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

FORM 10-Q

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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	$ 24,555
Vested and exercisable at September 30, 2018	4,284,706	$ 45.70	5.8	$ 21,421

The aggregate intrinsic value in the table above represents the pretax intrinsic value, based on our closing stock price of $29.37 as of September 28, 2018, which would have been received by the option holders had all option holders with in-the-money options exercised their options as of that date.

The following table summarizes information about our stock options as of and for the three and nine months ended September 30, 2018 and 2017 (in thousands, except per share amounts):

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Weighted-average grant date fair value per share	$ 28.97	$ 60.81	$ 38.52	$ 48.39
Intrinsic value of options exercised	$ 325	$ 3,400	$ 1,697	$ 17,684
Cash received from stock option exercises	$ 604	$ 2,149	$ 1,820	$ 13,262

As of September 30, 2018, the unrecognized share-based compensation expense related to unvested options, adjusted for expected forfeitures, was $60.4 million and the estimated weighted-average remaining vesting period was 2.46 years.

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Restricted Stock

The following table summarizes the activity relating to our unvested restricted stock units ("RSUs") for the nine months ended September 30, 2018:

	Number of Units	Weighted Average Grant Date Fair Value
Unvested at December 31, 2017	589,529	$ 41.67
Granted	479,255	55.05
Vested	(199,602)	40.43
Forfeited	(44,686)	46.65
Unvested as of September 30, 2018	824,496	$ 49.48
Expected to vest after September 30, 2018	706,795	$ 49.25

As of September 30, 2018, the unrecognized share-based compensation expense related to unvested RSUs, adjusted for expected forfeitures, was $31.2 million and the estimated weighted-average remaining vesting period was 3.0 years.

12. License Agreements

Rucaparib

In June 2011, we entered into a worldwide license agreement with Pfizer, Inc. to obtain exclusive global rights to develop and commercialize rucaparib, a small molecule inhibitor of poly (ADP-ribose) polymerase ("PARP"), used for the treatment of selected solid tumors. The exclusive rights are exclusive even as to Pfizer and include the right to grant sublicenses. Pursuant to the terms of the license agreement, we made a $7.0 million upfront payment to Pfizer and are required to make additional payments to Pfizer for the achievement of certain development and regulatory and sales milestones and royalties on sales as required by the license agreement. Prior to the FDA approval of rucaparib, discussed below, we made milestone payments of $1.4 million, which were recognized as acquired in-process research and development expense.

On August 30, 2016, we entered into a first amendment to the worldwide license agreement with Pfizer, which amends the June 2011 existing worldwide license agreement to permit us to defer payment of the milestone payments

payable upon (i) FDA approval of an NDA for 1st Indication in US and (ii) EMA approval of an MAA for 1st Indication in EU, to a date that is 18 months after the date of achievement of such milestones.

On December 19, 2016, the FDA approved Rubraca (rucaparib) tablets as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies, and selected for therapy based on an FDA-approved companion diagnostic for Rubraca. The FDA approval resulted in a $0.75 million milestone payment to Pfizer as required by the license agreement, which was made in the first quarter of 2017. The FDA approval also resulted in the obligation to pay a $20.0 million milestone payment, for which we exercised the option to defer payment by agreeing to pay $23.0 million within 18 months after the date of the FDA approval. We paid the $23.0 million milestone payment in June 2018.

On April 6, 2018, the FDA approved our sNDA for Rubraca as 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. This approval resulted in the obligation to pay a $15.0 million milestone payment, which we paid in April 2018.

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. This approval resulted in the obligation to pay a $20.0 million milestone payment, which we paid in June 2018.

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These milestone payments were recognized as intangible assets and will be amortized over the estimated remaining useful life of Rubraca.

We are obligated under the license agreement to use commercially reasonable efforts to develop and commercialize rucaparib and we are responsible for all remaining development and commercialization costs for rucaparib. We are required to make regulatory milestone payments to Pfizer of up to an additional $31.75 million in aggregate if specified clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, we are obligated to make sales milestone payments to Pfizer if specified annual sales targets for rucaparib are met, which relate to annual sales targets of $250.0 million and above, which, in the aggregate, could amount to total milestone payments of $170.0 million, and tiered royalty payments at a mid-teen percentage rate on our net sales, with standard provisions for royalty offsets to the extent we need to obtain any rights from third parties to commercialize rucaparib.

In April 2012, we entered into a license agreement with AstraZeneca UK Limited to acquire exclusive rights associated with rucaparib under a family of patents and patent applications that claim methods of treating patients with PARP inhibitors in certain indications. The license enables the development and commercialization of rucaparib for the uses claimed by these patents. AstraZeneca receives royalties on any net sales of rucaparib.

Lucitanib

In connection with our acquisition of EOS in November 2013, we gained rights to develop and commercialize lucitanib, an oral, selective tyrosine kinase inhibitor. As further described below, EOS licensed the worldwide rights, excluding China, to develop and commercialize lucitanib from Advenchen Laboratories LLC (“Advenchen”). Subsequently, rights to develop and commercialize lucitanib in markets outside the U.S. and Japan were sublicensed by EOS to Servier in exchange for upfront milestone fees, royalties on sales of lucitanib in the sublicensed territories and research and development funding commitments.

In October 2008, EOS entered into an exclusive license agreement with Advenchen to develop and commercialize lucitanib on a global basis, excluding China. We are obligated to pay Advenchen tiered royalties at percentage rates in the mid-single digits on net sales of lucitanib, based on the volume of annual net sales achieved. In addition, after giving effect to the first and second amendments to the license agreement, we are required to pay to Advenchen 25% of any consideration, excluding royalties, received pursuant to any sublicense agreements for lucitanib, including the agreement with Servier. We are obligated under the agreement to use commercially reasonable efforts to develop and commercialize at least one product candidate containing lucitanib, and we are also responsible for all remaining development and commercialization costs for lucitanib.

The license agreement with Advenchen will remain in effect until the expiration of all our royalty obligations to Advenchen, determined on a product-by-product and country-by-country basis, unless we elect to terminate the

agreement earlier. If we fail to meet our obligations under the agreement and are unable to cure such failure within specified time periods, Advenchen can terminate the agreement, resulting in a loss of our rights to lucitanib.

During 2017, we completed the committed on-going development activities related to lucitanib and received full reimbursement of our development costs from Servier. Reimbursements are recorded as a reduction to research and development expense on the Consolidated Statements of Operations. 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 the 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 are party to a product license agreement for our other drug candidate rociletinib (see our 2017 Form 10-K for additional details).

13. Net Loss Per Common Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common share equivalents outstanding using the treasury-stock method for the stock options and RSUs and the if-converted method for the 2021 Notes and 2025 Notes. As a result of our net losses for the periods presented, all

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potentially dilutive common share equivalents were considered anti-dilutive and were excluded from the computation of diluted net loss per share.

The shares outstanding at the end of the respective periods presented in the table below were excluded from the calculation of diluted net loss per share due to their anti-dilutive effect (in thousands):

	Three and Nine months ended September 30,	
	2018	2017
Common shares under option	3,381	5,696
Convertible senior notes	8,584	4,646
Total potential dilutive shares	11,965	10,342

14. Commitments and Contingencies

Royalty and License Fee Commitments

We have entered into certain license agreements, as identified in Note 12, License Agreements, with third parties that include the payment of development and regulatory milestones, as well as royalty payments, upon the achievement of pre-established development, regulatory and commercial targets. Our payment obligation related to these license agreements is contingent upon the successful development, regulatory approval and commercialization of the licensed products. Due to the nature of these arrangements, the future potential payments are inherently uncertain, and accordingly, we only recognize payment obligations which are probable and estimable as of the balance sheet date. Milestone liabilities of $0.0 million and $22.0 million are recorded on our Consolidated Balance Sheets at September 30, 2018 and December 31, 2017, respectively, and relate to milestone payments for the licensing of our rucaparib product, which was approved by the FDA on December 19, 2016.

