

Clovis Oncology, Inc.
Form 10-Q
August 08, 2014
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2014.

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

For the transition period from _____ to _____.

Commission file number: 001-35347

Clovis Oncology, Inc.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

90-0475355
(I.R.S. Employer
Identification No.)

2525 28th Street, Suite 100

Boulder, Colorado
(Address of principal executive offices)

80301
(Zip Code)

(303) 625-5000

(Registrant's telephone number, including area code)

Not Applicable

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

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

Indicate by check mark whether the registrant has submitted electronically 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

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 August 1, 2014 was 33,963,957.

Table of Contents

CLOVIS ONCOLOGY, INC.

FORM 10-Q

TABLE OF CONTENTS

<u>PART I. Financial Information</u>	3
ITEM 1. <u>Financial Statements (unaudited)</u>	3
<u>Consolidated Statements of Operations and Comprehensive Loss for the three months and six months ended June 30, 2014 and 2013</u>	3
<u>Consolidated Balance Sheets as of June 30, 2014 and December 31, 2013</u>	4
<u>Consolidated Statements of Cash Flows for the six months ended June 30, 2014 and 2013</u>	5
<u>Notes to Unaudited Consolidated Financial Statements</u>	6
ITEM 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12
ITEM 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	19
ITEM 4. <u>Controls and Procedures</u>	19
<u>PART II. Other Information</u>	20
ITEM 1. <u>Legal Proceedings</u>	20
ITEM 1A. <u>Risk Factors</u>	20
ITEM 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	20
ITEM 3. <u>Defaults Upon Senior Securities</u>	20
ITEM 4. <u>Mine Safety Disclosures</u>	20
ITEM 5. <u>Other Information</u>	20
ITEM 6. <u>Exhibits</u>	21
<u>SIGNATURES</u>	24

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,	
	2014	2013	2014	2013
Revenues:				
License and milestone revenue	\$	\$	\$ 13,625	\$
Operating expenses:				
Research and development	28,440	15,816	52,591	27,938
General and administrative	5,265	3,492	10,585	6,710
Acquired in-process research and development	400		8,806	250
Amortization of intangible asset			3,409	
Accretion of contingent purchase consideration	861		1,683	
Total expenses	34,966	19,308	77,074	34,898
Operating loss	(34,966)	(19,308)	(63,449)	(34,898)
Other income (expense), net	270	(33)	164	(111)
Loss before income taxes	(34,696)	(19,341)	(63,285)	(35,009)
Income taxes	(68)		(2,197)	
Net loss	\$ (34,764)	\$ (19,341)	\$ (65,482)	\$ (35,009)
Basic and diluted net loss per common share	\$ (1.03)	\$ (0.72)	\$ (1.93)	\$ (1.33)
Basic and diluted weighted average common shares outstanding	33,872	26,717	33,846	26,377
Comprehensive loss	\$ (37,118)	\$ (19,338)	\$ (67,317)	\$ (35,015)

See accompanying notes.

Table of Contents

CLOVIS ONCOLOGY, INC.
CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands, except for share amounts)

	June 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	\$ 273,232	\$ 323,228
Prepaid research and development expenses	581	976
Other current assets	5,830	4,392
Total current assets	279,643	328,596
Property and equipment, net	1,298	955
Intangible assets	239,215	244,518
Goodwill	74,219	74,811
Other assets	4,507	755
Total assets	\$ 598,882	\$ 649,635
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	\$ 2,891	\$ 4,420
Accrued research and development expenses	18,809	12,548
Other accrued expenses	3,274	3,984
Total current liabilities	24,974	20,952
Contingent purchase consideration	57,172	55,754
Deferred income taxes, net	75,113	74,955
Other non-current liabilities	17	88
Total liabilities	157,276	151,749
Commitments and contingencies (Note 14)		
Stockholders equity:		
Preferred stock, par value \$0.001 per share; 10,000,000 shares authorized, no shares issued and outstanding at June 30, 2014 and December 31, 2013		
Common stock, \$0.001 par value per share, 100,000,000 shares authorized at June 30, 2014 and December 31, 2013; 33,963,957 and 33,897,321 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively		
	34	34
Additional paid-in capital	773,206	762,170
Accumulated other comprehensive income	2,862	4,696
Accumulated deficit	(334,496)	(269,014)

Total stockholders' equity	441,606	497,886
Total liabilities and stockholders' equity	\$ 598,882	\$ 649,635

See accompanying notes.

Table of Contents

CLOVIS ONCOLOGY, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(Dollars in thousands)

	Six Months Ended June 30,	
	2014	2013
Operating activities		
Net loss	\$ (65,482)	\$ (35,009)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,557	123
Share-based compensation expense	10,149	3,872
Change in value of contingent purchase consideration	1,418	
Deferred income taxes	761	
Changes in operating assets and liabilities, net of acquisition of a business:		
Prepaid and accrued research and development expenses	5,023	(165)
Other operating assets	(1,527)	121
Accounts payable	(2,087)	(755)
Other accrued expenses	(691)	(474)
Net cash used in operating activities	(48,879)	(32,287)
Investing activities		
Purchases of property and equipment	(1,909)	(66)
Net cash used in investing activities	(1,909)	(66)
Financing activities		
Proceeds from sale of common stock, net of issuance costs		259,146
Proceeds from exercise of stock options and employee stock purchase plan	763	1,368
Net cash provided by financing activities	763	260,514
Effect of exchange rate changes on cash and cash equivalents	29	(18)
Increase (decrease) in cash and cash equivalents	(49,996)	228,143
Cash and cash equivalents at beginning of period	323,228	144,097
Cash and cash equivalents at end of period	\$ 273,232	\$ 372,240

See accompanying notes.

