

Clovis Oncology, Inc.  
Form 10-Q  
May 09, 2018  
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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FORM 10-Q

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

For the quarterly period ended March 31, 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

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Clovis Oncology, Inc.

(Exact name of Registrant as specified in its charter)

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Delaware 90-0475355  
(State or other jurisdiction of (I.R.S. Employer  
incorporation or organization) 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)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	(Do not check if a smaller reporting company)	Smaller reporting company
		Emerging growth company

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

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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 May 4, 2018 was 52,548,995.

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Table of Contents

CLOVIS ONCOLOGY, INC.

FORM 10-Q

TABLE OF CONTENTS

<u>PART I. Financial Information</u>	3
<u>ITEM 1. Financial Statements (unaudited)</u>	3
<u>Consolidated Statements of Operations and Comprehensive Loss — for the three months ended March 31, 2018 and 2017</u>	3
<u>Consolidated Balance Sheets — as of March 31, 2018 and December 31, 2017</u>	4
<u>Consolidated Statements of Cash Flows — for the three months ended March 31, 2018 and 2017</u>	5
<u>Notes to Unaudited Consolidated Financial Statements</u>	6
<u>ITEM 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	22
<u>ITEM 3. Quantitative and Qualitative Disclosures About Market Risk</u>	31
<u>ITEM 4. Controls and Procedures</u>	32
<u>PART II. Other Information</u>	33
<u>ITEM 1. Legal Proceedings</u>	33
<u>ITEM 1A. Risk Factors</u>	35
<u>ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	37
<u>ITEM 3. Defaults Upon Senior Securities</u>	37
<u>ITEM 4. Mine Safety Disclosures</u>	37
<u>ITEM 5. Other Information</u>	37

<u>ITEM 6.</u>	<u>Exhibits</u>	38
<u>SIGNATURES</u>		41

Table of Contents

## 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 March 31,	
	2018	2017
	(in thousands, except per share amounts)	
Revenues:		
Product revenue	\$ 18,523	\$ 7,045
Operating expenses:		
Cost of sales - product	4,006	1,163
Cost of sales - intangible asset amortization	372	372
Research and development	43,543	32,447
Selling, general and administrative	39,274	29,224
Total expenses	87,195	63,206
Operating loss	(68,672)	(56,161)
Other income (expense):		
Interest expense	(2,635)	(2,581)
Foreign currency loss	(81)	(159)
Legal settlement loss	(7,975)	—
Other income	1,409	354
Other expense, net	(9,282)	(2,386)
Loss before income taxes	(77,954)	(58,547)
Income tax benefit	260	83
Net loss	\$ (77,694)	\$ (58,464)
Other comprehensive income (loss):		
Foreign currency translation adjustments, net of tax	1,517	467
Net unrealized loss on available-for-sale securities, net of tax	(5)	(5)
Other comprehensive income:	1,512	462
Comprehensive loss	\$ (76,182)	\$ (58,002)

Loss per basic and diluted common share:

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Basic and diluted net loss per common share	\$ (1.54)	\$ (1.33)
Basic and diluted weighted average common shares outstanding	50,602	44,039

See accompanying Notes to Unaudited Consolidated Financial Statements.

3

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Table of Contents

CLOVIS ONCOLOGY, INC.

## CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except for share amounts)

	March 31, 2018	December 31, 2017
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 374,114	\$ 464,198
Accounts receivable, net	12,936	6,181
Inventories	69,192	27,508
Available-for-sale securities	89,697	99,533
Prepaid research and development expenses	4,619	1,559
Deposit on inventory	—	20,461
Other current assets	9,115	7,500
Total current assets	559,673	626,940
Deposit on inventory	9,303	—
Property and equipment, net	3,938	4,007
Intangible assets, net	19,189	19,561
Goodwill	66,960	65,217
Other assets	19,861	19,505
Total assets	\$ 678,924	\$ 735,230
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 13,378	\$ 15,147
Accrued research and development expenses	22,224	18,465
Milestone liability	22,534	22,022
Other accrued expenses	27,306	25,883
Total current liabilities	85,442	81,517
Deferred income taxes	371	—
Convertible senior notes	282,732	282,406
Deferred rent, long-term	4,143	3,671
Total liabilities	372,688	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 March 31, 2018 and December 31, 2017	—	—
Common stock, \$0.001 par value per share, 100,000,000 shares authorized at March 31, 2018 and December 31, 2017; 50,697,471 and 50,565,119 shares issued and outstanding at March 31, 2018 and December 31, 2017 respectively	51	51
Additional paid-in capital	1,899,624	1,887,198



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Accumulated other comprehensive loss	(40,661)	(42,173)
Accumulated deficit	(1,552,778)	(1,477,440)
Total stockholders' equity	306,236	367,636
Total liabilities and stockholders' equity	\$ 678,924	\$ 735,230

See accompanying Notes to Unaudited Consolidated Financial Statements.

4

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Table of Contents

CLOVIS ONCOLOGY, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Three months ended	
	March 31,	2017
	2018	
Operating activities		
Net loss	\$ (77,694)	\$ (58,464)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	11,913	8,947
Depreciation and amortization	586	639
Amortization of premiums and discounts on available-for-sale securities	(171)	214
Amortization of debt issuance costs	326	317
Deferred income taxes	(101)	(60)
Changes in operating assets and liabilities:		
Accounts receivable	(3,418)	(2,257)
Inventory	(41,716)	(6,504)
Prepaid and accrued research and development expenses	637	(10,047)
Deposit on inventory	11,157	(18,237)
Other operating assets	(1,890)	1,223
Accounts payable	(1,730)	13,780
Other accrued expenses	1,466	(9,990)
Net cash used in operating activities	(100,635)	(80,439)
Investing activities		
Purchases of property and equipment	(217)	(53)
Deposits for purchases of property and equipment	—	(2,515)
Purchases of available-for-sale securities	—	(133,000)
Sales of available-for-sale securities	10,000	50,000
Acquired in-process research and development - milestone payment	—	(1,100)
Net cash provided by (used in) investing activities	9,783	(86,668)
Financing activities		
Proceeds from the sale of common stock, net of issuance costs	—	221,224
Proceeds from the exercise of stock options and employee stock purchases	514	5,674
Net cash provided by financing activities	514	226,898
Effect of exchange rate changes on cash and cash equivalents	254	72
Increase (decrease) in cash and cash equivalents	(90,084)	59,863
Cash and cash equivalents at beginning of period	464,198	216,186
Cash and cash equivalents at end of period	\$ 374,114	\$ 276,049
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 3,594	\$ 3,594

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Non-cash investing and financing activities:

Vesting of restricted stock units	\$ 6,409	\$ 2,534
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See accompanying Notes to Unaudited Consolidated Financial Statements.

