based chemotherapy.

In addition to Rubraca, we have two other product candidates.

Lucitanib is an oral, potent inhibitor of the tyrosine kinase activity of vascular endothelial growth factor receptors 1 through 3 (VEGFR1-3), platelet-derived growth factor receptors alpha and beta (PDGFR /) and fibroblast growth

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factor receptors 1 through 3 (FGFR1-3). Lucitanib was originally developed by Clovis and Servier with the hypothesis of activity in FGFR driven tumors; however, data in breast and lung cancer were insufficient to move that program forward. We received notice from Servier of termination of their rights to lucitanib, resulting in the return of global rights (excluding China) for lucitanib to us during October 2018. We believe that recent data for a drug similar to lucitanib that inhibits these same pathways – when combined with a PD-1 inhibitor – provide support for development of lucitanib in combination with a PD-(L)1 inhibitor, and we intend to initiate a study of the combination. We also intend to initiate a study of lucitanib in combination with Rubraca, based on encouraging data of VEGF and PARP inhibitors in combination. Each of these studies is expected to initiate in the first quarter of 2019. We maintain certain development and commercialization rights for lucitanib. Because of termination of the Servier license agreement, we have global development and commercialization rights (except for China) for lucitanib.

Rociletinib is an oral mutant-selective inhibitor of epidermal growth factor receptor (“EGFR”). While we have stopped enrollment in ongoing trials for rociletinib, we continue to provide drug to patients whose clinicians recommend continuing therapy. We have global development and commercialization rights for rociletinib.

Basis of Presentation

All financial information presented includes the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

The unaudited financial statements of Clovis Oncology, Inc. included herein reflect all adjustments that, in the opinion of management, are necessary to fairly state our financial position, results of operations and cash flows for the periods presented herein. Interim results may not be indicative of the results that may be expected for the full year. Certain information and footnote disclosures normally included in audited financial statements prepared in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”) have been condensed or omitted pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”). These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto which are included in our Annual Report on Form 10-K for the year ended December 31, 2017 (“2017 Form 10-K”) for a broader discussion of our business and the opportunities and risks inherent in such business.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and revenue and related disclosures. On an ongoing basis, we evaluate our estimates, including estimates related to revenue deductions, intangible asset impairment, clinical trial accruals and share-based compensation expense. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be reasonable under the

circumstances. Actual results may differ from those estimates or assumptions.

Liquidity

We have incurred significant net losses since inception and have relied on our ability to fund our operations through debt and equity financings. We expect operating losses and negative cash flows to continue for the foreseeable future. As we continue to incur losses, transition to profitability is dependent upon achieving a level of revenues from Rubraca adequate to support our cost structure. We may never achieve profitability, and unless or until we do, we will continue to need to raise additional cash.

In April 2018, we sold 1,837,898 shares of our common stock in a public offering at $54.41 per share. The net proceeds from the offering were $93.9 million, after deducting underwriting discounts and commissions and offering expenses. Concurrently, we completed the public offering of $300.0 million aggregate principal amount of 1.25% convertible senior notes due 2025. The net proceeds from this offering were $290.9 million, after deducting underwriting discounts and commissions and offering expenses. We intend to use the net proceeds of the offerings for general corporate purposes, including sales and marketing expenses associated with Rubraca in the United States and Europe, funding of our development programs, general and administrative expenses, acquisition or licensing of additional product candidates or businesses and working capital. Based on current estimates, we believe that our existing cash, cash equivalents and available-for-sale securities will allow us to fund our operating plan through at least the next 12 months.