Manufacture and Services Agreement Commitments

On October 3, 2016, we entered into a Manufacturing and Services Agreement (the “Agreement”) with a non-exclusive third-party supplier for the production of the active ingredient for Rubraca. Under the terms of the Agreement, we will provide the third-party supplier a rolling forecast for the supply of the active ingredient in Rubraca that will be

updated by us on a quarterly basis. We are obligated to order material sufficient to satisfy an initial quantity specified in any forecast. In addition, the third-party supplier will construct, in its existing facility, a production train that will be exclusively dedicated to the manufacture of the Rubraca active ingredient. We are obligated to make scheduled capital program fee payments toward capital equipment and other costs associated with the construction of the dedicated production train. Further, once the facility is operational, we are obligated to pay a fixed facility fee each quarter for the duration of the Agreement, which expires on December 31, 2025, unless extended by mutual consent of the parties. As of September 30, 2018, $165.1 million of purchase commitments exist under the Agreement.

Legal Proceedings

We and certain of our officers were named as defendants in several lawsuits, as described below. We cannot reasonably predict the outcome of these legal proceedings, nor can we estimate the amount of loss or range of loss, if any, that may result. An adverse outcome in these proceedings could have a material adverse effect on our results of operations, cash flows or financial condition.

Rociletinib-Related Litigation

Following Clovis' regulatory announcement in November 2015 of adverse developments in its ongoing clinical trials for rociletinib, Clovis and certain of its current and former executives were named in various securities lawsuits, the largest of which was a putative class action lawsuit in the District of Colorado (the "Medina Action") which was settled on October 26, 2017 (the "Medina Settlement"). The open actions currently pending against Clovis are discussed below.

On November 10, 2016, Antipodean Domestic Partners ("Antipodean") filed a complaint (the "Antipodean Complaint") against Clovis and certain of its officers, directors and underwriters in New York Supreme Court, County of New York. The Antipodean Complaint alleges that the defendants violated certain sections of the Securities Act by

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making allegedly false statements to Antipodean and in the offering materials for the July 2015 Offering relating to the efficacy of rociletinib, its safety profile, and its prospects for market success. In addition to the Securities Act claims, the Antipodean Complaint also asserts Colorado state law claims and common law claims. Both the state law and common law claims are based on allegedly false and misleading statements regarding rociletinib's progress toward FDA approval. The Antipodean Complaint seeks compensatory, recessionary, and punitive damages. On December 15, 2016, the Antipodean Plaintiffs filed an amended complaint (the "Antipodean Amended Complaint") asserting substantially the same claims against the same defendants and purporting to correct certain details in the original Antipodean Complaint.

Following a stay that Justice Masley of the New York Supreme Court, County of New York entered in favor of the Medina Action and briefing on defendants' motions to dismiss, the parties participated in a Preliminary Conference on April 17, 2018, following which the Court entered a preliminary conference order, providing deadlines for document productions, depositions, and other discovery. The Court has scheduled a status conference for January 21, 2019, following which the Court anticipates setting an end date for discovery.

On May 2, 2018, the Court issued an order denying the defendants' motion to dismiss. Defendants filed an answer to the Antipodean Amended Complaint on June 6, 2018.

The Company intends to vigorously defend against the allegations in the Antipodean Amended Complaint. However, there can be no assurance that the defense will be successful.

In March 2017, two putative shareholders of the Company, Macalinao and McKenry (the "Derivative Plaintiffs"), filed shareholder derivative complaints against certain directors and officers of the Company in the Court of Chancery of the State of Delaware. On May 4, 2017, the Macalinao and McKenry actions were consolidated for all purposes in a single proceeding under the caption In re Clovis Oncology, Inc. Derivative Litigation, Case No, 2017-0222 (the "Consolidated Derivative Action").

On May 18, 2017, the Derivative Plaintiffs filed a Consolidated Verified Shareholder Derivative Complaint (the "Consolidated Derivative Complaint"). The Consolidated Derivative Complaint generally alleged that the defendants breached their fiduciary duties owed to the Company by allegedly causing or allowing misrepresentations of the Company's business operations and prospects, failing to ensure that the TIGER-X clinical trial was being conducted in accordance with applicable rules, regulations and protocols, and engaging in insider trading. The Consolidated Derivative Complaint purported to rely on documents produced by the Company in response to prior demands for inspection of the Company's books and records served on the Company by each of Macalinao and McKenry under 8 Del. C. § 220. The Consolidated Derivative Complaint sought, among other things, an award of money damages.

On July 31, 2017, the defendants filed a motion to dismiss the Consolidated Derivative Complaint. Plaintiffs filed an opposition to the motion to dismiss on August 31, 2017, and the defendants filed a reply in further support of the motion to dismiss on September 26, 2017. Oral argument on the defendants' motion to dismiss the Consolidated Derivative Complaint has been scheduled for February 4, 2019.

The Company intends to vigorously defend against the allegations in the Consolidated Derivative Complaint, but there can be no assurance that the defense will be successful.

On March 20, 2017, a purported shareholder of the Company, filed a shareholder derivative complaint (the "Guo Complaint") against certain officers and directors of the Company in the United States District Court for the District of Colorado. The Guo Complaint generally alleged that the defendants breached their fiduciary duties owed to the Company by either recklessly or with gross negligence approving or permitting misrepresentations of the Company's business operations and prospects. The Guo Complaint also alleged claims for waste of corporate assets and unjust enrichment. Finally, the Guo Complaint alleged that certain of the individual defendants violated Section 14(a) of the Securities Exchange Act, by allegedly negligently issuing, causing to be issued, and participating in the issuance of materially misleading statements to stockholders in the Company's Proxy Statement on Schedule DEF 14A in connection with the 2015 Annual Meeting of Stockholders, held on June 11, 2015. The Guo Complaint sought, among other things, an award of money damages.

On June 19, 2017, the parties filed a joint motion to stay the Guo action pending resolution of the motion to dismiss the Consolidated Derivative Complaint. On June 20, 2017, the court granted the motion to stay.

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The Company intends to vigorously defend against the allegations in the Guo Complaint, but there can be no assurance that the defense will be successful.

As previously disclosed, the Company has received inquiries and requests for information from governmental agencies, including the U.S. Securities and Exchange Commission ("SEC") and the U.S. Department of Justice, relating to the Company's regulatory update announcement in November 2015 that the FDA requested additional clinical data on the efficacy and safety of rociletinib.

Earlier this year, the Company and Mr. Mahaffy engaged in discussions with the SEC staff to resolve this matter. On September 18, 2018, the SEC announced it had reached an agreement with the Company to settle this matter on negligence-based charges. Pursuant to the settlement, without admitting or denying the SEC's allegations, the Company paid a $20.0 million civil penalty, which the Company reserved as a loss contingency on its consolidated balance sheet as of June 30, 2018, and stipulated to a standard injunction against future violations of those provisions of the federal securities laws. Also, on September 18, 2018, the SEC announced that Mr. Mahaffy also reached a settlement with the SEC on similar negligence-based allegations, to which he neither admits nor denies, and paid a civil penalty and will be similarly enjoined. Mr. Mahaffy will continue to serve as the Company's Chief Executive Officer and as a member of the Company's Board of Directors.

The settlements do not allege that the Company or any of its current or former officers engaged in any intentional fraud or misconduct. The settlements were approved by the United States District Court for the District of Colorado on September 19, 2018 and resolve the SEC's nearly three year investigation into the regulatory approval process of rociletinib.

European Patent Opposition

Two oppositions were filed in the granted European counterpart of the rucaparib camsylate salt/polymorph patent on June 20, 2017. The grounds of opposition related to Rubraca were lack of novelty and lack of inventive step. A preliminary opinion and summons to oral proceedings were issued on April 4, 2018. The oral hearing is scheduled for December 4, 2018. The preliminary opinion provides a non-binding indication of the tribunal's view. In the preliminary opinion, the tribunal agreed with some of our positions and agreed with certain objections made by the opponents. As part of the proceeding, we have the opportunity to submit further arguments and pursue alternative claims in the form of auxiliary requests. On October 3, 2018, we submitted further arguments and auxiliary requests and on October 4, 2018, both opponents submitted further arguments. While the ultimate results of patent challenges can be difficult to predict, we believe a number of factors, including a constellation of unexpected properties, support the novelty and non-obviousness of our rucaparib camsylate salt/polymorph composition of matter patent.