5

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Table of Contents

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.

Our marketed product Rubraca® (rucaparib) is approved in the United States by the Food and Drug Administration (“FDA”) for 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. We launched Rubraca in the United States in December 2016.

On April 6, 2018, the FDA 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 March 2018, the Committee for Medicinal Products for Human Use (“CHMP”) of the European Union’s European Medicines Agency (“EMA”) adopted a positive opinion recommending the granting of 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. We anticipate receiving a formal marketing authorization from the European Commission for Rubraca for this indication in the second quarter of 2018. 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 the event of such an approval from the European Commission for this treatment indication, we intend to submit 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 anticipate a CHMP opinion may come during the fourth quarter of 2018.

In addition to Rubraca, we have two other product candidates: lucitanib, 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), and rociletinib, an oral mutant-selective inhibitor of epidermal growth factor receptor (“EGFR”). While we have stopped enrollment in ongoing trials for each of these candidates, we continue to provide drug to patients whose clinicians recommend continuing therapy. We maintain certain development and commercialization rights for lucitanib and global development and commercialization rights for rociletinib.

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 have received notice from Servier of termination of their rights to lucitanib, resulting in the return of global rights (excluding China) for lucitanib to us later in 2018. We believe that recent data for a drug similar to lucitanib that inhibits these same pathways – when

## Table of Contents

combined with a PD-1 inhibitor – provide support for development of lucitanib in combination with a PD(L)-1 inhibitor, and we are exploring 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 by the end of 2018 or in the first quarter of 2019.

## 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, consisting only of normal recurring 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 approximately \$94 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 approximately \$292 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, if approved by the European Commission, in 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.

Table of Contents

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. Adoption of ASC 606 is required for annual and interim periods beginning after December 15, 2017. Upon adoption, we must elect to adopt either retrospectively to each prior reporting period presented or use the modified retrospective transition method with the cumulative effect of initial adoption recognized at the date of initial application. 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 have examined our revenue recognition policy specific to revenue streams from representative 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 have reviewed a representative sample of 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 have 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.



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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
<b>ASSETS</b>			
Accounts receivable, net	\$ 6,181	\$ 3,336	\$ 9,517
Inventories	\$ 27,508	(62)	\$ 27,446
Total assets	\$ 735,230	\$ 3,274	\$ 738,504
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>			
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 increase the significance of estimating variable consideration. The impact of adoption on our consolidated statement of

Table of Contents

operations and comprehensive loss and consolidated balance sheet for the quarter ended March 31, 2018 was as follows (in thousands, except per share amounts):

	As reported	Balances without Adoption of ASC 606	Effect of Change  Higher/(Lower)
<b>CONSOLIDATED STATEMENT OF OPERATIONS AND COMPREHENSIVE LOSS</b>			
Product revenue	\$ 18,523	\$ 17,956	\$ 567
Cost of sales - product	\$ 4,006	\$ 3,541	\$ 465
Selling, general and administrative	\$ 39,274	\$ 39,234	\$ 40
Net loss	\$ (77,694)	\$ (77,756)	\$ (62)
Loss per basic and diluted common share:			
Basic and diluted net loss per common share	\$ (1.54)	\$ (1.54)	\$ (0.00)
<b>CONSOLIDATED BALANCE SHEET</b>			
<b>ASSETS</b>			
Accounts receivable, net	\$ 12,936	\$ 12,322	\$ 614
Inventories	\$ 69,192	\$ 69,559	\$ (367)
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>			
Other accrued expenses	\$ 27,306	\$ 27,120	\$ 186
Accumulated deficit	\$ (1,552,778)	\$ (1,552,840)	\$ (62)

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.

In May 2017, the FASB issued ASU 2017-09, "Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting", which amends the scope of modification accounting for share-based payment arrangements. The ASU provides guidance on the types of changes to the terms or conditions of share-based payment awards to which we would be required to apply modification accounting under ASC 718. Specifically, we would not apply modification accounting if the fair value, vesting conditions, and classification of the awards are the same immediately before and after the modification. The guidance is effective for us on January 1, 2018 and the adoption resulted in no change to our consolidated financial statements and related disclosures.

## 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. Early adoption is permitted. ASU 2016-02 requires modified retrospective adoption for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. 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. Early adoption is permitted. We are currently evaluating the impact the standard may have on our consolidated financial statements and related disclosures.

## Table of Contents

### 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

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.

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 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

Table of Contents

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 approximately 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.

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.

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.

Table of Contents

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
March 31, 2018				
Assets:				
Money market	\$ 294,559	\$ 294,559	\$ —	\$ —
U.S. treasury securities	89,697	—	89,697	—
Total assets at fair value	\$ 384,256	\$ 294,559	\$ 89,697	\$ —
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 months ended March 31, 2018.

Financial instruments not recorded at fair value include our convertible senior notes. At March 31, 2018, the carrying amount of the convertible senior notes was \$282.7 million, which represents the aggregate principal amount net of remaining debt issuance costs, and the fair value was \$335.5 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 March 31, 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	\$ 89,821	\$ —	\$ (124)	\$ 89,697

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

Table of Contents

As of March 31, 2018, there were no available-for-sale securities that have been in a continuous unrealized loss position for less than 12 months.