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2. Summary of Significant Accounting Policies

Recently Adopted Accounting Standards

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU 2014-09, "Revenue from Contracts with Customers", and has subsequently issued several supplemental and/or clarifying ASUs (collectively, "ASC 606"). ASC 606 prescribes a single common revenue standard that replaces most existing U.S. GAAP revenue recognition guidance. ASC 606 is intended to provide a more consistent interpretation and application of the principles outlined in the standard across filers in multiple industries and within the same industries compared to current practices, which should improve comparability. We adopted the new standard using the modified retrospective method on January 1, 2018 for contracts that are not completed as of the adoption date.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs 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) the entity satisfies a performance obligation. ASC 606 also impacts certain other areas, such as the accounting for costs to obtain or fulfill a contract. The standard also requires disclosure of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers.

We examined our revenue recognition policy specific to revenue streams from contracts governing product sales from Rubraca and have come to conclusions on the impact of the new standard using the 5-step process prescribed by ASC 606. We reviewed all of our contracts, including our collaboration agreements with Servier and Bristol-Myers Squibb, and determined the potential impact to our accounting policies, financial controls and operations. Our conclusions include recognizing revenue on product sales once the product is sold to the specialty distributor and specialty pharmacy providers.

As noted above, we used the modified retrospective method to adopt the new standard. This means that we did not restate previously issued financial statements, but we recorded a one-time adjustment to retained earnings of $2.4 million. This adjustment represents the sales of our product to our customers prior to January 1, 2018, that had not been sold to patients or healthcare providers, offset by related gross-to-net adjustments and other direct costs, including royalties and sales incentive compensation.

The cumulative effect of the changes made to our consolidated January 1, 2018 balance sheet for the adoption of ASC 606 was as follows (in thousands):

	Balance at December 31, 2017	Adjustments due to Adoption of ASC 606	Balance at January 1, 2018
ASSETS			
Accounts receivable, net	$ 6,181	$ 3,336	$ 9,517
Inventories	$ 27,508	(62)	$ 27,446
Total assets	$ 735,230	$ 3,274	$ 738,504
LIABILITIES AND STOCKHOLDERS' EQUITY			
Other accrued expenses	$ 25,883	$ 918	$ 26,801
Accumulated deficit	$ (1,477,440)	2,356	$ (1,475,084)
Total liabilities and stockholders' equity	$ 735,230	$ 3,274	$ 738,504

Previously, we recognized revenue on product sales once the product was sold to the patient or healthcare provider by the specialty distributor or specialty pharmacy provider, i.e. when product is sold through the channel. Effective January 1, 2018, we began recognizing revenue when our customers, the specialty distributors and specialty pharmacy providers, take control of our product or when product is sold into the channel. This will have the impact of us recognizing revenue approximately two to four weeks earlier than before adopting the new standard and will also

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increase the significance of estimating variable consideration. The following financial statement line items for the three and nine months ended September 30, 2018 were affected as a result of the adoption.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except for per share amounts)

	Three months ended September 30, 2018		
	As reported	Balances without Adoption of ASC 606	Effect of Change Higher/(Lower)
Product revenue	$ 22,757	$ 25,213	$ (2,456)
Cost of sales - product	$ 4,766	$ 5,158	$ 392
Selling, general and administrative	$ 42,495	$ 42,689	$ 194
Net loss	$ (89,864)	$ (87,994)	$ (1,870)
Loss per basic and diluted common share:			
Basic and diluted net loss per common share	$ (1.71)	$ (1.67)	$ (0.04)

	Nine months ended September 30, 2018		
	As reported	Balances without Adoption of ASC 606	Effect of Change Higher/(Lower)
Product revenue	$ 65,037	$ 63,541	$ 1,496
Cost of sales - product	$ 13,262	$ 12,697	$ (565)
Selling, general and administrative	$ 126,634	$ 126,602	$ (32)
Net loss	$ (268,750)	$ (269,648)	$ 898
Loss per basic and diluted common share:			
Basic and diluted net loss per common share	$ (5.18)	$ (5.20)	$ 0.02

CONSOLIDATED BALANCE SHEET

(In thousands)

	September 30, 2018		
	As reported	Balances without Adoption of ASC 606	Effect of Change Higher/(Lower)
ASSETS			
Accounts receivable, net	$ 14,495	$ 12,907	$ 1,588
Inventories	$ 63,687	$ 63,992	$ (305)
LIABILITIES AND STOCKHOLDERS' EQUITY			
Other accrued expenses	$ 24,732	$ 24,347	$ 385
Accumulated deficit	$ (1,743,834)	$ (1,744,732)	$ 898

ASC 606 did not have an aggregate impact on our net cash provided by operating activities but resulted in offsetting changes in certain assets and liabilities presented within net cash used in operating activities in our consolidated statement of cash flows, as reflected in the above tables.

