

Clovis Oncology, Inc.
Form 10-Q
August 03, 2017
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2017.

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

For the transition period from to .

Commission file number: 001-35347

Clovis Oncology, Inc.

(Exact name of Registrant as specified in its charter)

Edgar Filing: Clovis Oncology, Inc. - Form 10-Q

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)

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.

Edgar Filing: Clovis Oncology, Inc. - Form 10-Q

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 July 28, 2017 was 48,879,354.

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 and six months ended June 30, 2017 and 2016</u>	3
<u>Consolidated Balance Sheets — as of June 30, 2017 and December 31, 2016</u>	4
<u>Consolidated Statements of Cash Flows — for the six months ended June 30, 2017 and 2016</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>	21
<u>ITEM 3. Quantitative and Qualitative Disclosures About Market Risk</u>	33
<u>ITEM 4. Controls and Procedures</u>	33
<u>PART II. Other Information</u>	35
<u>ITEM 1. Legal Proceedings</u>	35
<u>ITEM 1A. Risk Factors</u>	37
<u>ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	38
<u>ITEM 3. Defaults Upon Senior Securities</u>	38
<u>ITEM 4. Mine Safety Disclosures</u>	38
<u>ITEM 5. Other Information</u>	38
<u>ITEM 6. Exhibits</u>	38
<u>SIGNATURES</u>	42

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 June 30,		Six months ended June 30,	
	2017	2016	2017	2016
	(in thousands, except per share amounts)			
Product revenue, net	\$ 14,620	\$ —	\$ 21,665	\$ —
Operating expenses:				
Cost of sales - product	2,730	—	3,893	—
Cost of sales - intangible asset amortization	372	—	743	—
Research and development	33,108	67,729	65,555	142,337
Selling, general and administrative	36,149	9,552	65,373	19,379
Acquired in-process research and development	—	300	—	300
Impairment of intangible asset	—	104,517	—	104,517
Change in fair value of contingent purchase consideration	—	(25,452)	—	(24,936)
Total expenses	72,359	156,646	135,564	241,597
Operating loss	(57,739)	(156,646)	(113,899)	(241,597)
Other income (expense):				
Interest expense	(2,598)	(2,106)	(5,178)	(4,210)
Foreign currency gain (loss)	76	183	(83)	(368)
Legal settlement loss, net of insurance receivable	(117,000)	—	(117,000)	—
Other income	594	196	946	221
Other income (expense), net	(118,928)	(1,727)	(121,315)	(4,357)
Loss before income taxes	(176,667)	(158,373)	(235,214)	(245,954)
Income tax benefit	1,281	29,059	1,365	33,240
Net loss	\$ (175,386)	\$ (129,314)	\$ (233,849)	\$ (212,714)
Other comprehensive income:				
Foreign currency translation adjustments, net of tax	2,812	(1,381)	3,279	2,132
	—	48	(5)	278

Edgar Filing: Clovis Oncology, Inc. - Form 10-Q

Net unrealized gain (loss) on available-for-sale securities, net of tax

Other comprehensive income (loss)	2,812	(1,333)	3,274	2,410
Comprehensive loss	\$ (172,574)	\$ (130,647)	\$ (230,575)	\$ (210,304)

Loss per basic and diluted common share:

Basic and diluted net loss per common share	\$ (3.88)	\$ (3.37)	\$ (5.24)	\$ (5.54)
---	-----------	-----------	-----------	-----------

Basic and diluted weighted average common shares outstanding

	45,176	38,389	44,610	38,375
--	--------	--------	--------	--------

See accompanying Notes to Unaudited Consolidated Financial Statements.

Table of Contents

CLOVIS ONCOLOGY, INC.

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except for share amounts)

	June 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 491,786	\$ 216,186
Accounts receivable, net	1,143	121
Insurance receivable	25,000	—
Inventories	6,478	—
Available-for-sale securities	179,744	49,997
Prepaid research and development expenses	4,854	6,427
Other current assets	6,766	6,679
Total current assets	715,771	279,410
Property and equipment, net	4,155	4,440
Intangible assets, net	20,304	21,047
Goodwill	62,018	57,192
Other assets	47,648	2,468
Total assets	\$ 849,896	\$ 364,557
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 13,360	\$ 10,912
Accrued research and development expenses	21,158	35,198
Milestone liability	21,011	20,062
Accrued liability for legal settlement	142,000	—
Other accrued expenses	21,848	19,487
Total current liabilities	219,377	85,659
Deferred income taxes, net	632	—
Convertible senior notes	281,761	281,126
Deferred rent, long-term	4,333	1,406
Total liabilities	506,103	368,191
Commitments and contingencies (Note 14)		
Stockholders' equity (deficit):		
Preferred stock, par value \$0.001 per share; 10,000,000 shares authorized, no shares issued and outstanding at June 30, 2017 and December 31, 2016	—	—
Common stock, \$0.001 par value per share, 100,000,000 shares authorized at June 30, 2017 and December 31, 2016; 48,843,131 and 38,724,090 shares issued and outstanding at June 30, 2017 and December 31, 2016 respectively	49	39
Additional paid-in capital	1,752,943	1,174,950

Edgar Filing: Clovis Oncology, Inc. - Form 10-Q

Accumulated other comprehensive loss	(44,306)	(47,580)
Accumulated deficit	(1,364,893)	(1,131,043)
Total stockholders' equity (deficit)	343,793	(3,634)
Total liabilities and stockholders' equity (deficit)	\$ 849,896	\$ 364,557

See accompanying Notes to Unaudited Consolidated Financial Statements.

4

Table of Contents

CLOVIS ONCOLOGY, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Six months ended June 30,	
	2017	2016
Operating activities		
Net loss	\$ (233,849)	\$ (212,714)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	19,563	20,542
Depreciation and amortization	1,281	550
Amortization of premiums and discounts on available-for-sale securities	245	151
Amortization of debt issuance costs	635	616
Legal settlement loss, net of insurance receivable	117,000	—
Impairment of intangible asset	—	104,517
Change in fair value of contingent purchase consideration	—	(24,661)
Loss on disposal of property and equipment	—	170
Deferred income taxes	(1,266)	(33,207)
Changes in operating assets and liabilities:		
Accounts receivable	(1,023)	—
Inventory	(6,478)	—
Prepaid and accrued research and development expenses	(15,162)	(12,772)
Other operating assets	(36,855)	1,260
Accounts payable	3,202	3,608
Other accrued expenses	3,166	270
Net cash used in operating activities	(149,541)	(151,670)
Investing activities		
Purchases of property and equipment	(249)	(756)
Deposits for purchases of property and equipment	(2,515)	—
Purchases of available-for-sale securities	(180,000)	—
Maturities of available-for-sale securities	50,000	100,000
Acquired in-process research and development - milestone payment	(1,100)	—
Net cash (used in) provided by investing activities	(133,864)	99,244
Financing activities		
Proceeds from the sale of common stock, net of issuance costs	546,170	—
Proceeds from the exercise of stock options and employee stock purchases	12,270	1,943
Net cash provided by financing activities	558,440	1,943
Effect of exchange rate changes on cash and cash equivalents	565	106
Increase (decrease) in cash and cash equivalents	275,600	(50,377)
Cash and cash equivalents at beginning of period	216,186	278,756
Cash and cash equivalents at end of period	\$ 491,786	\$ 228,379

Edgar Filing: Clovis Oncology, Inc. - Form 10-Q

Supplemental disclosure of cash flow information:

Cash paid for interest	\$ 3,594	\$ 3,594
Non-cash investing and financing activities:		
Vesting of restricted stock units	\$ 2,627	\$ 34

See accompanying Notes to Unaudited Consolidated Financial Statements.

5

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 other international markets. We have and intend to continue to license or acquire rights to oncology compounds in all stages of 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.

During the second quarter of 2016, we completed the submission of our New Drug Application (“NDA”) with the U.S. Food and Drug Administration (“FDA”) for approval of rucaparib in the U.S. 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. We began selling Rubraca in the U.S. in the fourth quarter of 2016. Our Marketing Authorization Application (MAA) for rucaparib that was submitted to the European Medicines Agency (“EMA”) for an ovarian cancer treatment indication comparable to what was approved by the FDA is currently under review. We anticipate an opinion from the Committee for Medicinal Products for Human Use (CHMP) in late 2017, and, pending a favorable opinion from the CHMP, a potential approval would follow during the first quarter of 2018. Following a potential approval for the treatment indication, we intend to submit a supplemental application for the second-line or later maintenance treatment indication, for which we anticipate a potential approval during the third quarter of 2018.