As of March 31, 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	\$ 89,821	\$ 89,697
Due in one year to two years	—	—
Total	\$ 89,821	\$ 89,697

## 5. Inventories

The following table presents inventories as of March 31, 2018 and December 31, 2017:

	March 31, 2018	December 31, 2017
Work-in-process	\$ 67,437	\$ 24,721
Finished goods	1,755	2,787
Total inventories	\$ 69,192	\$ 27,508

Some of the costs related to our finished goods on-hand as of March 31, 2018 were expensed as incurred prior to the commercialization of Rubraca on December 19, 2016.

At March 31, 2018, deposit on inventory on the Consolidated Balance Sheets is a cash deposit of \$9.3 million made to a manufacturer for the purchase of work-in-process inventory which we expect to be converted to finished goods beyond the next twelve months.

## 6. Other Current Assets

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

	March 31, 2018	December 31, 2017
Prepaid insurance	\$ 1,427	\$ 1,926
Prepaid expenses - other	5,684	3,355
Receivable - other	1,780	2,023
Other	224	196
Total	\$ 9,115	\$ 7,500

## 7. Intangible Assets and Goodwill

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

	March 31, 2018	December 31, 2017
Intangible asset - milestones	\$ 21,100	\$ 21,100
Accumulated amortization	(1,911)	(1,539)
Total intangible asset, net	\$ 19,189	\$ 19,561

Table of Contents

The estimated useful lives of these intangible assets are based on the estimated remaining patent life of Rubraca and extend through 2031.

We recorded amortization expense of \$0.4 million and \$0.4 million related to capitalized milestone payments during the three months ended March 31, 2018 and March 31, 2017, respectively, 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	\$ 1,114
2019	1,486
2020	1,486
2021	1,486
2022	1,486
Thereafter	12,131
	\$ 19,189

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	1,743
Balance at March 31, 2018	\$ 66,960

8. Other Accrued Expenses

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

March 31, 2018	December 31, 2017
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Accrued personnel costs	\$ 7,381	\$ 13,889
Accrued interest payable	299	2,096
Income tax payable	45	—
Accrued corporate legal fees and professional services	137	415
Accrued royalties	4,025	2,984
Accrued variable considerations	1,391	1,008
Payable to third party logistics provider	2,661	2,661
Accrued legal settlement cost	7,975	—
Accrued expenses - other	3,392	2,830
Total	\$ 27,306	\$ 25,883

## 9. Convertible Senior 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

Table of Contents

price of approximately \$61.88 per share. The conversion rate is subject to adjustment upon the occurrence of certain events described in the indenture, but will not be adjusted for any accrued and unpaid interest. 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 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. As of March 31, 2018 and December 31, 2017, the balance of unamortized debt issuance costs was \$4.8 million and \$5.1 million, respectively.

The following table sets forth total interest expense recognized during the three months ended March 31, 2018 and 2017 (in thousands):

Three months ended  
March 31,

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	2018	2017
Contractual interest expense	\$ 1,797	\$ 1,797
Accretion of interest on milestone liability	512	467
Amortization of debt issuance costs	326	317
Total interest expense	\$ 2,635	\$ 2,581

In April 2018, 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 approximately \$292 million, after deducting underwriting discounts and commissions and offering expenses.

## 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 approximately \$94 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.

Table of Contents

## 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 March 31, 2018 and 2017, as follows (in thousands):

	Foreign Currency		Unrealized		Total Accumulated	
	Translation Adjustments		(Losses)	Gains	Other Comprehensive	
	2018	2017	2018	2017	2018	2017
Balance at December 31,	\$ (41,917)	\$ (47,434)	\$ (256)	\$ (146)	\$ (42,173)	\$ (47,580)
Other comprehensive income (loss)	1,991	735	(7)	(5)	1,984	730
Total before tax	(39,926)	(46,699)	(263)	(151)	(40,189)	(46,850)
Tax effect	(474)	(268)	2	—	(472)	(268)
Balance at March 31,	\$ (40,400)	\$ (46,967)	\$ (261)	\$ (151)	\$ (40,661)	\$ (47,118)

The period change between December 31, 2017 and March 31, 2018 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 months ended March 31, 2018 and 2017.

## 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 months ended March 31, 2018 and 2017 was recognized in the accompanying Consolidated Statements of Operations as follows (in thousands):

Three months ended	
March 31,	
2018	2017



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Research and development	\$ 5,376	\$ 4,167
Selling, general and administrative	6,537	4,780
Total share-based compensation expense	\$ 11,913	\$ 8,947

We did not recognize a tax benefit related to share-based compensation expense during the three months ended March 31, 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 March 31, 2018.

Stock Options

The following table summarizes the activity relating to our options to purchase common stock for the three months ended March 31, 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	384,518	58.47		
Exercised	(21,431)	23.96		
Forfeited	(49,420)	67.03		
Outstanding at March 31, 2018 (a)	6,103,402	\$ 47.42	7.0	\$ 91,682
Vested and expected to vest at March 31, 2018	5,805,355	\$ 47.12	6.9	\$ 89,099
Vested and exercisable at March 31, 2018	3,861,586	\$ 44.56	6.0	\$ 69,360

Table of Contents

The aggregate intrinsic value in the table above represents the pretax intrinsic value, based on our closing stock price of \$52.80 as of March 29, 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 months ended March 31, 2018 and 2017 (in thousands, except per share amounts):

	Three months ended March 31,	
	2018	2017
Weighted-average grant date fair value per share	\$ 43.14	\$ 47.71
Intrinsic value of options exercised	\$ 762	\$ 9,525
Cash received from stock option exercises	\$ 514	\$ 5,674

As of March 31, 2018, the unrecognized share-based compensation expense related to unvested options, adjusted for expected forfeitures, was \$75.3 million and the estimated weighted-average remaining vesting period was 2.65 years.

## Restricted Stock

The following table summarizes the activity relating to our unvested restricted stock units (“RSUs”) for the three months ended March 31, 2018:

	Number of Units	Weighted Average Grant Date Fair Value
Unvested at December 31, 2017	589,529	\$ 41.67
Granted	360,688	58.47
Vested	(110,889)	40.00
Forfeited	(9,746)	37.31
Unvested as of March 31, 2018	829,582	\$ 49.25
Expected to vest after March 31, 2018	695,398	\$ 48.78

As of March 31, 2018, the unrecognized share-based compensation expense related to unvested RSUs, adjusted for expected forfeitures, was \$32.3 million and the estimated weighted-average remaining vesting period was 3.4 years.