Recently Issued Accounting Standards

From time to time, the FASB or other standards setting bodies issue new accounting pronouncements. Updates to the FASB Accounting Standards Codification (“ASC”) are communicated through issuance of an ASU.

In February 2016, the FASB issued ASU 2016-02, “Leases (Topic 842)”, which requires lessees to recognize assets and liabilities for the rights and obligations created by most leases on their balance sheet. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. ASU

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2016-02 requires modified retrospective adoption for all leases existing at, or entered after, the date of initial application, with an option to use certain transition relief. We will adopt ASU 2016-02 as of January 1, 2019 using the effective date method which leaves the comparative period reporting unchanged. Comparative reporting periods are presented in accordance with Topic 840, while periods subsequent to the effective date are presented in accordance with Topic 842. We expect to recognize substantially all our leases on the balance sheet by recording a right-of-use asset and corresponding lease liability. We are currently evaluating the impact the standard may have on our consolidated financial statements and related disclosures.

In February 2018, the FASB issued ASU 2018-02, “Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income”, which allow a reclassification from accumulated other comprehensive income (loss) (“AOCI”) to retained earnings for stranded tax effects resulting from the change in the U.S. federal corporate income tax rate on the gross deferred tax amounts at the date of enactment of the Tax Cuts and Jobs Act of 2017 (the “2017 Tax Act”). The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. We will adopt ASU 2018-02 as of January 1, 2019. We are currently evaluating the impact the standard may have on our consolidated financial statements and related disclosures.

In June 2018, the FASB issued ASU 2018-07, “Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting”, simplifies the accounting for share-based payment granted to nonemployees for goods and services. Under the standard, most of the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. We will adopt ASU 2018-07 as of January 1, 2019. We do not expect significant impact on our consolidated financial statements and related disclosures since our accounting for share-based payments to employees and nonemployees is similar.

In August 2018, the FASB issued ASU 2018-13, “Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement”. The guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. We will adopt ASU 2018-02 as of January 1, 2020. We will evaluate the impact the standard may have on our consolidated financial statements and related disclosures as the adoption date approaches.

Revenue Recognition

We are currently approved to sell Rubraca in the United States market. We distribute our product principally through a limited number of specialty distributor and specialty pharmacy providers, collectively, our customers. Our customers subsequently sell our products to patients and health care providers. Separately, we have arrangements with certain payors and other third parties that provide for government-mandated and privately-negotiated rebates, chargebacks and discounts.

Product Revenue

Revenue from product sales are recognized when the performance obligation is satisfied, which is when customers obtain control of our product at a point in time, typically upon delivery. We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that we would have recognized is one year or less.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from rebates, chargebacks, discounts, co-pay assistance, estimated product returns and other allowances that are offered within contracts between us and our customers, health care providers, payors and other indirect customers relating to the sales of our product. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the customers) or a current liability (if the amount is payable to a party other than a customer). Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment

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patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration which is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we adjust these estimates, which would affect product revenue and earnings in the period such variances become known.

Rebates. Rebates include mandated discounts under the Medicaid Drug Rebate Program and the Medicare coverage gap program. Rebates are amounts owed after the final dispensing of products to a benefit plan participant and are based upon contractual agreements or legal requirements with the public-sector benefit providers. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses on the consolidated balance sheet. We estimate our Medicaid and Medicare rebates based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. The accrual for rebates is based on statutory discount rates and known sales to specialty pharmacy patients or expected utilization for specialty distributor sales to healthcare providers. As we gain more historical experience, the accrual will be based solely on the expected utilization from historical data we have accumulated since the Rubraca product launch. Rebates are generally invoiced and paid quarterly in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter’s activity, plus an accrual balance for known or estimated prior quarters’ unpaid rebates.