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, 2016 (“2016 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.

Table of Contents

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 January 2017, we sold 5,750,000 shares of our common stock in a public offering at \$41.00 per share. The net proceeds from the offering were \$221.2 million, after deducting underwriting discounts and commissions and offering expenses. In June 2017, we sold 3,920,454 shares of our common stock in a public offering at \$88.00 per share. The net proceeds from the offering were \$324.9 million, after deducting underwriting discounts and commissions and offering expenses. We intend to use the net proceeds of the offerings for general corporate purposes, including sales and marketing expenses associated with Rubraca in the United States and, 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.

2. Summary of Significant Accounting Policies

Revenue Recognition

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 resell 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.

Revenues from product sales are recognized when persuasive evidence of an arrangement exists, delivery has occurred and title of the product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer has been reasonably assured and all performance obligations have been met and returns and allowances can be reasonably estimated. Revenue is recorded net of estimated rebates, chargebacks, discounts and other deductions as well as estimated product returns (collectively, "sales deductions"). We only recognize revenue on product sales once the product is resold to the patient or healthcare provider by the specialty distributor or specialty pharmacy provider, therefore reducing the significance of estimates made for product returns. To date, we have not had any 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. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, certain of the manufacturing costs of Rubraca units recognized as revenue during the three and six months ended June 30, 2017 were expensed prior to the December 19, 2016 FDA approval, and therefore are not included in costs of sales during the current period. We expect cost of sales to increase in relation to product revenues as we deplete these inventories and we expect to use the remaining pre-commercialization inventory for product sales through the third quarter of 2017.

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.

Table of Contents

Inventory

Inventories are stated at the lower of cost or estimated net realizable value, on a first-in, first-out, or 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 2016 Form 10-K.

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 (“ASC”) are communicated through issuance of an Accounting Standards Update (“ASU”).

Recently Issued Accounting Standards

In May 2014, the FASB issued ASU No. 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 expect to apply the new standard using the modified retrospective method upon its adoption date on January 1, 2018.

We have begun a comprehensive scoping process to identify and disaggregate all revenue streams that may be impacted by the adoption of ASC 606. To date, we have examined our revenue recognition policy specific to revenue streams from representative contracts governing product sales from Rubraca and have come to preliminary conclusions on the impact of the new standard using the 5-step process prescribed by ASC 606. However, a detailed analysis of individual contracts representative of each of the revenue streams planned for the assessment phase of our implementation plan may impact these preliminary conclusions. We are continuing to assess ASC 606's impact on our financial statements.

In February 2016, the FASB issued ASU No. 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 application 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 January 2017, the FASB issued ASU No. 2017-01, "Clarifying the Definition of a Business," which clarifies the definition of a business in ASC 805. The guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early application is permitted. Currently, there is no impact to our consolidated financial statements and related disclosures, but we will adopt on January 1, 2018 for any business combinations and will consider adopting early for any acquisitions prior to January 1, 2018.

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.

Table of Contents

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 annual reporting periods, including interim period within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period. We are currently evaluating the impact the standard may have on our consolidated financial statements and related disclosures should we have a modification to our share-based payment awards in the future.

3. Financial Instruments and Fair Value Measurements

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

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

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

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

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

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

	Balance	Level 1	Level 2	Level 3
June 30, 2017				
Assets:				
Money market	\$ 450,588	\$ 450,588	\$ —	\$ —
U.S. treasury securities	179,744	—	179,744	—
Total assets at fair value	\$ 630,332	\$ 450,588	\$ 179,744	\$ —

Edgar Filing: Clovis Oncology, Inc. - Form 10-Q

December 31, 2016

Assets:

Money market	\$ 202,361	\$ 202,361	\$ —	\$ —
U.S. treasury securities	49,997	—	49,997	—
Total assets at fair value	\$ 252,358	\$ 202,361	\$ 49,997	\$ —

There were no transfers between the Level 1 and Level 2 categories or into or out of the Level 3 category during the three and six months ended June 30, 2017.

Financial instruments not recorded at fair value include our convertible senior notes. At June 30, 2017, the carrying amount of the convertible senior notes was \$281.8 million, which represents the aggregate principal amount net of remaining debt issuance costs, and the fair value was \$487.0 million. The fair value was determined using Level 2 inputs based on the indicative pricing published by certain investment banks or trading levels of the 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.

Table of Contents

4. Available-for-Sale Securities

As of June 30, 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	\$ 179,758	\$ —	\$ (14)	\$ 179,744

As of December 31, 2016, 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	\$ 50,004	\$ —	\$ (7)	\$ 49,997

As of June 30, 2017, the fair value and gross unrealized losses of available-for-sale securities that have been in a continuous unrealized loss position for less than 12 months were as follows (in thousands):

	Aggregate Fair Value	Gross Unrealized Losses
U.S. treasury securities	\$ 179,744	\$ (14)

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

As of June 30, 2017, 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	\$ 179,758	\$ 179,744
Due in one year to two years	—	—
Total	\$ 179,758	\$ 179,744

5. Inventories

We generally have two categories of inventory: work-in-process and finished goods. As of June 30, 2017, the carrying value of all of our product inventory, which consisted only of the Rubraca API, was categorized as work-in-process. The costs related to our finished goods on-hand as of June 30, 2017 were expensed as incurred prior to the commercialization of Rubraca on December 19, 2016. The carrying value of our inventory as of December 31, 2016 was zero.

At June 30, 2017, other assets on the Consolidated Balance Sheets includes a cash deposit of \$31.8 million made to a manufacturer for the purchase of inventory which we do not expect to be commercially consumed within the next twelve months.

Table of Contents

6. Other Current Assets

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

	June 30, 2017	December 31, 2016
Receivable from partners	\$ 52	\$ 2,882
Prepaid insurance	817	1,234
Prepaid expenses - other	3,012	2,109
Receivable - other	2,750	364
Other	135	90
Total	\$ 6,766	\$ 6,679

7. Intangible Assets and Goodwill

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

	June 30, 2017	December 31, 2016
Intangible asset - milestones	\$ 21,100	\$ 21,100
Accumulated amortization	(796)	(53)
Total intangible asset, net	\$ 20,304	\$ 21,047

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 \$0.8 million related to capitalized milestone payments during the three and six months ended June 30, 2017, respectively, included in cost of sales – intangible asset amortization at the Consolidated Statements of Operations and Comprehensive Loss. There was no amortization expense during the three and six months ended June 30, 2016.

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

2017 (remaining)	\$ 743
2018	1,486
2019	1,486
2020	1,486
2021	1,486
Thereafter	13,617
	\$ 20,304

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, 2016	\$ 57,192
Change in foreign currency gains and losses	4,826
Balance at June 30, 2017	\$ 62,018

Table of Contents

8. Other Accrued Expenses

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

	June 30, 2017	December 31, 2016
Accrued personnel costs	\$ 11,928	\$ 15,850
Accrued interest payable	2,097	2,096
Income tax payable	662	556
Accrued corporate legal fees and professional services	1,072	589
Accrued royalties	2,551	—
Accrued sales deductions	1,003	—
Accrued expenses - other	2,535	396
Total	\$ 21,848	\$ 19,487

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 “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 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 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 Notes will mature on September 15, 2021, unless earlier converted, redeemed or repurchased.

Holders may convert all or any portion of the 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 Notes, equivalent to a conversion price of approximately \$61.88 per share. The conversion rate is subject to adjustment upon the occurrence of certain events described in the indenture, 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 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 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 Notes to be redeemed plus accrued and unpaid interest to, but excluding, the redemption date. No sinking fund is provided for 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 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The Notes rank senior in right of payment to any of our indebtedness that is expressly subordinated in right of payment to the 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 Notes, we incurred \$9.2 million of debt issuance costs. The debt issuance costs are presented as a deduction from convertible senior notes on the Consolidated Balance Sheets and are amortized as interest expense over the expected life of the Notes using the effective interest method. We determined the expected

Table of Contents

life of the debt was equal to the seven-year term of the Notes. As of June 30, 2017 and December 31, 2016, the balance of unamortized debt issuance costs was \$5.7 million and \$6.4 million, respectively.