## 12. License Agreements

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. In the event that we defer such milestone payments, we have agreed to certain higher payments related to the 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 have exercised the option to defer payment by agreeing to pay \$23.0 million

Table of Contents

within 18 months after the date of the FDA approval. These payments were recognized as intangible assets and will be amortized over the estimated remaining useful life of Rubraca.

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.

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 \$51.75 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 will receive royalties on any net sales of rucaparib.

We are party to other product license agreements for our other drug candidates, lucitanib and rociletinib (see our 2017 Form 10-K for additional details). 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 have received notice from Servier of termination of their rights to lucitanib, resulting in the return of global rights (excluding China) for lucitanib to us later in 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 are exploring 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 by the end of 2018 or in the first quarter of 2019.

13. Net Loss Per Common Share

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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. As a result of our net losses for the periods presented, all 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 months ended March 31,	
	2018	2017
Common shares under option	3,908	3,557
Convertible senior notes	4,646	4,646
Total potential dilutive shares	8,554	8,203

## Table of Contents

### 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 \$22.5 million and \$22.0 million are recorded on our Consolidated Balance Sheets at March 31, 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 March 31, 2018, \$197.3 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 January 22, 2016, the Electrical Workers Local #357 Pension and Health & Welfare Trusts, a purported shareholder of Clovis, filed a purported class action complaint (the "Electrical Workers Complaint") against Clovis and certain of its officers, directors, investors and underwriters in the Superior Court of the State of California, County of San Mateo (the "Electrical Workers Court"). The Electrical Workers Complaint purported to be asserted on behalf of a class of persons who purchased stock in the July 2015 Offering. The complaint asserted claims under certain provisions of the Securities Act of 1933 (the "Securities Act") relating to a July 2015 follow-on offering of Clovis securities (the "July 2015 Offering") based on substantially similar allegations to those asserted in the Medina Action. On June 30, 2016, the Electrical Workers Plaintiffs filed an amended complaint adding new allegations (the "Amended Complaint"). On April 10, 2018, the Court entered an order dismissing the Electrical Workers Action on the basis of the Medina Settlement.

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

Table of Contents

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. On January 31, 2017, the defendants filed a motion to stay the Antipodean action pending resolution of the Medina Action in the District of Colorado. Defendants also filed a motion to dismiss the Antipodean Amended Complaint on March 29, 2017. On March 14, 2017, the Clovis defendants and Antipodean participated in a mediation, which did not result in a settlement.

On August 8, 2017, the parties participated in a scheduled hearing on the defendants' motion to stay and motion to dismiss before Justice Masley of the New York Supreme Court, County of New York. At the hearing, Justice Masley granted the defendants' motion to stay. Per the Court's August 10, 2017 order, the defendants' motion to dismiss was held in abeyance and deemed submitted on November 1, 2017. On November 1, 2017, the defendants provided a status update to the Court regarding the outcome of the hearing. The update informed the Court that Antipodean had excluded itself from the Medina Settlement, as memorialized in the final judgment entered by the Medina Court.

On April 17, 2018, the parties participated in a Preliminary Conference, following which the Court entered a preliminary conference order, providing for, among other things, an end date for discovery of February 4, 2019.

On May 2, 2018, the Court issued an order denying the defendants' motion to dismiss. Defendants have 20 days from service of a copy of the order with notice of entry to answer the allegations in the Antipodean Amended Complaint.

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 August 2, 2018.

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

Table of Contents

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 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. On April 9, 2018, the Company received a "Wells Notice" letter from the staff of the SEC issued in connection with this investigation. Certain of our current and former officers also received Wells Notices.

The Wells Notices advise that the staff has made a preliminary determination to recommend to the SEC that it file an action against us and certain of our current and former officers regarding possible violations of Sections 17(a)(1), (2) and (3) of the Securities Act of 1933 and Sections 10(b) and 13(a) of the Securities Act of 1934 and Rules 10b-5(a), (b), and (c), 12b-20, and 13(a)-11 thereunder. The Wells Notices state that the SEC staff's recommendation may involve a civil injunctive action, public administrative proceeding, and/or cease-and-desist proceeding, and may seek remedies that include an injunction, cease-and-desist order, disgorgement, pre-judgment interest, and civil money penalties, and in the case of certain officers a bar from service as an officer or director of a public company.

Under SEC procedures, a recipient of a Wells Notice has an opportunity to respond in the form of a "Wells submission" that seeks to persuade the SEC that such an action should not be brought. The Company has provided to the SEC staff Wells submissions to further explain their views and beliefs that no enforcement action is warranted against the Company or any individuals associated with the Company. The receipt of the Wells Notice does not change the Company's beliefs that it has complied with all laws and regulations, and therefore, the Company intends to contest any charges that may be brought, though there can be no assurance that the defense will be successful.

Director Compensation Litigation

On May 10, 2017, John Solak, a purported shareholder of the Company, filed a shareholder derivative complaint in the Court of Chancery of the State of Delaware (the “Solak Complaint”) against certain directors and an officer of the Company. The Solak Complaint generally alleged that the defendants breached their fiduciary duties owed to the Company by adopting a compensation plan that overcompensated the non-employee director defendants, in relation to companies of comparable market capitalization and size. The Solak Complaint also alleged claims of waste of corporate assets and unjust enrichment. The Solak Complaint sought, among other things, an award of money damages and the imposition of corporate governance reforms.

On February 26, 2018, the defendants entered into a stipulation of compromise and settlement with plaintiff that is intended to settle the Solak action. The proposed settlement is subject to Court approval upon the conclusion of a settlement hearing concerning the fairness of the terms of the proposed settlement, which has been scheduled for May 30, 2018 at 2:00 p.m.