Chargebacks. Chargebacks are discounts that occur when contracted customers, which currently consist primarily of group purchasing organizations, Public Health Service organizations and federal government entities purchasing via the Federal Supply Schedule, purchase directly from our specialty distributors at a discounted price. The specialty distributor, in turn, charges back the difference between the price initially paid by the specialty distributor and the discounted price paid to the specialty distributor by the healthcare provider. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. The accrual for specialty distributor chargebacks is estimated based on known chargeback rates and known sales to specialty distributors adjusted for the estimated utilization by healthcare providers.

Discounts and Fees. Our payment terms are generally 30 days. Specialty distributors and specialty pharmacies are offered various forms of consideration, including service fees and prompt pay discounts for payment within a specified period. We expect these customers will earn prompt pay discounts and therefore, we deduct the full amount of these discounts and service fees from product sales when revenue is recognized.

Co-pay assistance. Patients who have commercial insurance and meet certain eligibility requirements may receive co-pay assistance. The intent of this program is to reduce the patient’s out of pocket costs. Liabilities for co-pay assistance are based on actual program participation provided by third-party administrators at month end.

Returns. Consistent with industry practice, we generally offer customers a right of return limited only to product that will expire in six months or product that is six months beyond the expiration date. To date, we have had minimal product returns and we currently do not have an accrual for product returns. We will continue to assess our estimate for product returns as we gain additional historical experience.

Cost of Sales – Product

Product cost of sales consists primarily of materials, third-party manufacturing costs as well as freight and royalties owed to our licensing partners for Rubraca sales.

Cost of Sales – Intangible Asset Amortization

Cost of sales for intangible asset amortization consists of the amortization of capitalized milestone payments made to our licensing partners upon FDA approval of Rubraca. Milestone payments are amortized on a straight-line basis over the estimated remaining patent life of Rubraca.

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Inventory

Inventories are stated at the lower of cost or estimated net realizable value, on a first-in, first-out ("FIFO") basis. We began capitalizing incurred inventory related costs upon the regulatory approval of Rubraca. Prior to the regulatory approval of Rubraca, we incurred costs for the manufacture of the drug that could potentially be available to support the commercial launch of Rubraca and all such costs were recognized as research and development expense. We periodically analyze our inventory levels, and write down inventory that has become obsolete, inventory that has a cost basis in excess of its estimated realizable value and/or inventory in excess of expected sales requirements as cost of product revenues. Expired inventory would be disposed of and the related costs would be written off as cost of product revenues.

The active pharmaceutical ingredient ("API") in Rubraca is currently produced by a single supplier. As the API has undergone significant manufacturing specific to its intended purpose at the point it is purchased by us, we classify the API as work-in-process inventory. Inventory used in clinical trials is expensed as research and development expense when it has been identified for such use.

Our other significant accounting policies are described in Note 2, Summary of Significant Accounting Policies of the Notes to the Consolidated Financial Statements included in our 2017 Form 10-K.

3. Financial Instruments and Fair Value Measurements

Fair value is defined as the exchange price that would be received to sell an asset or paid to transfer a liability (at exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

The three levels of inputs that may be used to measure fair value include:

Level 1: Quoted prices in active markets for identical assets or liabilities. Our Level 1 assets consist of money market investments. We do not have Level 1 liabilities.

Level 2: Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities in active markets or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Our Level 2 assets consist of U.S. treasury securities. We do not have Level 2 liabilities.

Level 3: Unobservable inputs that are supported by little or no market activity. We do not have Level 3 assets or liabilities that are measured at fair value on a recurring basis.