The following table sets forth total interest expense recognized during the three and six months ended June 30, 2017 and 2016 (in thousands):

	Three months ended		Six months ended	
	June 30, 2017	2016	June 30, 2017	2016
Contractual interest expense	\$ 1,797	\$ 1,797	\$ 3,594	\$ 3,594
Accretion of interest on milestone liability	483	—	949	—
Amortization of debt issuance costs	318	309	635	616
Total interest expense	\$ 2,598	\$ 2,106	\$ 5,178	\$ 4,210

10. Stockholders' Equity

Common Stock

In January 2017, we sold 5,750,000 shares of our common stock in a public offering at \$41.00 per share. The net proceeds from the offering were \$221.2 million, after deducting underwriting discounts and commissions and offering expenses. In June 2017, we sold 3,920,454 shares of our common stock in a public offering at \$88.00 per share. The net proceeds from the offering were \$324.9 million, after deducting underwriting discounts and commissions and offering expenses.

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

Accumulated Other Comprehensive Loss

Edgar Filing: Clovis Oncology, Inc. - Form 10-Q

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 June 30, 2017 and 2016 as follows (in thousands):

	Foreign Currency		Unrealized		Total Accumulated	
	Translation Adjustments		(Losses) Gains		Other Comprehensive	
	2017	2016	2017	2016	2017	2016
Balance at April 1,	\$ (46,967)	\$ (43,564)	\$ (151)	\$ (153)	\$ (47,118)	\$ (43,717)
Other comprehensive income (loss)	4,451	(2,170)	(3)	76	4,448	(2,094)
Total before tax	(42,516)	(45,734)	(154)	(77)	(42,670)	(45,811)
Tax effect	(1,639)	789	3	(28)	(1,636)	761
Balance at June 30,	\$ (44,155)	\$ (44,945)	\$ (151)	\$ (105)	\$ (44,306)	\$ (45,050)

The changes in accumulated balances related to each component of other comprehensive income (loss) are summarized for the six months ended June 30, 2017 and 2016 as follows (in thousands):

	Foreign Currency		Unrealized		Total Accumulated	
	Translation Adjustments		(Losses) Gains		Other Comprehensive	
	2017	2016	2017	2016	2017	2016
Balance at December 31,	\$ (47,434)	\$ (47,077)	\$ (146)	\$ (383)	\$ (47,580)	\$ (47,460)
Other comprehensive income (loss)	5,186	3,410	(8)	441	5,178	3,851
Total before tax	(42,248)	(43,667)	(154)	58	(42,402)	(43,609)
Tax effect	(1,907)	(1,278)	3	(163)	(1,904)	(1,441)
Balance at June 30,	\$ (44,155)	\$ (44,945)	\$ (151)	\$ (105)	\$ (44,306)	\$ (45,050)

Table of Contents

The period change in each of the periods presented was primarily due to the currency translation of the goodwill and deferred income taxes associated with the acquisition of EOS in November 2013. There were no reclassifications out of accumulated other comprehensive loss in each of the three and six months ended June 30, 2017 and 2016.

11. Share-Based Compensation

Share-based compensation expense for all equity based programs, including stock options, restricted stock units and the employee stock purchase plan, for the three and six months ended June 30, 2017 and 2016 was recognized in the accompanying Consolidated Statements of Operations as follows (in thousands):

	Three months ended		Six months ended	
	June 30, 2017	2016	June 30, 2017	2016
Research and development	\$ 4,825	\$ 6,615	\$ 8,991	\$ 13,924
Selling, general and administrative	5,792	2,962	10,572	6,618
Total share-based compensation expense	\$ 10,617	\$ 9,577	\$ 19,563	\$ 20,542

We did not recognize a tax benefit related to share-based compensation expense during the three and six months ended June 30, 2017 and 2016, respectively, as we maintain net operating loss carryforwards and have established a valuation allowance against the entire net deferred tax asset as of June 30, 2017.

Stock Options

The following table summarizes the activity relating to our options to purchase common stock for the six months ended June 30, 2017:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (Thousands)
Outstanding at December 31, 2016	5,520,482	\$ 42.00		

Edgar Filing: Clovis Oncology, Inc. - Form 10-Q

Granted	778,700			
Exercised	(372,464)			
Forfeited	(199,985)			
Outstanding at June 30, 2017	5,726,733	\$ 45.43	7.6	\$ 276,451
Vested and expected to vest at June 30, 2017	5,364,276	\$ 45.30	7.4	\$ 259,650
Vested and exercisable at June 30, 2017	2,935,211	\$ 44.63	6.2	\$ 143,983

The aggregate intrinsic value in the table above represents the pretax intrinsic value, based on our closing stock price of \$93.63 as of June 30, 2017, which would have been received by the option holders had all option holders with in-the-money options exercised their options as of that date.

The following table summarizes information about our stock options as of and for the three and six months ended June 30, 2017 and 2016 (in thousands):

	Three months ended		Six months ended	
	June 30, 2017	2016	June 30, 2017	2016
Weighted-average grant date fair value per share	\$ 44.94	\$ 11.01	\$ 46.53	\$ 14.65
Intrinsic value of options exercised	\$ 4,759	\$ 578,525	\$ 14,284	\$ 624,925
Cash received from stock option exercises	\$ 5,439	\$ 352,423	\$ 11,113	\$ 407,523

As of June 30, 2017, the unrecognized share-based compensation expense related to unvested options, adjusted for expected forfeitures, was \$83.4 million and the estimated weighted-average remaining vesting period was 2.6 years.

Table of Contents

Restricted Stock

During 2016, we issued restricted stock units (“RSUs”) to certain employees under the 2011 Stock Incentive Plan. The RSUs vest either (i) over two years, with 50% vesting one year from the date of grant and the remaining 50% vesting two years from the date of grant or (ii) 25% vest one year from the date of grant with the remaining RSUs vesting ratably each subsequent quarter over the following three years, as defined in the grant agreement. Vested RSUs are payable in shares of our common stock at the end of the vesting period. RSUs are measured based on the fair value of the underlying stock on the grant date. The minimum statutory tax on the value of common stock shares issued to employees upon vesting are paid by us through the sale of registered shares of our common stock.

The following table summarizes the activity relating to our unvested RSUs for the six months ended June 30, 2017:

	Number of Units	Weighted Average Grant Date Fair Value
Unvested at December 31, 2016	562,458	\$ 24.70
Granted	214,984	61.67
Vested	(44,443)	19.37
Forfeited	(27,177)	24.08
Unvested as of June 30, 2017	705,822	\$ 36.32
Expected to vest after June 30, 2017	604,394	\$ 35.81

As of June 30, 2017, the unrecognized share-based compensation expense related to unvested RSUs, adjusted for expected forfeitures, was \$18.5 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 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.

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 \$69.75 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

Table of Contents

met, the majority of which relate to annual sales targets of \$500.0 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. The FDA approval of rucaparib on December 19, 2016 resulted in a \$0.35 million milestone obligation to AstraZeneca as required by the license agreement, which was paid in the first quarter of 2017. This payment was recognized in intangible assets and will be amortized over the estimated remaining useful life of rucaparib. AstraZeneca will also 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 2016 Form 10-K for additional details). We and Les Laboratoires Servier (“Servier”) are developing lucitanib pursuant to a global development plan agreed to between the parties. Servier is responsible for all of the global development costs for lucitanib up to €80.0 million. Cumulative global development costs in excess of €80.0 million, if any, will be shared equally between us and Servier. We recorded a \$0.1 million and \$1.3 million receivable at June 30, 2017 and December 31, 2016, respectively, for the reimbursable development costs incurred under the global development plan, which is included in other current assets on the Consolidated Balance Sheets. For the three months ending June 30, 2017 and 2016, we incurred \$0.0 million and \$2.6 million, respectively, in research and development costs and recorded reductions in research and development expense of \$0.1 million and \$2.8 million, respectively, for reimbursable development costs due from Servier. For the six months ending June 30, 2017 and 2016, we incurred \$0.9 million and \$6.2 million, respectively, in research and development costs and recorded reductions in research and development expense of \$1.0 million and \$6.4 million, respectively, for reimbursable development costs due from Servier.