ITEM 2.MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward-Looking Information

This Quarterly Report on Form 10-Q and the information incorporated herein by reference includes statements that are, or may be deemed, "forward-looking statements." In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereo comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Quarterly Report on Form 10-Q and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned non-clinical studies and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change and depend on the economic circumstances that may or may not occur in the

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future or may occur on longer or shorter timelines than anticipated. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity and the development of the industry in which we operate may differ materially from the forward-looking statements contained herein.

Any forward-looking statements that we make in this Quarterly Report on Form 10-Q speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect the occurrence of unanticipated events.

You should also read carefully the factors described in the "Risk Factors" in Part I, Item 1A in our most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC"), as updated from time to time in our subsequent SEC filings, to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements.

Overview

We are 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.

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 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 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 June 2011, we obtained an exclusive, worldwide license from Pfizer to develop and commercialize rucaparib. U.S. Patent 6,495,541, and its equivalent counterparts issued in dozens of countries, directed to the rucaparib

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composition of matter, expire in 2020 and are potentially eligible for up to five years patent term extension in various jurisdictions. We believe that patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") could be available to extend our patent exclusivity for rucaparib to the fourth quarter of 2023 in the United States. In Europe, we believe that patent term extension under a supplementary protection certificate could be available for an additional five years for one European patent directed to Rubraca. In April 2012, we obtained an exclusive license from AstraZeneca under a family of patents and patent applications which will permit the development and commercialization of rucaparib for certain methods of treating patients with PARP inhibitors. Additionally, other patents and patent applications are directed to methods of making, methods of using, dosing regimens, various salt and polymorphic forms and formulations and have expiration dates ranging from 2020 through potentially 2035, including the camsylate salt/polymorph patent family licensed from Pfizer, which expires in 2031 and a patent family directed to high dosage strength rucaparib tablets that expires in 2035. As of May 3, 2018, the rucaparib camsylate salt/polymorph patent was issued in 47 countries to date (including US and Europe), with applications pending in 9 countries, and the rucaparib composition of matter patent was issued in 48 countries. We are aware of a number of challenges of salt and polymorph patents. Two oppositions were filed in the granted European counterpart of the rucaparib camsylate salt/polymorph patent on June 20, 2017. European oppositions are commonly filed against patents related to pharmaceutical products. The grounds of opposition related to Rubraca were lack of novelty and lack of inventive step. The novelty and inventive step challenges are based on prior art references (or closely related disclosures) that were previously raised by the European patent examiner during prosecution of the application. The claims of the granted patent were found to be patentable over this prior art. A preliminary opinion and summons to oral proceedings were issued on April 4, 2018. The oral hearing is scheduled for December 4, 2018. The preliminary opinion provides a non-binding indication of the tribunal's view. In the preliminary opinion, the tribunal agreed with some of our positions and agreed with certain objections made by the opponents. As part of the proceeding, we have the opportunity to submit further argument and pursue alternative claims in the form of auxiliary requests. On October 3, 2018, we submitted further arguments and auxiliary requests and on October 4, 2018, both opponents submitted further arguments. While the ultimate results of patent challenges can be difficult to predict, we believe a number of factors, including a constellation of unexpected properties, support the novelty and non-obviousness of our rucaparib camsylate salt/polymorph composition of matter patent. We believe a successful challenge of all claims relevant to Rubraca would be difficult. Our high dosage strength rucaparib tablets patent issued in the United States on June 5, 2018, with claims that cover the commercial Rubraca product, including all commercial dosage strengths expires in 2035. Additionally, in Europe, regulatory exclusivity is available for ten years, plus one year for a new indication, therefore, we have regulatory exclusivity for Rubraca in Europe until 2028, and if an additional indication is approved, until 2029.

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 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.

We commenced operations in April 2009. To date, we have devoted substantially all of our resources to identifying and in-licensing product candidates, performing development activities with respect to those product candidates and the general and administrative support of these operations. Through September 30, 2018, we have generated $13.6 million in license and milestone revenue related to our collaboration and license agreement with Servier and for the nine months ended September 30, 2018 and 2017 have generated $65.0 million and $38.5 million, respectively, product revenue related to sales of Rubraca, which we began to commercialize on December 19, 2016. We

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have principally funded our operations using the net proceeds from the sale of convertible preferred stock, the issuance of convertible promissory notes, public offerings of our common stock and our convertible senior notes offering.

We have never been profitable and, as of September 30, 2018, we had an accumulated deficit of $1,743.8 million. We incurred net losses of $268.8 million and $294.5 million for the nine months ended September 30, 2018 and 2017, respectively. We had cash, cash equivalents and available-for-sale securities totaling $604.4 million at September 30, 2018.

We expect to incur significant losses for the foreseeable future, as we incur costs related to commercial activities associated with Rubraca. 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, selling, 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. Until we can generate a sufficient amount of revenue from Rubraca, we expect to finance our operations in part through additional public or private equity or debt offerings and may seek additional capital through arrangements with strategic partners or from other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

On October 29, 2018, we announced that Corwin Dale Hooks, our Senior Vice President and Chief Commercial Officer, has resigned effective as of October 29, 2018. In connection with his termination of employment, Mr. Hooks will receive the severance payments and benefits set out in Section 8(d) of his employment agreement, except that Mr. Hooks will receive his severance in one lump sum payment and will receive a payment that equals the anticipated COBRA premiums for himself and his dependents for a period of 18, rather than six, months, also in one lump sum payment.

Product License Agreements

Rucaparib

In June 2011, we entered into a worldwide license agreement with Pfizer, Inc. to obtain exclusive global rights to develop and commercialize rucaparib, a small molecule inhibitor of poly (ADP-ribose) polymerase ("PARP"), used for the treatment of selected solid tumors. The exclusive rights are exclusive even as to Pfizer and include the right to grant sublicenses. Pursuant to the terms of the license agreement, we made a $7.0 million upfront payment to Pfizer and are required to make additional payments to Pfizer for the achievement of certain development and regulatory and sales milestones and royalties on sales as required by the license agreement. Prior to the FDA approval of rucaparib, discussed below, we made milestone payments of $1.4 million, which were recognized as acquired in-process research and development expense.

On August 30, 2016, we entered into a first amendment to the worldwide license agreement with Pfizer, which amends the June 2011 existing worldwide license agreement to permit us to defer payment of the milestone payments payable upon (i) FDA approval of an NDA for 1st Indication in US and (ii) EMA approval of an MAA for 1st Indication in EU, to a date that is 18 months after the date of achievement of such milestones.

On December 19, 2016, the FDA approved Rubraca (rucaparib) tablets as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies, and selected for therapy based on an FDA-approved companion diagnostic for Rubraca. The FDA approval resulted in a $0.75 million milestone payment to Pfizer as required by the license agreement, which was made in the first quarter of 2017. The FDA approval also resulted in the obligation to pay a $20.0 million milestone payment, for which we exercised the option to defer payment by agreeing to pay $23.0 million within 18 months after the date of the FDA approval. We paid the $23.0 million milestone payment in June 2018.

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On April 6, 2018, the FDA approved our sNDA for Rubraca as 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. This approval resulted in the obligation to pay a $15.0 million milestone payment, which we paid in April 2018.

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. This approval resulted in the obligation to pay a $20.0 million milestone payment, which we paid in June 2018.

These milestone payments were recognized as intangible assets and will be amortized over the estimated remaining useful life of Rubraca.

We are obligated under the license agreement to use commercially reasonable efforts to develop and commercialize rucaparib and we are responsible for all remaining development and commercialization costs for rucaparib. We are required to make regulatory milestone payments to Pfizer of up to an additional $31.75 million in aggregate if specified clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, we are obligated to make sales milestone payments to Pfizer if specified annual sales targets for rucaparib are met which relate to annual sales targets of $250.0 million and above, which, in the aggregate, could amount to total milestone payments of $170.0 million, and tiered royalty payments at a mid-teen percentage rate on our net sales, with standard provisions for royalty offsets to the extent we need to obtain any rights from third parties to commercialize rucaparib.