The following table identifies our assets and liabilities that were measured at fair value on a recurring basis (in thousands):

	Balance	Level 1	Level 2	Level 3
September 30, 2018				
Assets:				
Money market	$ 255,143	$ 255,143	$ —	$ —
U.S. treasury securities	313,525	—	313,525	—
Total assets at fair value	$ 568,668	$ 255,143	$ 313,525	$ —
December 31, 2017				
Assets:				
Money market	$ 433,136	$ 433,136	$ —	$ —
U.S. treasury securities	99,533	—	99,533	—
Total assets at fair value	$ 532,669	$ 433,136	$ 99,533	$ —

There were no transfers between the Level 1 and Level 2 categories or into or out of the Level 3 category during the three and nine months ended September 30, 2018.

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Financial instruments not recorded at fair value include our convertible senior notes. At September 30 2018, the carrying amount of the 2021 Notes was $283.4 million, which represents the aggregate principal amount net of remaining debt issuance costs, and the fair value was $268.2 million. At September 30 2018, the carrying amount of the 2025 Notes was $291.4 million, which represents the aggregate principal amount net of remaining debt issuance costs, and the fair value was $232.8 million. The fair value was determined using Level 2 inputs based on the indicative pricing published by certain investment banks or trading levels of these notes, which are not listed on any securities exchange or quoted on an inter-dealer automated quotation system. See Note 9, Convertible Senior Notes for discussion of the convertible senior notes.

4. Available-for-Sale Securities

As of September 30, 2018, available-for-sale securities consisted of the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value
U.S. treasury securities	$ 313,570	$ —	$ (45)	$ 313,525

As of December 31, 2017, available-for-sale securities consisted of the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value
U.S. treasury securities	$ 99,650	$ —	$ (117)	$ 99,533

As of September 30, 2018, our available-for-sale securities have been in a continuous loss position for less than 12 months. We have concluded that decline in the market value of the available-for-sale securities is temporary. A decline in the market value of a security below its cost that is deemed to be other than temporary is charged to earnings and results in the establishment of a new cost basis for the security. Factors evaluated to determine if an investment is other-than-temporarily impaired include significant deterioration in earnings performance, credit rating, asset quality or business prospects of the issuer; adverse changes in the general market conditions in which the issuer operates; and our intent and ability to hold the security until an anticipated recovery in value occurs.

As of September 30, 2018, the amortized cost and fair value of available-for-sale securities by contractual maturity were (in thousands):

	Amortized Cost	Fair Value
Due in one year or less	$ 313,570	$ 313,525
Due in one year to two years	—	—
Total	$ 313,570	$ 313,525

5. Inventories

The following table presents current and long-term inventories as of September 30, 2018 and December 31, 2017:

	September 30, 2018	December 31, 2017
Work-in-process	$ 51,707	$ 24,721
Finished goods	11,980	2,787
Total inventories	$ 63,687	$ 27,508

Some of the costs related to our finished goods on-hand as of September 30, 2018 were expensed as incurred prior to the commercialization of Rubraca on December 19, 2016.

At September 30, 2018, deposit on inventory on the Consolidated Balance Sheets is a cash deposit of $44.6 million made to a manufacturer for the purchase of work-in-process inventory which we expect to be converted to finished goods during the next twelve months and beyond.

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6. Other Current Assets

Other current assets were comprised of the following (in thousands):

	September 30, 2018	December 31, 2017
Prepaid insurance	$ 752	$ 1,926
Prepaid expenses - other	7,031	3,355
Receivable - other	3,741	2,023
Other	256	196
Total	$ 11,780	$ 7,500

7. Intangible Assets and Goodwill

Intangible assets related to capitalized milestones under license agreements consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Intangible asset - milestones	$ 56,100	$ 21,100
Accumulated amortization	(3,391)	(1,539)
Total intangible asset, net	$ 52,709	$ 19,561

The increase in our intangible asset – milestones since December 31, 2017 is due to a $15.0 million milestone payment to Pfizer related to the April 6, 2018 FDA approval of our sNDA for Rubraca as maintenance treatment and a $20.0 million milestone payment to Pfizer related to the European Commission approval of Rubraca in May 2018. See Note

12, License Agreements for further discussion of these approvals.