In accordance with the terms of the proposed settlement, the Company will present a new non-employee director compensation policy for shareholder vote at the next annual shareholder meeting. Under the proposed new non-employee director compensation policy, annual base compensation for incumbent non-employee directors would be set at \$400,000 for a three-year period. Additionally, the proposed policy sets annual base compensation for new non-employee directors at \$600,000 for a three-year period and includes fixed annual fees for board and committee service. The proposed settlement also sets forth a number of corporate governance reforms that the Company will undertake, including, enhanced proxy disclosures, the codification of the Company’s stock ownership guidelines for directors, and enhanced disclosure requirements for certain forms of director compensation. While no cash payments will be made to investors as part of the proposed settlement, plaintiff’s counsel is expected to file a fee application, which the Company has agreed not to oppose up to \$395,000. The proposed settlement contains no admission of wrongdoing.

Table of Contents

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 thereon or 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 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 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. We launched Rubraca in the United States in December 2016.

On April 6, 2018, the FDA 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 March 2018, the Committee for Medicinal Products for Human Use (“CHMP”) of the European Union’s European Medicines Agency (“EMA”) adopted a positive opinion recommending the granting of 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

Table of Contents

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. We anticipate receiving a formal marketing authorization from the European Commission for Rubraca for this indication in the second quarter of 2018. 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 the event of such an approval from the European Commission for this treatment indication, we intend to submit 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 anticipate a CHMP opinion may come during the fourth quarter of 2018.

We hold worldwide rights for rucaparib. 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 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 to at least 2025. 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 application directed to high dosage strength rucaparib tablets that, if issued, will expire 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 agree with some of our positions and agree 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. 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. We have received a notice of allowance in the United States for our high dosage strength rucaparib tablets patent application. We believe that, if issued, this patent will include claims that cover the commercial Rubraca product, including all commercial dosage strengths and will expire in 2035. Additionally, in Europe, regulatory exclusivity is available for ten years, plus one year for a new indication, therefore, we believe that we will have regulatory exclusivity for Rubraca in Europe, pending European Commission approval of the treatment indication, expected in the second quarter of 2018, and an additional indication, if approved, until at least 2029.

In addition to Rubraca, we have two other product candidates: lucitanib, 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), and rociletinib, an oral mutant-selective inhibitor of epidermal growth factor receptor (“EGFR”). While we have stopped enrollment in ongoing trials for each of these candidates, we continue to provide drug to patients whose clinicians recommend continuing therapy. We maintain certain development and commercialization rights for lucitanib and global development and commercialization rights for rociletinib.

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 have received notice from Servier for termination of their rights to lucitanib, resulting in the return of global rights (excluding China) for lucitanib

Table of Contents

to us later in 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 are exploring 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 by the end of 2018 or in the first quarter of 2019.

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 March 31, 2018, we have generated \$13.6 million in license and milestone revenue related to our collaboration and license agreement with Servier and for the three months ended March 31, 2018 and 2017 have generated \$18.5 million and \$7.0 million, respectively, product revenue related to sales of Rubraca, which we began to commercialize on December 19, 2016. We 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 March 31, 2018, we had an accumulated deficit of \$1,552.8 million. We incurred net losses of \$77.7 million and \$58.5 million for the three months ended March 31, 2018 and 2017, respectively. We had cash, cash equivalents and available-for-sale securities totaling \$463.8 million at March 31, 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 approximately \$94 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 approximately \$292 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, if approved by the EMA, in 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.

Product License Agreements



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. In the event that we defer such milestone payments, we have agreed to certain higher payments related to the 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

## Table of Contents

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 have exercised the option to defer payment by agreeing to pay \$23.0 million within 18 months after the date of the FDA approval. These payments were recognized as intangible assets and will be amortized over the estimated remaining useful life of Rubraca.

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.

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 \$51.75 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 will receive royalties on any net sales of rucaparib.

We are party to other product license agreements for our other drug candidates, lucitanib and 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 Policies in the Revenue Recognition section.

In the three months ended March 31, 2018, we recorded product revenue of \$18.5 million 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. 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 March 31, 2018, the supply of this free drug was approximately 22% of the overall commercial

Table of Contents

supply or the equivalent of \$5.1 million in commercial value. We expect this free product amount to remain in the 22% of total commercial supply or slightly higher for the remainder of 2018.

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.

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 investigative 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 months ended March 31, 2018 compared to the same period in the prior year. Our research and development expenses will continue to increase compared to last year in support of commercial activities related to Rubraca in the United States and Europe.

Table of Contents

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	
	March 31,	
	2018	2017
Rucaparib Expenses		
Research and development	\$ 24,507	\$ 14,511
Rucaparib Total	24,507	14,511
Lucitanib Expenses		
Research and development (a)	10	(87)
Lucitanib Total	10	(87)
Rociletinib Expenses		
Research and development	1,015	3,190
Rociletinib Total	1,015	3,190
Personnel and other expenses	18,011	14,833
Total	\$ 43,543	\$ 32,447

(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 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

Table of Contents

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.

Results of Operations

Comparison of Three Months Ended March 31, 2018 and 2017:

The following table summarizes the results of our operations for the three months ended March 31, 2018 and 2017 (in thousands):

Change  
Favorable/(Unfavorable)



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	Three months ended			
	March 31,			
	2018	2017	\$	%
Product revenue	\$ 18,523	\$ 7,045	\$ 11,478	163 %
Operating expenses:				
Cost of sales - product	4,006	1,163	2,843	(244) %
Cost of sales - intangible asset amortization	372	372	—	— %
Research and development	43,543	32,447	11,096	(34) %
Selling, general and administrative	39,274	29,224	10,050	(34) %
Total expenses	87,195	63,206	23,989	(38) %
Operating loss	(68,672)	(56,161)	(12,511)	(22) %
Other income (expense):				
Interest expense	(2,635)	(2,581)	(54)	(2) %
Foreign currency loss	(81)	(159)	78	49 %
Legal settlement loss	(7,975)	—	(7,975)	(100) %
Other income	1,409	354	1,055	298 %
Other expense, net	(9,282)	(2,386)	(6,896)	(289) %
Loss before income taxes	(77,954)	(58,547)	(19,407)	(33) %
Income tax benefit	260	83	177	213 %
Net loss	\$ (77,694)	\$ (58,464)	\$ (19,230)	(33) %