In April 2012, we entered into a license agreement with AstraZeneca UK Limited to acquire exclusive rights associated with rucaparib under a family of patents and patent applications that claim methods of treating patients with PARP inhibitors in certain indications. The license enables the development and commercialization of rucaparib for the uses claimed by these patents. AstraZeneca receives royalties on any net sales of rucaparib.

Lucitanib

In connection with our acquisition of EOS in November 2013, we gained rights to develop and commercialize lucitanib, an oral, selective tyrosine kinase inhibitor. As further described below, EOS licensed the worldwide rights, excluding China, to develop and commercialize lucitanib from Advenchen Laboratories LLC (“Advenchen”). Subsequently, rights to develop and commercialize lucitanib in markets outside the U.S. and Japan were sublicensed by EOS to Servier in exchange for upfront milestone fees, royalties on sales of lucitanib in the sublicensed territories

and research and development funding commitments.

In October 2008, EOS entered into an exclusive license agreement with Advenchen to develop and commercialize lucitanib on a global basis, excluding China. We are obligated to pay Advenchen tiered royalties at percentage rates in the mid-single digits on net sales of lucitanib, based on the volume of annual net sales achieved. In addition, after giving effect to the first and second amendments to the license agreement, we are required to pay to Advenchen 25% of any consideration, excluding royalties, received pursuant to any sublicense agreements for lucitanib, including the agreement with Servier. We are obligated under the agreement to use commercially reasonable efforts to develop and commercialize at least one product candidate containing lucitanib, and we are also responsible for all remaining development and commercialization costs for lucitanib.

The license agreement with Advenchen will remain in effect until the expiration of all our royalty obligations to Advenchen, determined on a product-by-product and country-by-country basis, unless we elect to terminate the agreement earlier. If we fail to meet our obligations under the agreement and are unable to cure such failure within specified time periods, Advenchen can terminate the agreement, resulting in a loss of our rights to lucitanib.

During 2017, we completed the committed on-going development activities related to lucitanib and received full reimbursement of our development costs from Servier. Reimbursements are recorded as a reduction to research and development expense on the Consolidated Statements of Operations. Lucitanib was originally developed by Clovis and

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Servier with the hypothesis of activity in FGFR driven tumors; however, data in breast and lung cancer were insufficient to move the 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 are party to a product license agreement for our other drug candidate rociletinib (see our 2017 Form 10-K for additional details).

Financial Operations Overview

Revenue

Product revenue is derived from sales of our product, Rubraca, in the United States. We distribute our product in the U.S. principally through a limited number of specialty distributor and specialty pharmacy providers, collectively, our customers. Our customers subsequently sell our products to patients and healthcare providers. Separately, we have arrangements with certain payors and other third parties that provide for government-mandated and privately-negotiated rebates, chargebacks and other discounts. Revenue is recorded net of estimated rebates, chargebacks, discounts and other deductions as well as estimated product returns (collectively, “variable considerations”). Revenue from product sales are recognized when customers obtain control of our product, which occurs at a point in time, typically upon delivery to the customers. For further discussion of our revenue recognition policy, see Note 2, Summary of Significant Accounting Polices in the Revenue Recognition section.

In the three and nine months ended September 30, 2018, we recorded product revenue of $22.8 million and $65.0 million, respectively, related to sales of Rubraca, which we began to commercialize on December 19, 2016. Our ability to generate revenue and become profitable depends upon our ability to successfully commercialize products. Any inability on our part to successfully commercialize Rubraca in the United States and any foreign territories where it may be approved, or any significant delay in such approvals, could have a material adverse impact on our ability to execute upon our business strategy and, ultimately, to generate sufficient revenues from Rubraca to reach or maintain profitability or sustain our anticipated levels of operations.

We supply commercially labeled Rubraca free of charge to eligible patients who qualify due to financial need through our patient assistance program and the majority of these patients are on Medicare. This product is distributed through a separate vendor who administers the program on our behalf. It is not distributed through our specialty distributor and specialty pharmacy network. This product is neither included in the transaction price nor the variable considerations to arrive at product revenue. Manufacturing costs associated with this free product is included in selling, general and administrative expenses. In the three months ended September 30, 2018, the supply of this free drug was approximately 30% of the overall commercial supply or the equivalent of $9.6 million in commercial value. In the nine months ended September 30, 2018, the supply of this free drug was approximately 26% of the overall

commercial supply or the equivalent of $23.0 million in commercial value. We believe the increase in the free drug percentage not realized as revenue results primarily from an increase in the percentage of patients treated with Rubraca who qualify for our patient assistance program, the majority of whom are on Medicare, following label expansion to include the earlier-line, all-comers maintenance treatment label.

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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Research and Development Expenses

Research and development expenses consist of costs incurred for the development of our product candidates and companion diagnostics, which include:

- license fees and milestone payments related to the acquisition of in-licensed products, which are reported on our Consolidated Statements of Operations as acquired in-process research and development;
- employee-related expenses, including salaries, benefits, travel and share-based compensation expense;
- expenses incurred under agreements with contract research organizations and investigational sites that conduct our clinical trials;
- the cost of acquiring, developing and manufacturing clinical trial materials;
- costs associated with non-clinical activities and regulatory operations;
- market research, disease education and other commercial product planning activities, including the hiring of a U.S. sales and marketing and medical affairs organization in preparation for the commercial launch of rucaparib; and
- activities associated with the development of companion diagnostics for our product candidates.

Research and development costs are expensed as incurred. License fees and milestone payments related to in-licensed products and technology are expensed if it is determined that they have no alternative future use. Costs for certain development activities, such as clinical trials and manufacturing of clinical supply, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors. Our research and development expenses increased in the three and nine months ended September 30, 2018 compared to the same period in the prior year. Our research and development expenses will continue to increase compared to last year as planned Rubraca studies progress.

The following table identifies research and development and acquired in-process research and development costs on a program-specific basis for our products under development. Personnel-related costs, depreciation and share-based compensation are not allocated to specific programs, as they are deployed across multiple projects under development and, as such, are separately classified as personnel and other expenses in the table below (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
	(in thousands)			
Rucaparib Expenses				
Research and development	$ 44,375	$ 21,828	$ 101,931	$ 53,318
Rucaparib Total	44,375	21,828	101,931	53,318
Lucitanib Expenses				
Research and development (a)	169	(222)	396	(321)
Lucitanib Total	169	(222)	396	(321)

Rociletinib Expenses				
Research and development	$ 399	$ 1,752	1,993	6,471
Rociletinib Total	399	1,752	1,993	6,471
Personnel and other expenses	18,944	15,566	55,818	45,011
Total	$ 63,887	$ 38,924	$ 160,138	$ 104,479

(a)This amount reflects actual costs incurred less amounts due from Servier for reimbursable development expenses pursuant to the collaboration and license agreement described in Note 12, License Agreements to our unaudited consolidated financial statements included in this Quarterly Report on Form 10-Q.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist principally of salaries and related costs for personnel in executive, commercial, finance, legal, investor relations, human resources, and information technology functions. Other selling, general and administrative expenses include facilities expenses, communication expenses, information technology costs, corporate insurance and professional fees for legal, consulting and accounting services. With the FDA approval of Rubraca on December 19, 2016, all sales and marketing expenses associated with Rubraca are included in

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selling, general and administrative expenses. Our selling, general and administrative expenses will continue to increase compared to last year in support of our commercial activities related to Rubraca in the United States and Europe.

Acquired In-Process Research and Development Expenses

Acquired in-process research and development expenses consist of upfront payments to acquire a new drug compound, as well as subsequent milestone payments. Acquired in-process research and development payments are immediately expensed provided that the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use. Once regulatory approval is received, payments to acquire rights, and the related milestone payments, are capitalized and the amortization of such assets recorded to intangible asset amortization cost of sales.

Other Income and Expense

Other income and expense is primarily comprised of foreign currency gains and losses resulting from transactions with contract research organizations (“CROs”), investigational sites and contract manufacturers where payments are made in currencies other than the U.S. dollar. Other expense also includes interest expense recognized related to our convertible senior notes.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, expenses and revenue and related disclosures. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue deductions, intangible asset impairment, clinical trial accruals and share-based compensation expense. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

For a description of our critical accounting policies, please see Management’s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017. Other than the change to our revenue recognition policy discussed in Note 2, Summary of

Significant Accounting Policies, there have not been any material changes to our critical accounting policies since December 31, 2017.