The estimated useful lives of these intangible assets are based on the estimated remaining patent life of Rubraca and extend through 2035.

We recorded amortization expense of $0.8 million and $1.9 million related to capitalized milestone payments during the three and nine months ended September 30, 2018, respectively. We recorded amortization expense of $0.4 million and $1.2 million related to capitalized milestone payments during the three and nine months ended September 30, 2017, respectively. Amortization expense is included in cost of sales – intangible asset amortization on the Consolidated Statements of Operations and Comprehensive Loss.

Estimated future amortization expense associated with intangibles is expected to be as follows (in thousands):

2018	$ 779
2019	3,116
2020	3,116
2021	3,116
2022	3,116
Thereafter	39,466
	$ 52,709

The change in goodwill established as part of the purchase accounting of EOS in November 2013 consisted of the following (in thousands):

Balance at December 31, 2017	$ 65,217
Change in foreign currency gains and losses	(2,143)
Balance at September 30, 2018	$ 63,074

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8. Other Accrued Expenses

Other accrued expenses were comprised of the following (in thousands):

	September 30, 2018	December 31, 2017
Accrued personnel costs	$ 14,217	$ 13,889
Accrued interest payable	—	2,096
Income tax payable	186	—
Accrued corporate legal fees and professional services	731	415
Accrued royalties	4,187	2,984
Accrued variable considerations	2,407	1,008
Payable to third party logistics provider	14	2,661
Accrued expenses - other	2,990	2,830
Total	$ 24,732	$ 25,883

9. Convertible Senior Notes

2021 Notes

On September 9, 2014, we completed a private placement of $287.5 million aggregate principal amount of 2.5% convertible senior notes due 2021 (the “2021 Notes”) resulting in net proceeds of $278.3 million after deducting offering expenses. In accordance with the accounting guidance, the conversion feature did not meet the criteria for bifurcation, and the entire principal amount was recorded as a long-term liability on the Consolidated Balance Sheets.

The 2021 Notes are governed by the terms of the indenture between the Company, as issuer, and The Bank of New York Mellon Trust Company, N.A., as trustee. The 2021 Notes are senior unsecured obligations and bear interest at a rate of 2.5% per year, payable semi-annually in arrears on March 15 and September 15 of each year. The 2021 Notes will mature on September 15, 2021, unless earlier converted, redeemed or repurchased.

Holders may convert all or any portion of the 2021 Notes at any time prior to the close of business on the business day immediately preceding the maturity date. Upon conversion, the holders will receive shares of our common stock at an initial conversion rate of 16.1616 shares per $1,000 in principal amount of 2021 Notes, equivalent to a conversion

price of approximately $61.88 per share. The conversion rate is subject to adjustment upon the occurrence of certain events described in the indenture. In addition, following certain corporate events that occur prior to the maturity date or upon our issuance of a notice of redemption, we will increase the conversion rate for holders who elect to convert the 2021 Notes in connection with such a corporate event or during the related redemption period in certain circumstances.

On or after September 15, 2018, we may redeem the 2021 Notes, at our option, in whole or in part, if the last reported sale price of our common stock has been at least 150% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending not more than two trading days preceding the date on which we provide written notice of redemption at a redemption price equal to 100% of the principal amount of the 2021 Notes to be redeemed plus accrued and unpaid interest to, but excluding, the redemption date. No sinking fund is provided for the 2021 Notes.