During the second quarter of 2016, we and Servier agreed to discontinue the development of lucitanib for breast cancer and lung cancer and are continuing to evaluate, what, if any, further development of lucitanib will be pursued. Based on current estimates, we expect to complete the committed on-going development activities in 2017 and expect 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.

13. Net Loss Per Common Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common share equivalents outstanding using the treasury-stock method for the stock options and RSUs and the if-converted method for the 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 and Six months ended June 30,	
	2017	2016
Common shares under option	6,373	455
Convertible senior notes	4,646	4,646
Total potential dilutive shares	11,019	5,101

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

Table of Contents

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 \$21.0 million and \$20.1 million are recorded on our Consolidated Balance Sheets at June 30, 2017 and December 31, 2016, 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 June 30, 2017, \$183.6 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.

On November 19, 2015, Sonny P. Medina, a purported Clovis shareholder, filed a purported shareholder class action complaint in the United States District Court for the District of Colorado (the “Medina Complaint”). The Medina Complaint purported to be asserted on behalf of a class of persons who purchased Clovis stock between May 20, 2014 and November 13, 2015, and it generally alleged that Clovis and certain of its officers violated federal securities laws by making allegedly false and misleading statements regarding the progress toward FDA approval and the potential for market success of rociletinib.

Throughout November and December 2015, three other purported shareholders filed similar purported class actions concerning alleged misstatements about rociletinib. On January 19, 2016, a number of motions were filed seeking to consolidate the shareholder class actions into one matter and for appointment of a lead plaintiff. On February 18,

2016, the Medina Court consolidated the various actions into a single proceeding and appointed M. Arkin (1999) LTD and Arkin Communications LTD (the “Arkin Plaintiffs”) as the lead plaintiffs and Bernstein Litowitz Berger & Grossmann LLP as lead counsel for the putative class.

The Arkin Plaintiffs filed a consolidated complaint on May 6, 2016 (the “Consolidated Complaint”). The Consolidated Complaint named as defendants the Company and certain of its current and former officers (the “Clovis Defendants”), certain underwriters (the “Underwriter Defendants”) for a Company follow-on offering conducted in July 2015 (the “July 2015 Offering”), and certain Company venture capital investors (the “Venture Capital Defendants”). The Consolidated Complaint alleged that defendants violated particular sections of the Securities Exchange Act of 1934 (the “Exchange Act”) and the Securities Act of 1933 (the “Securities Act”). The purported misrepresentations and omissions concerned allegedly misleading statements about rociletinib. The consolidated action was purportedly brought on behalf of investors who purchased the Company’s securities between May 31, 2014 and April 7, 2016 (with respect to the Exchange Act claims) and investors who purchased the Company’s securities pursuant or traceable to the July 2015 Offering (with respect to the Securities Act claims). The Consolidated Complaint sought unspecified compensatory and recessionary damages.

The Clovis Defendants, the Underwriter Defendants and the Venture Capital Defendants filed motions to dismiss on July 27, 2016. On February 9, 2017, the Medina Court issued an opinion and order granting in part and denying in part the Clovis Defendants’ motion to dismiss, granting in part and denying in part the Underwriter Defendants’ motion to dismiss, and granting the Venture Capital Defendants’ motion to dismiss. On February 22, 2017, the Arkin Plaintiffs

Table of Contents

filed an amended consolidated class action complaint, directed solely at repleading its Section 12(a) claims against the Underwriter Defendants.

On March 14, 2017, the Clovis Defendants and the Arkin Plaintiffs participated in a mediation, which did not result in a settlement.

On June 18, 2017, the Clovis Defendants entered into a stipulation and agreement of settlement with the Arkin Plaintiffs whereby Clovis will issue to the plaintiffs and participating class members a total consideration comprised of \$25.0 million in cash and the issuance of a to be determined number of shares of Clovis common stock (the "Settlement Shares") equal to \$117.0 million divided by the volume weighted average price of Clovis common stock over the 10 trading days immediately preceding the date of the hearing set by the Medina Court to consider the final approval of the settlement. The cash portion of the consideration is expected to be funded by Clovis' insurance carriers. At June 30, 2017, the liability for the issuance of the shares and cash, including the amount to be reimbursed through insurance proceeds, was recorded to accrued liability for legal settlement on the Consolidated Balance Sheets in the amount of approximately \$142.0 million and a receivable of approximately \$25.0 million from the insurance carriers on the Consolidated Balance Sheets. Clovis will issue the Settlement Shares no later than 5 business days after the date the judgment is entered by the Medina Court approving the settlement whereby the issuance of the shares will be recorded in common stock and additional paid-in capital and the accrued liability for legal settlement will be cleared.

As the settlement agreement is in response to the alleged violation of securities laws by certain of our officers, we have determined that the resulting loss does not relate to activities that are in the normal course of our operations and therefore, should not be recognized in operating losses for the period. Accordingly, we have recognized the entire expense associated to the settlement agreement in legal settlement loss within the other income (expense), net of insurance receivable on the Consolidated Statements of Operations and Comprehensive Loss.

On July 14, 2017, the Medina Court issued an order preliminarily approving the settlement. A final hearing to determine whether the settlement should be approved is scheduled for October 26, 2017.

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 Complaint purports to be asserted on behalf of a class of persons who purchased stock in the July 2015 Offering. The Electrical Workers Complaint generally alleges that the defendants violated the Securities Act because the offering documents for the July 2015 Offering contained allegedly false and misleading statements regarding the progress toward FDA approval and the potential for market success of rociletinib. The Electrical Workers Complaint seeks unspecified damages. On June 30, 2016, the Electrical Workers Plaintiffs filed an amended complaint asserting substantially similar claims (the "Electrical Workers Amended Complaint").

On September 23, 2016, following briefing and after hearing oral argument, the Electrical Workers Court granted defendants' motion to stay proceedings pending resolution of the Medina action. Per the order to stay proceedings, the parties' first status report as to the progress of the Medina action was filed on March 23, 2017. The parties' second status report is due on September 21, 2017.

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

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.

Table of Contents

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, 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. A hearing on both motions is scheduled for August 8, 2017.

On March 14, 2017, the Clovis Defendants and Antipodean participated in a mediation, which did not result in a settlement. 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.

Clovis received a letter dated May 31, 2016 from an alleged owner of its common stock, which purports to set forth a demand for inspection of certain of our books and records pursuant to 8 Del. C. § 220 (the “Macalinao Demand Letter”). Clovis also received a letter dated December 15, 2016 from a second alleged owner of Clovis common stock, which purports to set forth a similar demand for inspection of the Company’s books and records pursuant to 8 Del. C. § 220 (the “McKenry Demand Letter”). Both the Macalinao and McKenry Demand Letters were purportedly made for the purposes of investigating alleged misconduct at the Company relating to rociletinib. Clovis submitted a response to the Macalinao Demand Letter on June 24, 2016, and likewise submitted a response to the McKenry Demand Letter on January 4, 2017. The Company produced certain books and records in response to the Macalinao and McKenry Demand Letters in January and February 2017, respectively.

In March 2017, 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 the 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 the Macalinao and McKenry Demand Letters. The Consolidated Derivative Complaint sought, among other things, an award of money damages.

On July 13, 2017, the court ordered the following briefing schedule with respect to the defendants' forthcoming motion to dismiss the Consolidated Derivative Complaint: Defendants' motion to dismiss was due, and was filed, on July 31, 2017; Plaintiffs' opposition is due on August 30, 2017; and Defendants' reply is due on September 14, 2017.

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 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 due to this allegedly wrongful compensation plan. The Solak Complaint sought, among other things, an award of money damages and the imposition of corporate governance reforms.

On June 12, 2017, the parties in the Solak action entered into a stipulation extending the defendants' time to respond to the Solak Complaint until August 11, 2017, which was entered by the Court on June 20, 2017.

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

Table of Contents

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.

In addition, 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. The Company is continuing to cooperate with these agencies with respect to their investigations. The proposed settlement of the Medina action does not resolve these inquiries and the Company cannot predict their timing or outcome.

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 thereof 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 commercial product Rubraca® (rucaparib) is the first and only oral, small molecule poly ADP-ribose polymerase, or PARP, inhibitor of PARP1, PARP2 and PARP3 approved in the United States by the FDA as monotherapy for the treatment of patients with deleterious BRCA (human genes associated with the repair of damaged DNA) 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.