New Accounting Standards

From time to time, the Financial Accounting Standards Board ("FASB") or other standards-setting bodies issue new accounting pronouncements. Updates to the FASB Accounting Standards Codification are communicated through the issuance of an Accounting Standards Update. Unless otherwise discussed, we believe that the impact of recently issued guidance, whether adopted or to be adopted in the future, is not expected to have a material impact on our Consolidated Financial Statements upon adoption.

To understand the impact of recently issued guidance, whether adopted or to be adopted, please review the information provided in Note 2, Summary of Significant Accounting Policies, in the Notes to the Unaudited Consolidated Financial Statements included in Part I, Item 1 of this Form 10-Q.

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Results of Operations

Comparison of Three Months Ended September 30, 2018 and 2017:

The following table summarizes the results of our operations for the three months ended September 30, 2018 and 2017 (in thousands):

	Three months ended September 30,		Change Favorable/(Unfavorable)	
	2018	2017	$	%
Revenues:				
Product revenue	$ 22,757	$ 16,806	$ 5,951	35 %
Operating expenses:				
Cost of sales - product	4,766	3,026	(1,740)	(58) %
Cost of sales - intangible asset amortization	771	372	(399)	(107) %
Research and development	63,887	38,924	(24,963)	(64) %
Selling, general and administrative	42,495	35,011	(7,484)	(21) %
Total expenses	111,919	77,333	(34,586)	(45) %
Operating loss	(89,162)	(60,527)	(28,635)	(47) %
Other income (expense):				
Interest expense	(3,376)	(2,618)	(758)	(29) %
Foreign currency gain (loss)	151	(44)	195	443 %
Other income	2,536	1,291	1,245	96 %
Other expense, net	(689)	(1,371)	682	50 %
Loss before income taxes	(89,851)	(61,898)	(27,953)	(45) %
Income tax (expense) benefit	(13)	1,234	(1,247)	(101) %
Net loss	$ (89,864)	$ (60,664)	$ (29,200)	(48) %

Product Revenue. Product revenue for the three months ended September 30, 2018 increased compared to the same period in the prior year primarily due to continued growth in sales of Rubraca, which was approved for sale in the United States markets and we began shipping on December 19, 2016. Product revenue is recorded net of variable considerations comprised of rebates, chargebacks and other discounts. Variable considerations represented approximately 11.1% and 7.4% of the transaction price recognized in the three months ended September 30, 2018 and 2017, respectively. This increase primarily relates to an increase in older patients on Medicare as well as additional patients filling prescriptions at low-income clinics. Amounts are summarized as follows:

	Three months ended	Three months ended

	September 30, 2018		September 30, 2017	
	$ (in thousands)	% of Gross Sales	$ (in thousands)	% of Gross Sales
Transaction price	$ 25,626	100.0%	$ 18,144	100.0%
Variable considerations:				
Government rebates and chargebacks	1,664	6.4%	748	4.1%
Discounts and fees	1,204	4.7%	590	3.3%
Total variable considerations	2,868	11.1%	1,338	7.4%
Product revenue	$ 22,758	88.9%	$ 16,806	92.6%

Cost of Sales – Product. Product cost of sales for the three months ended September 30, 2018 increased compared to the same period in the prior year primarily due to the increase in product revenue. Product cost of sales primarily relate to manufacturing, freight and royalties costs associated with Rubraca sales in the period. Manufacturing costs associated with sales in the three months ended September 30, 2017 were expensed as incurred based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, and therefore, a minimal amount is included as product cost of sales. These costs increased in the three months ended September 30, 2018, as we depleted these inventories as of the fourth quarter 2017.

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Cost of Sales – Intangible Asset Amortization. In the three months ended September 30, 2018 and 2017, we recognized cost of sales of $0.8 million and $0.4 million, respectively, associated with the amortization of capitalized milestone payments related to the approvals of Rubraca by the FDA in December 2016 and April 2018 and by the European Commission in May 2018.

Research and Development Expenses. Research and development expenses increased during the three months ended September 30, 2018 compared to the same period in the prior year primarily due to higher research and development costs for rucaparib. Clinical trial costs for rucaparib were higher compared to the same quarter a year ago due to increased enrollment in our TRITON2 and TRITON3 studies for prostate cancer. We have increased costs related to our new ATLAS study for bladder cancer and our ATHENA combination study with Bristol-Myers Squibb Company's immunotherapy OPDIVO for ovarian cancer. In addition, personnel costs increased during the three months ended September 30, 2018 due to higher headcount to support increased rucaparib clinical trial activities.

Clinical trial costs for rociletinib were $1.4 million lower than the third quarter of 2017 primarily due to patients discontinuing drug treatment and investigational sites closing for all of the TIGER studies in non-small cell lung cancer.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased during the three months ended September 30, 2018 compared to the same period in the prior year primarily due to increased commercialization activities for Rubraca and the increase of costs associated with building out the European infrastructure in anticipation of commercialization there.

Interest Expense. Interest expense increased during the three months ended September 30, 2018 compared to the same period in the prior year primarily due to the issuance of the 2025 Notes on April 19, 2018.

Legal Settlement Loss. During the second quarter of 2017, we recorded a one-time charge of $117.0 million related to an agreement to resolve a litigation claim against us and certain of our officers.

Other Income. Other income increased during the three months ended September 30, 2018 compared to the same period in the prior year due to interest income earned on our available-for-sale securities.

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Comparison of Nine Months Ended September 30, 2018 and 2017:

The following table summarizes the results of our operations for the nine months ended September 30, 2018 and 2017 (in thousands):

	Nine months ended September 30,		Change Favorable/(Unfavorable)	
	2018	2017	$	%
Revenues:				
Product revenue	$ 65,037	$ 38,471	$ 26,566	69 %
Operating expenses:				
Cost of sales - product	13,262	6,920	(6,342)	(92) %
Cost of sales - intangible asset amortization	1,851	1,115	(736)	(66) %
Research and development	160,138	104,479	(55,659)	(53) %
Selling, general and administrative	126,634	100,384	(26,250)	(26) %
Total expenses	301,885	212,898	(88,987)	(42) %
Operating loss	(236,848)	(174,427)	(62,421)	(36) %
Other income (expense):				
Interest expense	(9,592)	(7,796)	(1,796)	(23) %
Foreign currency loss	(34)	(127)	93	73 %
Legal settlement loss	(7,975)	(117,000)	109,025	93 %
SEC settlement costs	(20,000)	—	(20,000)	(100) %
Other income	5,419	2,237	3,182	142 %
Other expense, net	(32,182)	(122,686)	90,504	74 %
Loss before income taxes	(269,030)	(297,113)	28,083	9 %
Income tax benefit	280	2,599	(2,319)	(89) %
Net loss	$ (268,750)	$ (294,514)	$ 25,764	9 %

Product Revenue. Product revenue for the nine months ended September 30, 2018 increased compared to the same period in the prior year primarily due to continued growth in sales of Rubraca, which was approved for sale in the United States markets and we began shipping on December 19, 2016. Product revenue is recorded net of variable considerations comprised of rebates, chargebacks and other discounts. Variable considerations represented 10.6% and 8.2% of the transaction price recognized in the nine months ended September 30, 2018 and 2017, respectively. This increase primarily relates to an increase in older patients on Medicare as well as additional patients filling prescriptions at low-income clinics. Amounts are summarized as follows:

Nine months ended September 30, 2018 $	Nine months ended September 30, 2017 $

	(in thousands)	% of Gross Sales	(in thousands)	% of Gross Sales
Gross product revenue	$ 72,717	100.0%	$ 41,923	100.0%
Sales deductions:				
Government rebates and chargebacks	4,627	6.4%	1,820	4.3%
Discounts and fees	3,053	4.2%	1,632	3.9%
Total sales deductions	7,680	10.6%	3,452	8.2%
Product revenue, net	$ 65,037	89.4%	$ 38,471	91.8%

Cost of Sales – Product. Product cost of sales for the nine months ended September 30, 2018 increased compared to the same period in the prior year primarily due to the increase in product revenue. Product cost of sales primarily relate to manufacturing, freight and royalties costs associated with Rubraca sales in the period. Manufacturing costs associated with sales in the nine months ended September 30, 2017 were expensed as incurred based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, and therefore, a minimal amount is included as product cost of sales. These costs increased in the nine months ended September 30, 2018, as we depleted the these inventories as of the fourth quarter 2017.