If we undergo a fundamental change, as defined in the indenture, prior to the maturity date of the 2021 Notes, holders may require us to repurchase for cash all or any portion of the 2021 Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2021 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The 2021 Notes rank senior in right of payment to any of our indebtedness that is expressly subordinated in right of payment to the 2021 Notes; equal in right of payment to all of our liabilities that are not so subordinated; effectively junior in right of payment to any secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all indebtedness and other liabilities (including trade payables) of our subsidiaries.

In connection with the issuance of the 2021 Notes, we incurred $9.2 million of debt issuance costs. The debt issuance costs are presented as a deduction from the convertible senior notes on the Consolidated Balance Sheets and are

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amortized as interest expense over the expected life of the 2021 Notes using the effective interest method. We determined the expected life of the debt was equal to the seven-year term of the 2021 Notes.

2025 Notes

On April 19, 2018, we completed an underwritten public offering of $300.0 million aggregate principal amount of 1.25% convertible senior notes due 2025 (the “2025 Notes”) resulting in net proceeds of $290.9 million, after deducting underwriting discounts and commissions and offering expenses. In accordance with the accounting guidance, the conversion feature did not meet the criteria for bifurcation, and the entire principal amount was recorded as a long-term liability on the Consolidated Balance Sheets.

The 2025 Notes are governed by the terms of the indenture between the Company, as issuer, and The Bank of New York Mellon Trust Company, N.A., as trustee, as supplemented by the terms of that certain first supplemental indenture thereto. The 2025 Notes are senior unsecured obligations and bear interest at a rate of 1.25% per year, payable semi-annually in arrears on May 1 and November 1 of each year. The 2025 Notes will mature on May 1, 2025, unless earlier converted, redeemed or repurchased.

Holders may convert all or any portion of the 2025 Notes at any time prior to the close of business on the business day immediately preceding the maturity date. Upon conversion, the holders will receive shares of our common stock at an initial conversion rate of 13.1278 shares per $1,000 in principal amount of 2025 Notes, equivalent to a conversion price of approximately $76.17 per share. The conversion rate is subject to adjustment upon the occurrence of certain events described in the indenture. In addition, following certain corporate events that occur prior to the maturity date or upon our issuance of a notice of redemption, we will increase the conversion rate for holders who elect to convert the 2025 Notes in connection with such a corporate event or during the related redemption period in certain circumstances.

On or after May 2, 2022, we may redeem the 2025 Notes, at our option, in whole or in part, if the last reported sale price of our common stock has been at least 150% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending not more than two trading days preceding the date on which we provide written notice of redemption at a redemption price equal to 100% of the principal amount of the 2025 Notes to be redeemed plus accrued and unpaid interest to, but excluding, the redemption date. No sinking fund is provided for the 2025 Notes.

If we undergo a fundamental change, as defined in the indenture, prior to the maturity date of the 2025 Notes, holders may require us to repurchase for cash all or any portion of the 2025 Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2025 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The 2025 Notes rank senior in right of payment to any of our indebtedness that is expressly subordinated in right of payment to the 2025 Notes; equal in right of payment to all of our liabilities that are not so subordinated, including the 2021 Notes; effectively junior in right of payment to any secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all indebtedness and other liabilities (including trade payables) of our subsidiaries.

In connection with the issuance of the 2025 Notes, we incurred $9.1 million of debt issuance costs. The debt issuance costs are presented as a deduction from the convertible senior notes on the Consolidated Balance Sheets and are amortized as interest expense over the expected life of the 2025 Notes using the effective interest method. We determined the expected life of the debt was equal to the seven-year term of the 2025 Notes.

As of September 30, 2018 and December 31, 2017, the balance of unamortized debt issuance costs was $12.7 million and $5.1 million, respectively.

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The following table sets forth total interest expense recognized during the three and nine months ended September 30, 2018 and 2017 (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Contractual interest expense	$ 2,735	$ 1,797	$ 7,078	$ 5,391
Accretion of interest on milestone liability	—	500	978	1,449
Amortization of debt issuance costs	641	321	1,536	956
Total interest expense	$ 3,376	$ 2,618	$ 9,592	$ 7,796

10. Stockholders' Equity

Common Stock

In April 2018, we sold 1,837,898 shares of our common stock in a public offering at $54.41 per share. The net proceeds from the offering were $93.9 million, after deducting underwriting discounts and commissions and offering expenses.