Product Revenue. Product revenue for the three months ended March 31, 2018 increased compared to the same period in the prior year primarily due to continued growth in sale 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 10.5% and

Table of Contents

10.8% of the transaction price recognized in the three months ended March 31, 2018 and 2017, respectively, and are summarized as follows:

	Three months ended March 31, 2018		Three months ended March 31, 2017	
	\$	% of Gross Sales	\$	% of Gross Sales
	(in thousands)		(in thousands)	
Transaction price	\$ 20,701	100.0%	\$ 7,902	100.0%
Variable considerations:				
Government rebates and chargebacks	1,379	6.6%	436	5.5%
Discounts and fees	799	3.9%	421	5.3%
Total variable considerations	2,178	10.5%	857	10.8%
Product revenue	\$ 18,523	89.5%	\$ 7,045	89.2%

**Cost of Sales – Product.** Product cost of sales for the three months ended March 31, 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 March 31, 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 March 31, 2018, as we depleted the majority of these inventories during the fourth quarter 2017.

**Cost of Sales – Intangible Asset Amortization.** In the three months ended March 31, 2018 and 2017, we recognized cost of sales of \$0.4 million associated with the amortization of capitalized milestone payments related to the FDA approval of Rubraca.

**Research and Development Expenses.** Research and development expenses increased during the three months ended March 31, 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 higher costs from increased enrollment in ARIEL4, our confirmatory ovarian cancer trials, and increased enrollment in our TRITON2 and TRITON3 studies for prostate cancer. In addition, 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.

Clinical trial costs for rociletinib were \$2.2 million lower than the first quarter of 2017 primarily due to the completion of patient enrollment 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 March 31, 2018 compared to the same period in the prior year primarily due to the increase of costs associated with building out the European infrastructure in anticipation of commercialization there.

**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 certain of our officers.

### 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 approximately \$94 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 approximately \$292 million, after deducting underwriting discounts and commissions and offering expenses. At March 31, 2018, we had cash, cash equivalents and available-for-sale securities totaling \$463.8 million.

Table of Contents

The following table sets forth the primary sources and uses of cash for the three months ended March 31, 2018 and 2017 (in thousands):

	Three months ended	
	March 31,	
	2018	2017
Net cash used in operating activities	\$ (100,635)	\$ (80,439)
Net cash provided by (used in) investing activities	9,783	(86,668)
Net cash provided by financing activities	514	226,898
Effect of exchange rate changes on cash and cash equivalents	254	72
Net (decrease) increase in cash and cash equivalents	\$ (90,084)	\$ 59,863

## 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 three months ended March 31, 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 provided by investing activities for the three months ended March 31, 2018 includes sales of available-for-sale securities of \$10.0 million. Net cash used in investing activities in the same period in the prior year was mainly the result of net purchases of available-for-sale securities of \$83.0 million in that period.

## Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2018 and 2017 includes \$0.5 million and \$5.7 million, respectively, received from employee stock option exercises. In addition, we completed the sale of \$221.2 million of common stock, net of issuance costs, during the three months ended March 31, 2017.

## 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 March 31, 2018, we had cash, cash equivalents and available-for-sale securities totaling \$463.8 million and total current liabilities of \$85.4 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 approximately \$94 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 approximately \$292 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, if approved by the EMA, in 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.

Our product supply costs will be approximately \$44 million in the second quarter of 2018 and will be approximately \$10 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 of approximately \$8 million in late 2018. Additionally, we will make one-time milestone payments to

Table of Contents

Pfizer of \$38.0 million in the second quarter of 2018 related to product approvals in December 2016 and April 2018 and potentially an additional \$20.0 million milestone payment in the second quarter if the Rubraca Marketing Authorization in Europe is granted prior to June 15, 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 March 31, 2018, we had cash, cash equivalents and available-for-sale securities of \$463.8 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 March 31, 2018, \$197.3 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 March 31, 2018, it would decrease the total US

Table of Contents

dollar purchase commitment under the Swiss Manufacturing and Services Agreement by approximately \$17.9 million. Similarly, a 10% weakening of the US dollar compared to the Swiss franc would increase the total US dollar purchase commitment by approximately \$21.9 million.

While we periodically hold foreign currencies, primarily Euro 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 both March 31, 2018 and December 31, 2017, approximately 1% 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 March 31, 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 March 31, 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 March 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



Table of Contents

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 January 22, 2016, the Electrical Workers Local #357 Pension and Health & Welfare Trusts, a purported shareholder of Clovis, filed a purported class action complaint (the "Electrical Workers Complaint") against Clovis and certain of its officers, directors, investors and underwriters in the Superior Court of the State of California, County of San Mateo (the "Electrical Workers Court"). The Electrical Workers Complaint purported to be asserted on behalf of a class of persons who purchased stock in the July 2015 Offering. The complaint asserted claims under certain provisions of the Securities Act of 1933 (the "Securities Act") relating to a July 2015 follow-on offering of Clovis securities (the "July 2015 Offering") based on substantially similar allegations to those asserted in the Medina Action. On June 30, 2016, the Electrical Workers Plaintiffs filed an amended complaint adding new allegations (the "Amended Complaint"). On April 10, 2018, the Court entered an order dismissing the Electrical Workers Action on the basis of the Medina Settlement.

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.

On January 31, 2017, the defendants filed a motion to stay the Antipodean action pending resolution of the Medina Action in the District of Colorado. Defendants also filed a motion to dismiss the Antipodean Amended Complaint on March 29, 2017. On March 14, 2017, the Clovis defendants and Antipodean participated in a mediation, which did not result in a settlement.

On August 8, 2017, the parties participated in a scheduled hearing on the defendants' motion to stay and motion to dismiss before Justice Masley of the New York Supreme Court, County of New York. At the hearing, Justice Masley granted the defendants' motion to stay. Per the Court's August 10, 2017 order, the defendants' motion to dismiss was held in abeyance and deemed submitted on November 1, 2017. On November 1, 2017, the defendants provided a status update to the Court regarding the outcome of the hearing. The update informed the Court that Antipodean had excluded itself from the Medina Settlement, as memorialized in the final judgment entered by the Medina Court.