Cost of Sales – Intangible Asset Amortization. In the nine months ended September 30, 2018 and 2017, we recognized cost of sales of $1.9 million and $1.1 million, respectively, associated with the amortization of capitalized

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milestone payments related to the approvals of Rubraca by the FDA in December 2016 and April 2018 and by the European Commission in May 2018.

Research and Development Expenses. Research and development expenses increased during the nine months ended September 30, 2018 compared to the same period in the prior year primarily due to higher research and development costs for rucaparib. Clinical trial costs for rucaparib were higher compared to the same period a year ago due to higher costs from increased enrollment in ARIEL4, our confirmatory ovarian cancer trials, and increased enrollment in our TRITON2 and TRITON3 studies for prostate cancer. We have increased costs related to our new ATLAS study for bladder cancer, our ATHENA combination study with Bristol-Myers Squibb Company's immunotherapy OPDIVO for ovarian cancer and our RUCA-J study for ovarian cancer in Japan. In addition, personnel costs increased during the nine months ended September 30, 2018 due to higher headcount to support increased rucaparib clinical trial activities.

Clinical trial costs for rociletinib were $4.5 million lower than the nine months ended September 30, 2017 primarily due to patients discontinuing drug treatment and investigational sites closing for all of the TIGER studies in non-small cell lung cancer.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased during the nine months ended September 30, 2018 compared to the same period in the prior year primarily due to increased commercialization activities for Rubraca and the increase of costs associated with building out the European infrastructure in anticipation of commercialization there, which includes an increase of $2.3 million in facilities expense and $2.2 million in personnel costs. In addition, there was an increase of $3.8 million in legal expense and $3.7 million in stock compensation expense.

Interest Expense. Interest expense increased during the nine months ended September 30, 2018 compared to the same period in the prior year primarily due to the issuance of the 2025 Notes on April 19, 2018.

Legal Settlement Loss. During the first quarter of 2018, we recorded a one-time charge of $8.0 million related to an agreement to resolve a potential litigation claim against us and our officers. During the second quarter of 2017, we recorded a one-time charge of $117.0 million related to an agreement to resolve a litigation claim against us and certain of our officers.

SEC Settlement Costs. During the second quarter of 2018, we recorded a one-time charge of $20.0 million related to an agreement reached with the SEC to resolve its investigation. See Note 14, Commitments and Contingencies for further information regarding this investigation and other legal proceedings.

Other Income. Other income increased during the nine months ended September 30, 2018 compared to the same period in the prior year due to interest income earned on our available-for-sale securities.

Liquidity and Capital Resources

To date, we have funded our operations through the public offering of our common stock and the private placement of convertible debt securities and preferred 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. 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. At September 30, 2018, we had cash, cash equivalents and available-for-sale securities totaling $604.4 million.

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The following table sets forth the primary sources and uses of cash for the nine months ended September 30, 2018 and 2017 (in thousands):

	Nine months ended September 30,	
	2018	2017
Net cash used in operating activities	$ (283,270)	$ (195,326)
Net cash (used in) provided by investing activities	(277,763)	29,469
Net cash provided by financing activities	387,974	560,257
Effect of exchange rate changes on cash and cash equivalents	(286)	886
Net (decrease) increase in cash and cash equivalents	$ (173,345)	$ 395,286

Operating Activities

Net cash used in operating activities for all periods resulted primarily from our net losses adjusted for non-cash items and changes in components of working capital. Net cash used in operating activities was higher during the nine months ended September 30, 2018 compared to the same period in the prior year due to a higher net loss as adjusted for non-cash items and increases in the operating assets needed to support the commercialization of Rubraca, most notably related to inventory.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2018 included purchases of available-for-sale securities of $320.0 million offset by cash from sales of available-for-sale securities of $105.0 million and milestone payments of $55.0 million. Net cash provided by investing activities in the same period in the prior year included purchases of available-for-sale securities of $180.0 million offset by cash from sales of available-for-sale securities of $213.5 million.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2018 and 2017 included $3.2 million and $14.4 million, respectively, received from employee stock option exercises. We completed the sale of $93.9 million and $545.8 million of common stock, net of issuance costs, respectively, during the nine months ended September 30, 2018 and September 30, 2017. In addition, we issued $290.9 million of convertible senior notes, net of

issuance costs during the nine months ended September 30, 2018.

Operating Capital Requirements

We expect to incur significant losses for the foreseeable future, as we commercialize Rubraca and expand our selling, general and administrative functions to support the growth in our commercial organization. Additionally, our operating plan for the remainder of 2018 includes a significant investment in inventory to meet the projected commercial requirements for Rubraca. We receive the active pharmaceutical ingredient in Rubraca from one supplier and we experience long lead times associated with its production. Accordingly, we expect to experience a decrease in our liquidity at the beginning of a production cycle and an increase as the inventory produced is sold through.

As of September 30, 2018, we had cash, cash equivalents and available-for-sale securities totaling $604.4 million and total current liabilities of $76.5 million. 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, selling, 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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Our product supply costs will be approximately $23 million for the remainder of 2018. These costs reflect our plan to produce additional inventory in advance of the transition to a new manufacturing facility for Rubraca. We will also incur final capital costs for the new manufacturing facility of approximately $8 million during the fourth quarter of 2018.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including but not limited to:

- the number and characteristics of the product candidates, companion diagnostics and indications we pursue;
- the achievement of various development, regulatory and commercial milestones resulting in required payments to partners pursuant to the terms of our license agreements;
- the scope, progress, results and costs of researching and developing our product candidates and related companion diagnostics and conducting clinical and non-clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates and companion diagnostics;
- the cost of commercialization activities, including marketing and distribution costs;
- the cost of manufacturing any of our product candidates we successfully commercialize;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and outcome of such litigation; and
- the timing, receipt and amount of sales, if any, of our product candidates.

Contractual Obligations and Commitments

For a discussion of our contractual obligations, see “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our 2017 Annual Report on Form 10-K. Other than the milestone payment to Pfizer triggered on April 6, 2018 upon the FDA’s approval of our sNDA for Rubraca as 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, there have not been any material changes to such contractual obligations or potential milestone payments since December 31, 2017. For further information regarding our contractual obligations and commitments, see Note 14, Commitments and Contingencies to our unaudited consolidated financial statements included elsewhere in this report.

ITEM 3.QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of September 30, 2018, we had cash, cash equivalents and available-for-sale securities of $604.4 million, consisting of bank demand deposits, money market funds and U.S. treasury securities. The primary objectives of our investment policy are to preserve principal and

maintain proper liquidity to meet operating needs. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Our available-for-sale securities are subject to interest rate risk and will decline in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair value of our portfolio.

We contract with contract research organizations, investigational sites and contract manufacturers globally where payments are made in currencies other than the U.S. dollar. In addition, on October 3, 2016, we entered into a Manufacturing and Services Agreement with a Swiss company for the production and supply of the active ingredient for Rubraca. Under the terms of this agreement, payments for the supply of the active ingredient in Rubraca as well as scheduled capital program fee payment toward capital equipment and other costs associated with the construction of a dedicated production train will be made in Swiss francs. Once the production facility is operational, we are obligated to pay a fixed facility fee each quarter for the duration of the agreement, which expires on December 31, 2025.

As of September 30, 2018, $165.1 million of purchase commitments exist under the Swiss Manufacturing and Services Agreement and we are required to remit amounts due in Swiss francs. Due to other variables that may exist, it is difficult to quantify the impact of a particular change in exchange rates. However, we estimate that if the value of the US dollar was to strengthen by 10% compared to the value of Swiss franc as of September 30, 2018, it would decrease the

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total US dollar purchase commitment under the Swiss Manufacturing and Services Agreement by $20.4 million. Similarly, a 10% weakening of the US dollar compared to the Swiss franc would increase the total US dollar purchase commitment by $11.8 million.