The holders of common stock are entitled to one vote per share on all matters to be voted upon by our stockholders. Subject to the preferences that may be applicable to any outstanding shares of preferred stock, the holders of common stock are entitled to receive ratably such dividends, if any, as may be declared by our Board of Directors.

Accumulated Other Comprehensive Loss

Accumulated other comprehensive loss consists of changes in foreign currency translation adjustments, which includes changes in a subsidiary's functional currency, and unrealized gains and losses on available-for-sale securities.

The changes in accumulated balances related to each component of other comprehensive income (loss) are summarized for the three months ended September 30, 2018 and 2017, as follows (in thousands):

	Foreign Currency Translation Adjustments		Unrealized (Losses) Gains		Total Accumulated Other Comprehensive Loss	
	2018	2017	2018	2017	2018	2017
Balance at July 1,	$ (43,870)	$ (44,155)	$ (175)	$ (151)	$ (44,045)	$ (44,306)
Other comprehensive income (loss)	(495)	2,510	(10)	15	(505)	2,525
Total before tax	(44,365)	(41,645)	(185)	(136)	(44,550)	(41,781)
Tax effect	—	(915)	—	(5)	—	(920)
Balance at September 30,	$ (44,365)	$ (42,560)	$ (185)	$ (141)	$ (44,550)	$ (42,701)

The changes in accumulated balances related to each component of other comprehensive income (loss) are summarized for the nine months ended September 30, 2018 and 2017, as follows (in thousands):

	Foreign Currency Translation Adjustments		Unrealized (Losses) Gains		Total Accumulated Other Comprehensive Loss	
	2018	2017	2018	2017	2018	2017
Balance at January 1,	$ (41,917)	$ (47,434)	$ (256)	$ (146)	$ (42,173)	$ (47,580)
Other comprehensive income (loss)	(2,448)	7,695	71	8	(2,377)	7,703
Total before tax	(44,365)	(39,739)	(185)	(138)	(44,550)	(39,877)
Tax effect	—	(2,821)	—	(3)	—	(2,824)
Balance at September 30,	$ (44,365)	$ (42,560)	$ (185)	$ (141)	$ (44,550)	$ (42,701)

The period change in each of the periods was primarily due to the currency translation of the goodwill and deferred income taxes associated with the acquisition of EOS in November 2013. There were no reclassifications out of accumulated other comprehensive loss in each of the three and nine months ended September 30, 2018 and 2017.

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11. Share-Based Compensation

Share-based compensation expense for all equity based programs, including stock options, restricted stock units and the employee stock purchase plan, for the three and nine months ended September 30, 2018 and 2017 was recognized in the accompanying Consolidated Statements of Operations as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Research and development	$ 5,038	$ 5,636	$ 15,380	$ 14,628
Selling, general and administrative	5,909	7,001	22,335	17,573
Total share-based compensation expense	$ 10,947	$ 12,637	$ 37,715	$ 32,201

We did not recognize a tax benefit related to share-based compensation expense during the three and nine months ended September 30, 2018 and 2017, respectively, as we maintain net operating loss carryforwards and have established a valuation allowance against the entire net deferred tax asset as of September 30, 2018.

Stock Options

The following table summarizes the activity relating to our options to purchase common stock for the nine months ended September 30, 2018:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (Thousands)
Outstanding at December 31, 2017	5,789,735	$ 46.77		
Granted	639,793	52.33		
Exercised	(70,480)	25.82		
Forfeited	(217,007)	60.47		
Outstanding at September 30, 2018	6,142,041	$ 47.11	6.6	$ 24,884
Vested and expected to vest at September 30, 2018	5,919,341	$ 47.00	6.5	