On April 17, 2018, the parties participated in a Preliminary Conference, following which the Court entered a preliminary conference order, providing for, among other things, an end date for discovery of February 4, 2019.

On May 2, 2018, the Court issued an order denying the defendants' motion to dismiss. Defendants have 20 days from service of a copy of the order with notice of entry to answer the allegations in the Antipodean Amended Complaint.

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.

Table of Contents

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 August 2, 2018.

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.

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 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. On April 9, 2018, the Company received a "Wells Notice" letter from the staff of the SEC issued in connection with this investigation. Certain of our current and former officers also received Wells Notices.

The Wells Notices advise that the staff has made a preliminary determination to recommend to the SEC that it file an action against us and certain of our current and former officers regarding possible violations of Sections 17(a)(1), (2) and (3) of the Securities Act of 1933 and Sections 10(b) and 13(a) of the Securities Act of 1934 and Rules 10b-5(a), (b), and (c), 12b-20, and 13(a)-11 thereunder. The Wells Notices state that the SEC staff's recommendation may involve a civil injunctive action, public administrative proceeding, and/or cease-and-desist proceeding, and may seek remedies that include an injunction, cease-and-desist order, disgorgement, pre-judgment interest, and civil money penalties, and in the case of certain officers a bar from service as an officer or director of a public company.

Under SEC procedures, a recipient of a Wells Notice has an opportunity to respond in the form of a "Wells submission" that seeks to persuade the SEC that such an action should not be brought. The Company has provided to the SEC staff Wells submissions to further explain their views and beliefs that no enforcement action is warranted

Table of Contents

against the Company or any individuals associated with the Company. The receipt of the Wells Notice does not change the Company's beliefs that it has complied with all laws and regulations, and therefore, the Company intends to contest any charges that may be brought, though there can be no assurance that the defense will be successful.

Director Compensation Litigation

On May 10, 2017, John Solak, a purported shareholder of the Company, filed a shareholder derivative complaint in the Court of Chancery of the State of Delaware (the "Solak Complaint") against certain directors and an officer of the Company. The Solak Complaint generally alleged that the defendants breached their fiduciary duties owed to the Company by adopting a compensation plan that overcompensated the non-employee director defendants, in relation to companies of comparable market capitalization and size. The Solak Complaint also alleged claims of waste of corporate assets and unjust enrichment. The Solak Complaint sought, among other things, an award of money damages and the imposition of corporate governance reforms.

On February 26, 2018, the defendants entered into a stipulation of compromise and settlement with plaintiff that is intended to settle the Solak action. The proposed settlement is subject to Court approval upon the conclusion of a settlement hearing concerning the fairness of the terms of the proposed settlement, which has been scheduled for May 30, 2018 at 2:00 p.m.

In accordance with the terms of the proposed settlement, the Company will present a new non-employee director compensation policy for shareholder vote at the next annual shareholder meeting. Under the proposed new non-employee director compensation policy, annual base compensation for incumbent non-employee directors would be set at \$400,000 for a three-year period. Additionally, the proposed policy sets annual base compensation for new non-employee directors at \$600,000 for a three-year period and includes fixed annual fees for board and committee service. The proposed settlement also sets forth a number of corporate governance reforms that the Company will undertake, including, enhanced proxy disclosures, the codification of the Company's stock ownership guidelines for directors, and enhanced disclosure requirements for certain forms of director compensation. While no cash payments will be made to investors as part of the proposed settlement, plaintiff's counsel is expected to file a fee application, which the Company has agreed not to oppose up to \$395,000. The proposed settlement contains no admission of wrongdoing.

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 Part I, Item 1A of our most recent Annual Report on Form 10-K, 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.

We are the subject of an ongoing investigation by the SEC, and the SEC's staff has notified us that the staff intends to recommend that the SEC bring a civil action against us and certain of our current and former officers.

As previously disclosed, the Company has received inquiries and requests for information from governmental agencies, including the U.S. Securities and Exchange Commission, 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. On April 9, 2018, we received a "Wells Notice" letter from the staff of the SEC, issued in connection with this investigation. Certain of our current and former officers also received Wells Notices.

The Wells Notices provide notification of the SEC staff's determination that it intends to recommend to the SEC that it bring a civil action against us and certain of our current and former officers regarding possible violations of Sections 17(a)(1), (2) and (3) of the Securities Act of 1933 and Sections 10(b) and 13(a) of the Securities Exchange Act of 1934 and Rules 10b-5(a), (b), and (c), 12b-20, and 13a-11 thereunder. The Wells Notices state that the SEC staff's recommendation may involve a civil injunctive action, public administrative proceeding, and/or cease-and-desist proceeding, and may seek remedies that include an injunction, a cease-and-desist order, disgorgement, pre-judgment interest, and civil money penalties, and in the case of certain officers a bar from service as an officer or director of a public company.

Table of Contents

Under SEC procedures, a recipient of a Wells Notice has an opportunity to respond in the form of a “Wells submission” that seeks to persuade the SEC that such an action should not be brought. The Company has provided to the SEC staff Wells submissions to further explain their views and beliefs that no enforcement action is warranted against the Company or any individuals associated with the Company. The receipt of the Wells Notice does not change the Company’s beliefs that it has complied with all laws and regulations, and therefore, the Company intends to contest any charges that may be brought.

We cannot predict the scope, timing, or other outcomes of the investigation or civil actions, if any, and other matters referred to herein, or the ultimate outcome of any proceedings that might be initiated which may result in the imposition of fines and penalties and disgorgement, which may be significant, and other remedies and sanctions, any of which could impact our ability to obtain financing, our stock price, or the ability to attract or retain key employees. Furthermore, regardless of the outcome of the investigation, the investigation itself has resulted, and may continue to result, in substantial uninsured costs, use of resources and diversion of the attention of management and other employees, which could adversely affect our business. Furthermore, publicity surrounding any civil action that may be brought by the SEC, even if ultimately resolved favorably for us, could have an adverse impact on our reputation, business, financial condition, results of operations or cash flows. We are currently incurring legal expenses in connection with this matter and anticipate that we will be required to indemnify certain current and former officers with respect thereto. We will not receive any further contributions from our insurance carriers for any amounts (including damages, settlement costs or legal fees) relating to these matters. We cannot predict what impact, if any, these matters may have on our business, financial condition, results of operations and cash flow, though they may be material.