While we periodically hold foreign currencies, primarily Euro, Swiss Franc and Pound Sterling, we do not use other financial instruments to hedge our foreign exchange risk. Transactions denominated in currencies other than the functional currency are recorded based on exchange rates at the time such transactions arise. As of September 30, 2018 and December 31, 2017, approximately 3% and 1%, respectively, of our total liabilities were denominated in currencies other than the functional currency.

ITEM 4.CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Securities Exchange Act of 1934, as amended (“Exchange Act”) is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Principal Financial and Accounting Officer, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective. With the participation of our Chief Executive Officer and Principal Financial and Accounting Officer, management performed an evaluation as of September 30, 2018 of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Based on this evaluation, our Chief Executive Officer and Principal Financial and Accounting Officer concluded that, as of September 30, 2018, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1.LEGAL PROCEEDINGS

Rociletinib-Related Litigation

Following Clovis' regulatory announcement in November 2015 of adverse developments in its ongoing clinical trials for rociletinib, Clovis and certain of its current and former executives were named in various securities lawsuits, the largest of which was a putative class action lawsuit in the District of Colorado (the "Medina Action") which was settled on October 26, 2017 (the "Medina Settlement"). The open actions currently pending against Clovis are discussed below.

On November 10, 2016, Antipodean Domestic Partners ("Antipodean") filed a complaint (the "Antipodean Complaint") against Clovis and certain of its officers, directors and underwriters in New York Supreme Court, County of New York. The Antipodean Complaint alleges that the defendants violated certain sections of the Securities Act by making allegedly false statements to Antipodean and in the offering materials for the July 2015 Offering relating to the efficacy of rociletinib, its safety profile, and its prospects for market success. In addition to the Securities Act claims, the Antipodean Complaint also asserts Colorado state law claims and common law claims. Both the state law and common law claims are based on allegedly false and misleading statements regarding rociletinib's progress toward FDA approval. The Antipodean Complaint seeks compensatory, recessionary, and punitive damages. On December 15, 2016, the Antipodean Plaintiffs filed an amended complaint (the "Antipodean Amended Complaint") asserting substantially the same claims against the same defendants and purporting to correct certain details in the original Antipodean Complaint.

Following a stay that Justice Masley of the New York Supreme Court, County of New York entered in favor of the Medina Action and briefing on defendants' motions to dismiss, the parties participated in a Preliminary Conference on April 17, 2018, following which the Court entered a preliminary conference order, providing deadlines for document productions, depositions, and other discovery. The Court has scheduled a status conference for January 21, 2019, following which the Court anticipates setting an end date for discovery.

On May 2, 2018, the Court issued an order denying the defendants' motion to dismiss. Defendants filed an answer to the Antipodean Amended Complaint on June 6, 2018.

The Company intends to vigorously defend against the allegations in the Antipodean Amended Complaint. However, there can be no assurance that the defense will be successful.

In March 2017, two putative shareholders of the Company, Macalinao and McKenry (the "Derivative Plaintiffs"), filed shareholder derivative complaints against certain directors and officers of the Company in the Court of Chancery of the State of Delaware. On May 4, 2017, the Macalinao and McKenry actions were consolidated for all purposes in a single proceeding under the caption In re Clovis Oncology, Inc. Derivative Litigation, Case No, 2017-0222 (the "Consolidated Derivative Action").

On May 18, 2017, the Derivative Plaintiffs filed a Consolidated Verified Shareholder Derivative Complaint (the "Consolidated Derivative Complaint"). The Consolidated Derivative Complaint generally alleged that the defendants breached their fiduciary duties owed to the Company by allegedly causing or allowing misrepresentations of the Company's business operations and prospects, failing to ensure that the TIGER-X clinical trial was being conducted in accordance with applicable rules, regulations and protocols, and engaging in insider trading. The Consolidated Derivative Complaint purported to rely on documents produced by the Company in response to prior demands for inspection of the Company's books and records served on the Company by each of Macalinao and McKenry under 8 Del. C. § 220. The Consolidated Derivative Complaint sought, among other things, an award of money damages.

On July 31, 2017, the defendants filed a motion to dismiss the Consolidated Derivative Complaint. Plaintiffs filed an opposition to the motion to dismiss on August 31, 2017, and the defendants filed a reply in further support of the motion to dismiss on September 26, 2017. Oral argument on the defendants' motion to dismiss the Consolidated Derivative Complaint has been scheduled for February 4, 2019.

The Company intends to vigorously defend against the allegations in the Consolidated Derivative Complaint, but there can be no assurance that the defense will be successful.

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On March 20, 2017, a purported shareholder of the Company, filed a shareholder derivative complaint (the "Guo Complaint") against certain officers and directors of the Company in the United States District Court for the District of Colorado. The Guo Complaint generally alleged that the defendants breached their fiduciary duties owed to the Company by either recklessly or with gross negligence approving or permitting misrepresentations of the Company's business operations and prospects. The Guo Complaint also alleged claims for waste of corporate assets and unjust enrichment. Finally, the Guo Complaint alleged that certain of the individual defendants violated Section 14(a) of the Securities Exchange Act, by allegedly negligently issuing, causing to be issued, and participating in the issuance of materially misleading statements to stockholders in the Company's Proxy Statement on Schedule DEF 14A in connection with the 2015 Annual Meeting of Stockholders, held on June 11, 2015. The Guo Complaint sought, among other things, an award of money damages.

On June 19, 2017, the parties filed a joint motion to stay the Guo action pending resolution of the motion to dismiss the Consolidated Derivative Complaint. On June 20, 2017, the court granted the motion to stay.

The Company intends to vigorously defend against the allegations in the Guo Complaint, but there can be no assurance that the defense will be successful.

As previously disclosed, the Company has received inquiries and requests for information from governmental agencies, including the U.S. Securities and Exchange Commission ("SEC") and the U.S. Department of Justice, relating to the Company's regulatory update announcement in November 2015 that the FDA requested additional clinical data on the efficacy and safety of rociletinib.

Earlier this year, the Company and Mr. Mahaffy engaged in discussions with the SEC staff to resolve this matter. On September 18, 2018, the SEC announced it had reached an agreement with the Company to settle this matter on negligence-based charges. Pursuant to the settlement, without admitting or denying the SEC's allegations, the Company paid a $20.0 million civil penalty, which the Company reserved as a loss contingency on its consolidated balance sheet as of June 30, 2018, and stipulated to a standard injunction against future violations of those provisions of the federal securities laws. Also, on September 18, 2018, the SEC announced that Mr. Mahaffy also reached a settlement with the SEC on similar negligence-based allegations, to which he neither admits nor denies, and paid a civil penalty and will be similarly enjoined. Mr. Mahaffy will continue to serve as the Company's Chief Executive Officer and as a member of the Company's Board of Directors.

The settlements do not allege that the Company or any of its current or former officers engaged in any intentional fraud or misconduct. The settlements were approved by the United States District Court for the District of Colorado on September 19, 2018 and resolve the SEC's nearly three year investigation into the regulatory approval process of rociletinib.

European Patent Opposition

Two oppositions were filed in the granted European counterpart of the rucaparib camsylate salt/polymorph patent on June 20, 2017. The grounds of opposition related to Rubraca were lack of novelty and lack of inventive step. A preliminary opinion and summons to oral proceedings were issued on April 4, 2018. The oral hearing is scheduled for December 4, 2018. The preliminary opinion provides a non-binding indication of the tribunal's view. In the preliminary opinion, the tribunal agreed with some of our positions and agreed with certain objections made by the opponents. As part of the proceeding, we have the opportunity to submit further arguments and pursue alternative claims in the form of auxiliary requests. On October 3, 2018, we submitted further arguments and auxiliary requests and on October 4, 2018, both opponents submitted further arguments. While the ultimate results of patent challenges can be difficult to predict, we believe a number of factors, including a constellation of unexpected properties, support the novelty and non-obviousness of our rucaparib camsylate salt/polymorph composition of matter patent.