Our MAA for rucaparib that was submitted to the EMA for an ovarian cancer treatment indication comparable to what was approved by the FDA is currently under review. We anticipate an opinion from the CHMP in late 2017, and, pending a favorable opinion from the CHMP, a potential approval would follow during the first quarter of 2018. Following a potential approval for the treatment indication, we intend to submit a supplemental application for the second-line or later maintenance treatment indication, for which we anticipate a potential approval during the third quarter of 2018. Additionally, rucaparib is being studied as a potential maintenance therapy for ovarian cancer patients in the ARIEL3 trial. On June 19, 2017, we announced that the ARIEL3 trial successfully achieved the primary endpoint of improved progression-free survival (PFS) by investigator review in each of the three populations studied. PFS was also improved in the rucaparib group compared with placebo by blinded independent central review (BICR), a key secondary endpoint. Based on these findings, we plan to submit a supplemental New Drug Application (sNDA) before the end of

Table of Contents

October 2017 for a second-line and later maintenance treatment indication for all women with platinum-sensitive ovarian cancer who have responded to their most recent platinum therapy. Rucaparib is also being developed in patients with mutant BRCA tumors and other DNA repair deficiencies beyond BRCA – commonly referred to as homologous recombination deficiencies. Studies open for enrollment or under consideration include prostate, breast, pancreatic, gastroesophageal, bladder and lung cancers.

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, or 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 to 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. We are aware of a number of cases where salt and polymorph patents have been challenged. 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. 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. Based on these factors, we believe a successful challenge of that patent would be difficult.

In addition, we have two other product candidates: lucitanib, an oral inhibitor of the tyrosine kinase activity of vascular endothelial growth factor receptors (VEGFR) 1-3, platelet-derived growth factor receptors (PDGFR) alpha and beta and fibroblast growth factor receptors (FGFR) 1-3, 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 drugs to patients whose clinicians recommend continuing therapy. We maintain certain development and commercialization rights for lucitanib and global development and commercialization rights for rociletinib.

We commenced operations in April 2009. To date, we have devoted substantially all of our resources to identifying and in-licensing product candidates, performing development activities with respect to those product candidates and the general and administrative support of these operations. Through June 30, 2017, we have generated \$13.6 million in license and milestone revenue related to our collaboration and license agreement with Servier and have generated \$21.7 million net 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 June 30, 2017, we had an accumulated deficit of \$1,364.9 million. We incurred net losses of \$233.8 million and \$212.7 million for the six months ended June 30, 2017 and 2016, respectively. The net loss for the six months ended June 30, 2017 included a charge of \$117.0 million related to a legal settlement. The net loss for the six months ended June 30, 2016 included a charge of \$104.5 million for the impairment of intangible asset and a gain of \$24.9 million from a reduction in fair value of contingent purchase consideration. We had cash, cash equivalents and available-for-sale securities totaling \$671.5 million at June 30, 2017.

We expect to incur significant losses for the foreseeable future, as we incur costs related to commercial activities associated with Rubraca. In January 2017, we sold 5,750,000 shares of our common stock in a public offering at \$41.00 per share. The net proceeds from the offering were \$221.2 million, after deducting underwriting discounts and commissions and offering expenses. In June 2017, we sold 3,920,454 shares of our common stock in a public offering at \$88.00 per share. The net proceeds from the offering were \$324.9 million, after deducting underwriting discounts and

Table of Contents

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 our current estimates, we believe that our cash, cash equivalents and available-for-sale securities will allow us to fund activities 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 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.

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 \$69.75 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, the majority of which relate to annual sales targets of \$500.0 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. The FDA approval of rucaparib on December 19, 2016 resulted in a \$0.35 million milestone obligation to AstraZeneca as required by the license agreement, which was paid in the first quarter of 2017. This payment was recognized in intangible assets and will be amortized over the estimated remaining useful life of rucaparib. AstraZeneca will also receive royalties on any net sales of rucaparib.

Table of Contents

We are party to other product license agreements for our other drug candidates, lucitanib and rociletinib (see our 2016 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 resell 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, “sales deductions”). We only recognize revenue on product sales once the product is resold to the patient or healthcare provider by the specialty distributor or specialty pharmacy provider, therefore reducing the significance of estimates made for product returns.

Sales Deductions

Estimating sales deductions requires significant judgments about future events and uncertainties, and requires us to rely heavily on assumptions, as well as historical experience. Estimated sales deductions are provided for the following:

- **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. 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 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. If actual future rebates vary from estimates, we may need to adjust balances of such rebates to reflect our actual expenditures with respect to these programs, which would affect revenue in the period of adjustment.

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. 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. 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 from product sales when revenue is recognized. Service fees are recorded as a selling expense when product sales occur.
- 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 and estimates of program redemption using data provided by third-party administrators.
- Returns. Sales of our products are not subject to a general right of return at the point we recognize revenue, which is the point the product is sold to the patient or healthcare provider. To date, we have not had any 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.

Table of Contents

In the three and six months ended June 30, 2017, we recorded net product revenue of \$14.6 million and \$21.7 million, respectively, related to sales of Rubraca, which we began to commercialize on December 19, 2016. Our ability to generate revenue and become profitable depends upon our ability to successfully commercialize products. Any inability on our part to successfully commercialize Rubraca in the United States and any foreign territories where it may be approved, or any significant delay in such approvals, could have a material adverse impact on our ability to execute upon our business strategy and, ultimately, to generate sufficient revenues from Rubraca to reach or maintain profitability or sustain our anticipated levels of operations.

Cost of Sales – Product

We recorded product cost of sales from sales of Rubraca in the three and six months ended June 30, 2017. 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. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, certain of the manufacturing costs of Rubraca units recognized as revenue during the three and six months ended June 30, 2017 were expensed prior to the December 19, 2016 FDA approval, and therefore are not included in costs of sales during the current period. We expect cost of sales to increase in relation to product revenues as we deplete these inventories and we expect to use the remaining pre-commercialization inventory for product sales through the third quarter of 2017.

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. As a result of the FDA approval of Rubraca and the discontinuation of enrollment in rociletinib, our research and development expenses decreased in both the three and six months ended June 30, 2017 compared to the same periods in the prior year and are expected to decrease for the remainder of 2017 compared to prior year as we continue to commercialize Rubraca and commercialization related expenses are classified as selling, general and administrative expenses and not research and development costs.

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		Six months ended	
	June 30, 2017	2016	June 30, 2017	2016
	(in thousands)			
Rucaparib Expenses				
Research and development	\$ 16,980	\$ 24,379	\$ 31,490	\$ 48,936
Acquired in-process research and development		300	—	300
Rucaparib Total	16,980	24,679	31,490	49,236
Lucitanib Expenses				
Research and development (a)	(13)	(194)	(99)	(214)
Lucitanib Total	(13)	(194)	(99)	(214)
Rociletinib Expenses				
Research and development	\$ 1,528	\$ 16,821	4,719	37,415
Rociletinib Total	1,528	16,821	4,719	37,415
Personnel and other expenses	14,613	26,723	29,445	56,200
Total	\$ 33,108	\$ 68,029	\$ 65,555	\$ 142,637

(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. We anticipate that our selling, general and administrative expenses will continue to increase in the future in support of our commercial activities related to Rubraca.

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.

Change in Fair Value of Contingent Purchase Consideration

In connection with the acquisition of EOS in November 2013, we also recorded a purchase consideration liability equal to the estimated fair value of future payments that are contingent upon the achievement of various regulatory and sales milestones. Subsequent to the acquisition date, we re-measure contingent consideration arrangements at fair value each reporting period and record changes in fair value of contingent purchase consideration and foreign currency gains (losses) for changes in the foreign currency translation rate on the Consolidated Statements of Operations. Changes in fair value are primarily attributed to new information about the likelihood of achieving such milestones and the passage of time. In the absence of new information, changes in fair value reflect only the passage of time as we progress towards the achievement of future milestones. During the second quarter of 2016, we recorded a \$25.5 million reduction in the fair value of the contingent purchase consideration liability due to our and our development partner's decision to discontinue the development of lucitanib for breast cancer. At June 30, 2017, the contingent purchase consideration

Table of Contents

liability recorded on the Consolidated Balance Sheets was zero due to the uncertainty of achieving any of the lucitanib regulatory milestones.