Servicing our long-term debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

In September 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 to the Company of \$278.3 million after deducting offering expenses. In April 2018, we completed a public offering of \$300.0 million aggregate principal amount of 1.25% convertible senior notes due 2025 (the “2025 Notes” and together with the 2021 Notes, the “Notes”), resulting in net proceeds to the Company of \$292.0 million after deducting offering expenses. 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. Interest is payable on the 2021 Notes semi-annually, and the 2021 Notes mature on September 15, 2021, unless redeemed, repurchased or converted prior to that date. In addition, if, as defined by the terms of the indenture, a fundamental change occurs, holders of the 2021 Notes may require us to repurchase for cash all or any portion of their 2021 Notes at a purchase price equal to 100% of the principal amount of the 2021 Notes to be repurchased plus accrued and unpaid interest, if any, to, but excluding, the fundamental change repurchase date. 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. Interest is payable on the 2025 Notes semi-annually, and the 2025 Notes mature on May 1, 2025, unless redeemed, repurchased or converted prior to that date. In addition, if, as defined by the terms of the indenture, a fundamental change occurs, holders of the 2025 Notes may require us to repurchase for cash all or any portion of their Notes at a purchase price equal to 100% of the principal amount of the Notes to be

repurchased plus accrued and unpaid interest, if any, to, but excluding, the fundamental change repurchase date.

Our ability to make scheduled payments of interest and principal on the Notes, or to pay the repurchase price for the Notes on a fundamental change, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. We may not have sufficient cash in the future to service our debt. If we are unable to generate such cash flow or secure additional sources of funding, we may be required to adopt one or more alternatives, such as restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

We may not be able to raise the funds necessary to repurchase the Notes upon a fundamental change, and our future debt may contain limitations on our ability to repurchase the Notes.

If we undergo a fundamental change, as defined in the indenture, prior to the maturity date of the Notes, holders may require us to repurchase for cash all or any portion of the Notes at a fundamental change repurchase price equal to



Table of Contents

100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. We may not have or be able to borrow the funds required to repurchase the Notes on the fundamental change repurchase date. In addition, our ability to repurchase the Notes may otherwise be limited by law, regulatory authority or agreements governing our future indebtedness. Our failure to repurchase the Notes at a time when the repurchase is required by the indenture would constitute a default under the indenture. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes when required.

We may incur substantially more debt or take other actions which would intensify the risks discussed above; and we may not generate cash flow from operations in the future sufficient to satisfy our obligations under the Notes and any future indebtedness we may incur.

We may incur substantial additional debt in the future, subject to the restrictions contained in any debt instruments that we enter into in the future, some of which may be secured debt. We are not restricted under the terms of the indenture governing the Notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture governing the Notes that could have the effect of diminishing our ability to make payments on the Notes when due. Our ability to refinance the Notes or future indebtedness will depend on the capital markets and our financial condition at such time. In addition, agreements that govern any future indebtedness that we may incur may contain financial and other restrictive covenants that will limit our ability to engage in activities that may be in our long-term best interests. Our failure to comply with those covenants could result in an event of default that, if not cured or waived, could result in the acceleration of some or all of our debt.

Provisions in the indenture could delay or prevent an otherwise beneficial takeover of us.

Certain provisions in the Notes and the indentures governing the Notes could make a third party attempt to acquire us more difficult or expensive. For example, if a takeover constitutes a fundamental change, then holders will have the right to require us to repurchase their notes for cash. In addition, if a takeover constitutes a make-whole fundamental change, then we may be required to temporarily increase the conversion rate. In either case, and in other cases, our obligations under the Notes and the indentures governing the Notes could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management, including in a transaction that holders or holders of our common stock may view as favorable.

Other than the risk factors discussed above, 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. 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.

37

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Table of Contents

ITEM 6.EXHIBITS

INDEX TO EXHIBITS

o	
Exhibit	
Number	Exhibit Description
3.1(5)	<u>Amended and Restated Certificate of Incorporation of Clovis Oncology, Inc.</u>
3.2(5)	<u>Amended and Restated Bylaws of Clovis Oncology, Inc.</u>
4.1(3)	<u>Form of Common Stock Certificate of Clovis Oncology, Inc.</u>
4.2(8)	<u>Indenture dated as of September 9, 2014, by and between Clovis Oncology, Inc. and The Bank of New York Mellon Trust Company, N.A.</u>
4.3(16)	<u>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</u>
4.4(16)	<u>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.</u>
10.1*(4)	<u>Amended and Restated Strategic License Agreement, dated as of June 16, 2011, by and between Clovis Oncology, Inc. and Avila Therapeutics, Inc.</u>
10.2*(4)	<u>License Agreement, dated as of June 2, 2011, by and between Clovis Oncology, Inc. and Pfizer Inc.</u>
10.3+(1)	<u>Clovis Oncology, Inc. 2009 Equity Incentive Plan.</u>
10.4+(4)	<u>Clovis Oncology, Inc. 2011 Stock Incentive Plan.</u>
10.5+(1)	<u>Form of Clovis Oncology, Inc. 2009 Equity Incentive Plan Stock Option Agreement.</u>
10.6+(4)	<u>Form of Clovis Oncology, Inc. 2011 Stock Incentive Plan Stock Option Agreement.</u>
10.7+(3)	<u>Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Patrick J. Mahaffy.</u>
10.8+(3)	<u>Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Gillian C. Ivers-Read.</u>
10.9+(1)	<u>Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Paul Klingenstein.</u>

- 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.

Table of Contents

- 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+(4) Clovis Oncology, Inc. 2011 Employee Stock Purchase Plan.
- 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.
- 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.

39

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Table of Contents

- 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
- 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 March 31, 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.
- + 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.

40

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Table of Contents

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: May 9, 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