ITEM 1A.RISK FACTORS

Our business faces significant risks and uncertainties. Certain factors may have a material adverse effect on our business prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the risk factors described under the heading "Risk Factors" in

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Part I, Item 1A of our most recent Annual Report on Form 10-K as supplemented by our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, in addition to other information contained in or incorporated by reference into this Quarterly Report on Form 10-Q and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

There have no material changes to the risk factors included in our previously filed Annual Report on Form 10-K for the year ended December 31, 2017 as supplemented by our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial also may negatively impact our business.

ITEM 2.UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3.DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4.MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5.OTHER INFORMATION

None.

ITEM 6.EXHIBITS

INDEX TO EXHIBITS

o Exhibit Number	Exhibit Description
3.1(5)	Amended and Restated Certificate of Incorporation of Clovis Oncology, Inc.
3.2(5)	Amended and Restated Bylaws of Clovis Oncology, Inc.
4.1(3)	Form of Common Stock Certificate of Clovis Oncology, Inc.
4.2(8)	Indenture dated as of September 9, 2014, by and between Clovis Oncology, Inc. and The Bank of New York Mellon Trust Company, N.A.
4.3(16)	Indenture dated as of April 19, 2018, by and between Clovis Oncology, Inc. and The Bank of New York Mellon Trust Company, N.A., as Trustee
4.4(16)	First Supplemental Indenture dated as of April 19, 2018, by and between Clovis Oncology, Inc. and The Bank of New York Mellon Trust Company, N.A.
10.1*(4)	Amended and Restated Strategic License Agreement, dated as of June 16, 2011, by and between Clovis Oncology, Inc. and Avila Therapeutics, Inc.
10.2*(4)	License Agreement, dated as of June 2, 2011, by and between Clovis Oncology, Inc. and Pfizer Inc.
10.3+(1)	Clovis Oncology, Inc. 2009 Equity Incentive Plan.

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10.4+(4)	Clovis Oncology, Inc. 2011 Stock Incentive Plan.
10.5+(1)	Form of Clovis Oncology, Inc. 2009 Equity Incentive Plan Stock Option Agreement.
10.6+(4)	Form of Clovis Oncology, Inc. 2011 Stock Incentive Plan Stock Option Agreement.
10.7+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Patrick J. Mahaffy.
10.8+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Gillian C. Ivers-Read.
10.9+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Paul Klingenstein.
10.10+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and James C. Blair.
10.11+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Edward J. McKinley.
10.12+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Thorlef Spickschen.
10.13+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and M. James Barrett.
10.14+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Brian G. Atwood.
10.15+(1)	Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Patrick J. Mahaffy.
10.16+(1)	Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Erle T. Mast.
10.17+(1)	Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Gillian C. Ivers-Read.
10.18+(1)	Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Andrew R. Allen.
10.19+(17)	Clovis Oncology, Inc. 2011 Employee Stock Purchase Plan, as amended.
10.20+(4)	Clovis Oncology, Inc. 2011 Cash Bonus Plan.
10.21+(6)	Indemnification Agreement, dated as of March 22, 2012, between Clovis Oncology, Inc. and Steven L. Hoerter.

10.22+(2)	Indemnification Agreement, dated as of June 13, 2013, between Clovis Oncology, Inc. and Ginger L. Graham.

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10.23+(2)	Indemnification Agreement, dated as of June 13, 2013, between Clovis Oncology, Inc. and Keith Flaherty.
10.24(7)	Stock Purchase Agreement, dated as of November 19, 2013, by and among the Company, EOS, the Sellers listed on Exhibit A thereto and Sofinnova Capital V FCPR, acting in its capacity as the Sellers' Representative.
10.25*(7)	Development and Commercialization Agreement, dated as of October 24, 2008, by and between Advenchen Laboratories LLC and Ethical Oncology Science S.p.A., as amended by the First Amendment, dated as of April 13, 2010 and the Second Amendment, dated as of July 30, 2012.
10.26+(12)	Indemnification Agreement, effective as of August 3, 2015, by and between Clovis Oncology, Inc. and Lindsey Rolfe.
10.27+(12)	Employment Agreement, dated as of February 25, 2016, by and between Clovis Oncology, Inc. and Lindsey Rolfe.
10.28+(12)	Indemnification Agreement, effective as of February 1, 2016, by and between Clovis Oncology, Inc. and Dale Hooks.
10.29+(12)	Employment Agreement, effective as of February 1, 2016, by and between Clovis Oncology, Inc. and Dale Hooks.
10.30+(9)	Indemnification Agreement, dated as of February 17, 2016, by and between Clovis Oncology, Inc. and Daniel W. Muehl.
10.31+(15)	Employment Agreement, dated as of July 6, 2017, by and between Clovis Oncology, Inc. and Daniel W. Muehl.
10.32+(10)	Salary Waiver Letter, dated as of May 9, 2016, by and between Clovis Oncology, Inc. and Patrick J. Mahaffy.
10.33*(11)	First Amendment to License Agreement, by and between Clovis Oncology, Inc. and Pfizer Inc., dated as of August 30, 2016.
10.34+(13)	Form of Clovis Oncology, Inc. 2011 Stock Incentive Plan RSU Agreement.
10.35*(13)	Manufacturing Services Agreement, by and between Clovis Oncology, Inc. and Lonza Ltd, dated as of October 3, 2016.
10.36*(14)	Strata Trial Collaboration Agreement, by and between Clovis Oncology, Inc. and Strata Oncology, Inc., dated as of January 30, 2017
10.37+(18)	Indemnification Agreement, dated as of October 11, 2018, by and between Clovis Oncology, Inc. and Robert W. Azelby.
10.38+(18)	

	Indemnification Agreement, dated as of October 11, 2018, by and between Clovis Oncology, Inc. and Richard A. Fair.
21.1(17)	List of Subsidiaries of Clovis Oncology, Inc.

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31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from Clovis Oncology, Inc.'s Quarterly Report on Form 10-Q for the period ended September 30, 2018, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Statements of Operations and Comprehensive Loss, (ii) the Consolidated Balance Sheets, (iii) the Consolidated Statements of Cash Flows and (iv) Notes to Unaudited Consolidated Financial Statements.

(1) Filed as an exhibit with the Registrant's Registration Statement on Form S-1 (File No. 333-175080) on June 23, 2011.
(2) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on June 14, 2013.
(3) Filed as an exhibit with Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (File No. 333-175080) on August 31, 2011.
(4) Filed as an exhibit with Amendment No. 3 to the Registrant's Registration Statement on Form S-1 (File No. 333-175080) on October 31, 2011.
(5) Filed as an exhibit with the Registrant's Annual Report on Form 10-K on March 15, 2012.
(6) Filed as an exhibit with the Registrant's Registration Statement on Form S-1 (File No. 333-180293) on March 23, 2012.
(7) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on November 19, 2013.
(8) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on September 9, 2014.
(9) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on April 1, 2016.
(10) Filed as an exhibit with the Registrant's Quarterly Report on Form 10-Q on May 9, 2016.
(11) Filed as an exhibit with the Registrant's Quarterly Report on Form 10-Q on November 4, 2016.
(12) Filed as an exhibit with the Registrant's Annual Report on Form 10-K on February 29, 2016.
(13) Filed as an exhibit with the Registrant's Annual Report on Form 10-K on February 23, 2017.
(14) Filed as an exhibit with the Registrant's Quarterly Report on Form 10-Q on May 4, 2017.
(15) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on July 7, 2017.
(16) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on April 19, 2018.
(17) Filed as an exhibit with the Registrant's Current Report on Form 10-Q on August 2, 2018.
(18) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on October 12, 2018.
+ Indicates management contract or compensatory plan.

* Confidential treatment has been granted with respect to portions of this exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission.

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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, thereunto duly authorized.

Date: October 31, 2018 CLOVIS ONCOLOGY, INC.

By: /s/ PATRICK J. MAHAFFY
Patrick J. Mahaffy
President and Chief Executive Officer; Director

By: /s/ DANIEL W. MUEHL
Daniel W. Muehl
Senior Vice President of Finance and Principal Financial and Accounting Officer