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 contingent purchase consideration, the allocation of purchase consideration, intangible asset impairment, clinical trial accruals and share-based compensation. 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, 2016. There have not been any material changes to our critical accounting policies since December 31, 2016.

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.

Table of Contents

Results of Operations

Comparison of Three Months Ended June 30, 2017 and 2016:

The following table summarizes the results of our operations for the three months ended June 30, 2017 and 2016 (in thousands):

	Three months ended June 30,		Change	
	2017	2016	Favorable/(Unfavorable) \$	%
Product revenue, net	\$ 14,620	\$ —	\$ 14,620	n/a
Operating expenses:				
Cost of sales - product	2,730	—	(2,730)	n/a
Cost of sales - intangible asset amortization	372	—	(372)	n/a
Research and development	33,108	67,729	34,621	51 %
Selling, general and administrative	36,149	9,552	(26,597)	(278) %
Acquired in-process research and development	—	300	300	n/a
Impairment of intangible asset	—	104,517	104,517	n/a
Change in fair value of contingent purchase consideration	—	(25,452)	(25,452)	n/a
Total expenses	72,359	156,646	84,287	54 %
Operating loss	(57,739)	(156,646)	98,907	63 %
Other income (expense):				
Interest expense	(2,598)	(2,106)	(492)	(23) %
Foreign currency gains (losses)	76	183	(107)	58 %
Legal settlement loss	(117,000)	—	(117,000)	n/a
Other income	594	196	398	(203) %
Other income (expense), net	(118,928)	(1,727)	(117,201)	(6,786) %
Loss before income taxes	(176,667)	(158,373)	(18,294)	(12) %
Income tax benefit	1,281	29,059	(27,778)	96 %
Net loss	\$ (175,386)	\$ (129,314)	\$ (46,072)	(36) %

Product Revenue, Net. Product revenue for the three months ended June 30, 2017 was due to the recognition of \$14.6 million of net product revenue from the sale of our first commercial product, Rubraca, which was approved for sale in the United States markets and we began shipping on December 19, 2016. Revenue is recorded net of sales deductions comprised of rebates, chargebacks and other discounts. Sales deductions represented approximately 7.9% of the gross product revenue recognized in the three months ended June 30, 2017 and are summarized as follows:

	Three months ended June 30, 2017	
	\$	% of Gross Sales
	(in thousands)	
Gross product revenue	\$ 15,876	100.0%
Sales deductions:		
Government rebates and chargebacks	635	4.0%
Discounts and fees	621	3.9%
Total sales deductions	1,256	7.9%
Product revenue, net	\$ 14,620	92.1%

Cost of Sales – Product. Product cost of sales for the three months ended June 30, 2017 of \$2.7 million relate to freight and royalties costs associated with Rubraca sales in the period. Manufacturing costs associated with sales in the quarter were expensed as incurred based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, and therefore, were not included in product cost of sales for the three months ended June

Table of Contents

30, 2017. We expect cost of sales to increase in relation to product revenues once we deplete these inventories in the third quarter 2017.

Cost of Sales – Intangible Asset Amortization. In the three months ended June 30, 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. Prior to the FDA approval on December 16, 2016, all acquired license and milestone payments were expensed as incurred.

Research and Development Expenses. Research and development expenses decreased during the three months ended June 30, 2017 compared to the same period in the prior year primarily due to lower research and development costs for rucaparib and rociletinib and classification of commercialization related expenses associated with Rubraca in selling, general and administrative expenses rather than research and development expenses. In the three months ended June 30, 2017, Rubraca commercialization costs included in selling, general and administrative expenses were \$26.9 million.

Clinical trial costs for rucaparib were relatively flat compared to the same quarter a year ago as higher costs from enrollment in ARIEL4, our confirmatory ovarian cancer trials, and enrollment in our TRITON2 and TRITON3 studies for prostate cancer were largely offset by lower costs for the ARIEL2 and ARIEL3 studies, which have completed enrollment. Clinical supply and related manufacturing development costs were \$3.5 million lower than the second quarter of 2016 due to the capitalization of these costs subsequent to the FDA approval of rucaparib.

Clinical trial costs for rociletinib were \$8.2 million lower than the second quarter of 2016 primarily due to the completion of patient enrollment for all of the TIGER studies in non-small cell lung cancer. Clinical supply and related manufacturing development costs were \$4.3 million lower than the second quarter of 2016 driven by timing of production to support our clinical studies.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased during the three months ended June 30, 2017 compared to the same period in the prior year primarily due to classification of commercialization related expenses associated with Rubraca in selling, general and administrative expenses rather than research and development expenses.

Table of Contents

Comparison of Six Months Ended June 30, 2017 and 2016:

The following table summarizes the results of our operations for the six months ended June 30, 2017 and 2016 (in thousands):

	Six months ended June 30,		Change		
	2017	2016	Favorable/(Unfavorable) \$	%	
Product revenue, net	\$ 21,665	\$ —	\$ 21,665	n/a	
Operating expenses:					
Cost of sales - product	3,893	—	(3,893)	n/a	
Cost of sales - intangible asset amortization	743	—	(743)	n/a	%
Research and development	65,555	142,337	76,782	54	%
Selling, general and administrative	65,373	19,379	(45,994)	(237)	%
Acquired in-process research and development	—	300	300	n/a	
Impairment of intangible asset	—	104,517	104,517	n/a	
Change in fair value of contingent purchase consideration	—	(24,936)	(24,936)	n/a	
Total expenses	135,564	241,597	106,033	44	%
Operating loss	(113,899)	(241,597)	127,698	52.86	%
Other income (expense):					
Interest expense	(5,178)	(4,210)	(968)	(22.99)	%
Foreign currency gains (losses)	(83)	(368)	285	77.45	%
Legal settlement loss	(117,000)	—	(117,000)	n/a	
Other income	946	221	725	328	%
Other income (expense), net	(121,315)	(4,357)	(116,958)	(2,684.37)	%
Loss before income taxes	(235,214)	(245,954)	10,740	4.37	%
Income tax benefit	1,365	33,240	(31,875)	(96)	%
Net loss	\$ (233,849)	\$ (212,714)	\$ (21,135)	(10)	%

Product Revenue, Net. Product revenue for the six months ended June 30, 2017 was due to the recognition of \$21.7 million of net product revenue from the sale of our first commercial product, Rubraca, which was approved for sale in the United States markets and we began shipping on December 19, 2016. Revenue is recorded net of sales deductions comprised of rebates, chargebacks and other discounts. Sales deductions represented approximately 8.9% of the gross product revenue recognized in the six months ended June 30, 2017 and are summarized as follows:

Six months ended

Edgar Filing: Clovis Oncology, Inc. - Form 10-Q

	June 30, 2017	
	\$	% of Gross Sales
	(in thousands)	
Gross product revenue	\$ 23,778	100.0%
Sales deductions:		
Government rebates and chargebacks	1,072	4.5%
Discounts and fees	1,041	4.4%
Total sales deductions	2,113	8.9%
Product revenue, net	\$ 21,665	91.1%

Cost of Sales – Product. Product cost of sales for the six months ended June 30, 2017 of \$3.9 million relate to freight and royalties costs associated with Rubraca sales in the period. Manufacturing costs associated with sales in the quarter were expensed as incurred based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, and therefore, were not included in product cost of sales for the six months ended June 30, 2017. We expect cost of sales to increase in relation to product revenues once we deplete these inventories in the third quarter of 2017.

Table of Contents

Cost of Sales – Intangible Asset Amortization. In the six months ended June 30, 2017, we recognized cost of sales of \$0.7 million associated with the amortization of capitalized milestone payments related to the FDA approval of Rubraca. Prior to the FDA approval on December 19, 2016, all acquired license and milestone payments were expensed as incurred.

Research and Development Expenses. Research and development expenses decreased during the six months ended June 30, 2017 compared to the same period in the prior year primarily due to lower research and development costs for rucaparib and rociletinib and classification of commercialization related expenses associated with Rubraca in selling, general and administrative expenses rather than research and development expenses. In the six months ended June 30, 2017, Rubraca commercialization costs included in selling, general and administrative expenses were \$47.0 million.

Clinical trial costs for rucaparib were relatively flat compared to the same period a year ago as higher costs from enrollment in ARIEL4, our confirmatory ovarian cancer trials, and enrollment in our TRITON2 and TRITON3 studies for prostate cancer were largely offset by lower costs for the ARIEL2 and ARIEL3 studies, which have completed enrollment. Diagnostic development costs were \$6.1 million lower compared to the prior year as the prior year included the costs associated with our collaboration with Foundation Medicine, Inc. to develop a novel companion diagnostic test to identify patients most likely to respond to rucaparib. Finally, clinical supply and related manufacturing development costs were \$7.0 million lower than 2016 due to the capitalization of these costs subsequent to the FDA approval of rucaparib.

Clinical trial costs for rociletinib were \$18.5 million lower than 2016 primarily due to the completion of patient enrollment for all of the TIGER studies in non-small cell lung cancer. Clinical supply and related manufacturing development costs were \$7.2 million lower than 2016 driven by timing of production to support our clinical studies.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased during the six months ended June 30, 2017 compared to the same period in the prior year primarily due mainly to classification of commercialization related expenses associated with Rubraca in selling, general and administrative expenses rather than research and development expenses.

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 January 2017, we sold 5,750,000 shares of our common stock in a public offering at \$41.00 per share. The net proceeds from the offering were \$221.2 million, after deducting

Edgar Filing: Clovis Oncology, Inc. - Form 10-Q

underwriting discounts and commissions and offering expenses. In June 2017, we sold 3,920,454 shares of our common stock in a public offering at \$88.00 per share. The net proceeds from the offering were \$324.9 million, after deducting underwriting discounts and commissions and offering expenses. At June 30, 2017, we had cash, cash equivalents and available-for-sale securities totaling \$671.5 million.

The following table sets forth the primary sources and uses of cash for the six months ended March 31, 2017 and 2016 (in thousands):

	Six months ended June 30,	
	2017	2016
Net cash used in operating activities	\$ (149,541)	\$ (151,670)
Net cash (used in) provided by investing activities	(133,864)	99,244
Net cash provided by financing activities	558,440	1,943
Effect of exchange rate changes on cash and cash equivalents	565	106
Net increase (decrease) in cash and cash equivalents	\$ 275,600	\$ (50,377)

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 lower during the six months ended June 30, 2017 compared to the same period in the prior year due to a lower net loss as adjusted for non-

Table of Contents

cash items, partially offset by increases in the operating assets needed to support the commercialization of Rubraca, most notably related to inventory.

Investing Activities

Net cash used in investing activities for the six months ended June 30, 2017 includes purchases of available-for-sale securities of \$180.0 million offset by cash from maturities of available-for-sale securities of \$50.0 million. Net cash provided by investing activities in the same period in the prior year was mainly the result of maturities of available-for-sale securities of \$100.0 million in that period.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2017 and 2016 includes \$12.3 million and \$1.9 million, respectively, received from employee stock option exercises. In addition, we completed the sale of \$546.2 million of common stock, net of issuance costs, during the six months ended June 30, 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 next 12 months 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 June 30, 2017, we had cash, cash equivalents and available-for-sale securities totaling \$671.5 million and total current liabilities of \$219.4 million. In January 2017, we sold 5,750,000 shares of our common stock in a public offering at \$41.00 per share. The net proceeds from the offering were \$221.2 million, after deducting underwriting discounts and commissions and offering expenses. In June 2017, we sold 3,920,454 shares of our common stock in a public offering at \$88.00 per share. The net proceeds from the offering were \$324.9 million, after deducting underwriting discounts and commissions and offering expenses. We intend to use the net proceeds of the offerings for general corporate purposes, including commercial planning and sales and marketing expenses associated with the launch of 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.

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.

Table of Contents

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 2016 Annual Report on Form 10-K. There have not been any material changes to such contractual obligations or potential milestone payments since December 31, 2016. 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 June 30, 2017, we had cash, cash equivalents and available-for-sale securities of \$671.5 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 June 30, 2017, \$183.6 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 June 30, 2017, it would decrease the total US dollar purchase commitment under the Swiss Manufacturing and Services Agreement by approximately \$16.7 million. Similarly, a 10% weakening of the US dollar compared to the Swiss franc would increase the total US dollar purchase commitment by approximately \$20.4 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 June 30, 2017 and December 31, 2016, 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 June 30, 2017 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

Table of Contents

concluded that, as of June 30, 2017, 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 June 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

34

Table of Contents

PART II. OTHER INFORMATION

ITEM 1.LEGAL PROCEEDINGS

On November 19, 2015, Sonny P. Medina, a purported Clovis shareholder, filed a purported shareholder class action complaint in the United States District Court for the District of Colorado (the “Medina Complaint”). The Medina Complaint purported to be asserted on behalf of a class of persons who purchased Clovis stock between May 20, 2014 and November 13, 2015, and it generally alleged that Clovis and certain of its officers violated federal securities laws by making allegedly false and misleading statements regarding the progress toward FDA approval and the potential for market success of rociletinib.

Throughout November and December 2015, three other purported shareholders filed similar purported class actions concerning alleged misstatements about rociletinib. On January 19, 2016, a number of motions were filed seeking to consolidate the shareholder class actions into one matter and for appointment of a lead plaintiff. On February 18, 2016, the Medina Court consolidated the various actions into a single proceeding and appointed M. Arkin (1999) LTD and Arkin Communications LTD (the “Arkin Plaintiffs”) as the lead plaintiffs and Bernstein Litowitz Berger & Grossmann LLP as lead counsel for the putative class.

The Arkin Plaintiffs filed a consolidated complaint on May 6, 2016 (the “Consolidated Complaint”). The Consolidated Complaint named as defendants the Company and certain of its current and former officers (the “Clovis Defendants”), certain underwriters (the “Underwriter Defendants”) for a Company follow-on offering conducted in July 2015 (the “July 2015 Offering”), and certain Company venture capital investors (the “Venture Capital Defendants”). The Consolidated Complaint alleged that defendants violated particular sections of the Securities Exchange Act of 1934 (the “Exchange Act”) and the Securities Act of 1933 (the “Securities Act”). The purported misrepresentations and omissions concerned allegedly misleading statements about rociletinib. The consolidated action was purportedly brought on behalf of investors who purchased the Company’s securities between May 31, 2014 and April 7, 2016 (with respect to the Exchange Act claims) and investors who purchased the Company’s securities pursuant or traceable to the July 2015 Offering (with respect to the Securities Act claims). The Consolidated Complaint sought unspecified compensatory and recessionary damages.

The Clovis Defendants, the Underwriter Defendants and the Venture Capital Defendants filed motions to dismiss on July 27, 2016. On February 9, 2017, the Medina Court issued an opinion and order granting in part and denying in part the Clovis Defendants’ motion to dismiss, granting in part and denying in part the Underwriter Defendants’ motion to dismiss, and granting the Venture Capital Defendants’ motion to dismiss. On February 22, 2017, the Arkin Plaintiffs filed an amended consolidated class action complaint, directed solely at repleading its Section 12(a) claims against the Underwriter Defendants.

On March 14, 2017, the Clovis Defendants and the Arkin Plaintiffs participated in a mediation, which did not result in a settlement.

On June 18, 2017, the Clovis Defendants entered into a stipulation and agreement of settlement with the Arkin Plaintiffs whereby Clovis will issue to the plaintiffs and participating class members total consideration comprised of \$25.0 million in cash and the issuance of a to be determined number of shares of Clovis common stock (the "Settlement Shares") equal to \$117.0 million divided by the volume weighted average price of Clovis common stock over the 10 trading days immediately preceding the date of the hearing set by the Medina Court to consider the final approval of the settlement. The cash portion of the consideration is expected to be funded by Clovis' insurance carriers. At June 30, 2017, the liability for the issuance of the shares and cash, including the amount to be reimbursed through insurance proceeds, was recorded to accrued liability for legal settlement on the Consolidated Balance Sheets in the amount of approximately \$142.0 million and a receivable of approximately \$25.0 million from the insurance carriers on the Consolidated Balance Sheets. Clovis will issue the Settlement Shares no later than 5 business days after the date the judgment is entered by the Medina Court approving the settlement whereby the issuance of the shares will be recorded in common stock and additional paid-in capital and the accrued liability for legal settlement will be cleared.

On July 14, 2017, the Medina Court issued an order preliminarily approving the settlement. A final hearing to determine whether the settlement should be approved is scheduled for October 26, 2017.

Table of Contents

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 Complaint purports to be asserted on behalf of a class of persons who purchased stock in the July 2015 Offering. The Electrical Workers Complaint generally alleges that the defendants violated the Securities Act because the offering documents for the July 2015 Offering contained allegedly false and misleading statements regarding the progress toward FDA approval and the potential for market success of rociletinib. The Electrical Workers Complaint seeks unspecified damages. On June 30, 2016, the Electrical Workers Plaintiffs filed an amended complaint asserting substantially similar claims (the “Electrical Workers Amended Complaint”).

On September 23, 2016, following briefing and after hearing oral argument, the Electrical Workers Court granted defendants’ motion to stay proceedings pending resolution of the Medina action. Per the order to stay proceedings, the parties’ first status report as to the progress of the Medina action was filed on March 23, 2017. The parties’ second status report is due on September 21, 2017.

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

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, 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. A hearing on both motions is scheduled for August 8, 2017.

On March 14, 2017, the Clovis Defendants and Antipodean participated in a mediation, which did not result in a settlement. 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.

Clovis received a letter dated May 31, 2016 from an alleged owner of its common stock, which purports to set forth a demand for inspection of certain of our books and records pursuant to 8 Del. C. § 220 (the “Macalinao Demand Letter”). Clovis also received a letter dated December 15, 2016 from a second alleged owner of Clovis common stock, which purports to set forth a similar demand for inspection of the Company’s books and records pursuant to 8 Del. C. § 220 (the “McKenry Demand Letter”). Both the Macalinao and McKenry Demand Letters were purportedly made for the purposes of investigating alleged misconduct at the Company relating to rociletinib. Clovis submitted a response to the Macalinao Demand Letter on June 24, 2016, and likewise submitted a response to the McKenry Demand Letter on January 4, 2017. The Company produced certain books and records in response to the Macalinao and McKenry Demand Letters in January and February 2017, respectively.

In March 2017, 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 the 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

Table of Contents

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 the Macalinao and McKenry Demand Letters. The Consolidated Derivative Complaint sought, among other things, an award of money damages.

On July 13, 2017, the court ordered the following briefing schedule with respect to the defendants' forthcoming motion to dismiss the Consolidated Derivative Complaint: Defendants' motion to dismiss was due, and was filed, on July 31, 2017; Plaintiffs' opposition is due on August 30, 2017; and Defendants' reply is due on September 14, 2017.

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 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 due to this allegedly wrongful compensation plan. The Solak Complaint sought, among other things, an award of money damages and the imposition of corporate governance reforms.

On June 12, 2017, the parties in the Solak action entered into a stipulation extending the defendants' time to respond to the Solak Complaint until August 11, 2017, which was entered by the Court on June 20, 2017.

The Company intends to vigorously defend against the allegations in the Solak 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.

In addition, 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. The Company is continuing to cooperate with these agencies with respect to their investigations. The proposed settlement of the Medina action does not resolve these inquiries and the Company cannot predict their timing or outcome.

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

Table of Contents

incorporated by reference into this Quarterly Report on Form 10-Q and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

There have been no material changes to the risk factors included in our previously filed Annual Report on Form 10-K for the year ended December 31, 2016. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial also may negatively impact our business.

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

None.

ITEM 3.DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4.MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5.OTHER INFORMATION

None.

ITEM 6.EXHIBITS

INDEX TO EXHIBITS

o

Exhibit

Number Exhibit Description

- 3.1(5) Amended and Restated Certificate of Incorporation of Clovis Oncology, Inc.
- 3.2(5) Amended and Restated Bylaws of Clovis Oncology, Inc.
- 4.1(3) Form of Common Stock Certificate of Clovis Oncology, Inc.
- 4.2(8) Indenture dated as of September 9, 2014, by and between Clovis Oncology, Inc. and The Bank of New York Mellon Trust Company, N.A.
- 10.1*(4) Amended and Restated Strategic License Agreement, dated as of June 16, 2011, by and between Clovis Oncology, Inc. and Avila Therapeutics, Inc.
- 10.2*(4) License Agreement, dated as of June 2, 2011, by and between Clovis Oncology, Inc. and Pfizer Inc.
- 10.3+(1) Clovis Oncology, Inc. 2009 Equity Incentive Plan.
- 10.4+(4) Clovis Oncology, Inc. 2011 Stock Incentive Plan.
- 10.5+(1) Form of Clovis Oncology, Inc. 2009 Equity Incentive Plan Stock Option Agreement.
- 10.6+(4) Form of Clovis Oncology, Inc. 2011 Stock Incentive Plan Stock Option Agreement.
- 10.7+(3) Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Patrick J. Mahaffy.
- 10.8+(3) Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Erle T. Mast.

38

Table of Contents

- 10.9+(3) Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Gillian C. Ivers-Read.
- 10.10+(1) Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Paul Klingenstein.
- 10.11+(1) Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and James C. Blair.
- 10.12+(1) Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Edward J. McKinley.
- 10.13+(1) Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Thorlef Spickschen.
- 10.14+(1) Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and M. James Barrett.
- 10.15+(1) Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Brian G. Atwood.
- 10.16+(1) Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Patrick J. Mahaffy.
- 10.17+(1) Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Erle T. Mast.
- 10.18+(1) Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Gillian C. Ivers-Read.
- 10.19+(1) Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Andrew R. Allen.
- 10.20+(4) Clovis Oncology, Inc. 2011 Employee Stock Purchase Plan.
- 10.21+(4) Clovis Oncology, Inc. 2011 Cash Bonus Plan.
- 10.22+(6) Indemnification Agreement, dated as of March 22, 2012, between Clovis Oncology, Inc. and Steven L. Hoerter.
- 10.23+(2) Indemnification Agreement, dated as of June 13, 2013, between Clovis Oncology, Inc. and Ginger L. Graham.
- 10.24+(2) Indemnification Agreement, dated as of June 13, 2013, between Clovis Oncology, Inc. and Keith Flaherty.
- 10.25(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.
- 10.26*(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,

Edgar Filing: Clovis Oncology, Inc. - Form 10-Q

dated as of April 13, 2010 and the Second Amendment, dated as of July 30, 2012.

10.27*(7) Collaboration and License Agreement, dated as of September 28, 2012, by and between Ethical Oncology Science S.p.A. and Les Laboratoires Servier and Institut de Recherches Internationales Servier.

39

Table of Contents

10.28+(12)	Indemnification Agreement, dated as of January 29, 2016, by and between Clovis Oncology, Inc. and Lindsey Rolfe.
10.29+(12)	Employment Agreement, dated as of February 25, 2016, by and between Clovis Oncology, Inc. and Lindsey Rolfe.
10.30+(12)	Indemnification Agreement, dated as of January 26, 2016, by and between Clovis Oncology, Inc. and Dale Hooks.
10.31+(12)	Employment Agreement, dated as of January 26, 2016, by and between Clovis Oncology, Inc. and Dale Hooks.
10.32+(9)	Indemnification Agreement, dated as of February 17, 2016, by and between Clovis Oncology, Inc. and Daniel W. Muehl.
10.33+(15)	Employment Agreement, dated as of July 6, 2017, by and between Clovis Oncology, Inc. and Daniel W. Muehl.
10.34+(10)	Salary Waiver Letter, dated as of May 9, 2016, by and between Clovis Oncology, Inc. and Patrick J. Mahaffy.
10.35*(11)	First Amendment to License Agreement, by and between Clovis Oncology, Inc. and Pfizer Inc., dated as of August 30, 2016.
10.36+(13)	Form of Clovis Oncology, Inc. 2011 Stock Incentive Plan RSU Agreement.
10.37*(13)	Manufacturing Services Agreement, by and between Clovis Oncology, Inc. and Lonza Ltd, dated as of October 3, 2016.
10.38*(14)	Strata Trial Collaboration Agreement, by and between Clovis Oncology, Inc. and Strata Oncology, Inc., dated as of January 30, 2017
21.1	List of Subsidiaries of Clovis Oncology, Inc.
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 June 30, 2017, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated

Edgar Filing: Clovis Oncology, Inc. - Form 10-Q

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.

40

Table of Contents

- (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.
- + 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.

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: August 3, 2017 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