Table of Contents

CLOVIS ONCOLOGY, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Basis of Presentation

Clovis Oncology, Inc. (the Company) was incorporated in Delaware on April 20, 2009, and commenced operations in May 2009. The Company is a biopharmaceutical company focused on acquiring, developing and commercializing innovative anti-cancer agents in the United States, Europe and other international markets. The Company has and intends 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, the Company generally expects to provide the licensor with a combination of up-front payments, milestone payments and royalties on future sales. In addition, the Company generally expects to assume the responsibility for future drug development and commercialization costs. The Company currently operates in one segment. Since inception, the Company's operations have consisted primarily of developing in-licensed compounds, evaluating new product acquisition candidates, and general corporate activities. In the first quarter of 2014, the Company exited the development stage, with the recognition of \$13.6 million in license and milestone revenue related to its lucitanib collaboration and license agreement with Les Laboratoires Servier (Servier). The license and milestone revenue recognized is the first significant revenue from principal operations and therefore the Company is no longer considered a development stage company.

The Company received notice on July 30, 2014 that the nonproprietary name *rociletinib* was adopted for our drug candidate CO-1686 by the United States Adopted Names Council. All future references to this drug candidate will now be presented as rociletinib.

Basis of Presentation

All financial information presented includes the accounts of the Company's 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, which in the opinion of management are necessary to fairly state our financial position, results of operations and cash flows for the periods presented. 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 information prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP, have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission, or SEC. Subsequent events have been evaluated through the date these financial statements were filed with the Securities & Exchange Commission. 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, 2013 for a broader discussion of our business and the opportunities and risks inherent in such business.

Use of Estimates

The preparation of these unaudited consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses, revenue, other comprehensive loss and related disclosures. On an ongoing basis, management evaluates its estimates, including estimates related to contingent purchase consideration, the allocation of purchase consideration, intangible assets, clinical trial accruals and share-based compensation expense. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results

may differ from those estimates or assumptions.

Liquidity

The Company has incurred significant net losses since inception and has relied on its ability to fund its operations through debt and equity financings, and management expects operating losses and negative cash flows to continue for at least the next several years. As the Company continues to incur losses, transition to profitability is dependent upon the successful development, approval, and commercialization of its product candidates and achieving a level of revenues adequate to support the Company's cost structure. The Company may never achieve profitability, and unless or until it does, the Company will continue to need to raise additional cash. Management intends to fund future operations through additional private or public debt or equity offerings, and may seek additional capital through arrangements with strategic partners or from other sources.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2 of the Notes to the Consolidated Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2013.

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update Revenue from Contracts with Customers (Topic 606) (ASU 2014-09). ASU 2014-09 specifies the accounting for revenue from contracts with customers and establishes disclosure requirements relating to the nature, timing and uncertainty of revenue and cash flows arising from the entity's contracts with customers. This update is effective for public entities for annual and interim periods beginning after December 15, 2016 and allows for either full retrospective or modified retrospective adoption. Early adoption is not permitted. The Company is currently evaluating the planned method of adoption and if this update will have a material impact on our financial position or results of operations.

3. EOS Acquisition

On November 19, 2013, the Company acquired all of the outstanding common and preferred stock of Ethical Oncology Science, S.p.A. (EOS). The initial purchase consideration was comprised of a cash payment of \$11.8 million and the issuance of \$173.7 million of Company's common stock to the former EOS shareholders. The Company may make additional purchase payments to the previous EOS shareholders if certain lucitanib regulatory and sales milestones are achieved. The range of the potential contingent milestone payments are zero to an estimated maximum of \$65.0 million US dollars and 115.0 million Euros. The Company records a liability for the estimated fair value of these payments, which totaled \$57.2 million at June 30, 2014.

Table of Contents**4. Financial Instruments and Fair Value Measurement*****Cash, Cash Equivalents and Available for Sale Securities***

The Company considers all highly liquid investments with original maturities at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include bank demand deposits and money market funds that invest primarily in certificate of deposits, commercial paper and U.S. government and U.S. government agency obligations.

Marketable securities with original maturities greater than three months are considered to be available for sale securities and historically consisted of U.S. agency obligations, U.S. government obligations and corporate debt obligations. Available for sale securities are reported at fair market value and unrealized gains and losses are included as a separate component of stockholders' equity. Realized gains, realized losses, the amortization of premiums and discounts, interest earned and dividends earned are included in other income (expense). The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Investments with maturities beyond one year are classified as short-term based on management's intent to fund current operations with these securities or to make them available for current operations. A decline in the market value of a security below its cost value 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.

Fair Value of Financial Instruments

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. The Company's Level 1 assets and liabilities consist of money market investments.
- 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. The Company does not have Level 2 assets and liabilities.
- Level 3: Unobservable inputs that are supported by little or no market activity. The Company does not have Level 3 assets. The contingent purchase consideration related to the undeveloped lucitanib product rights acquired in 2013 with the purchase of Ethical Oncology Science, S.p.A. (EOS) is a level 3 liability. The fair value of this liability is based on unobservable inputs and includes valuations for which there is little, if any, market activity. See Note 3 of the Company's 2013 Form 10-K for further discussion of the unobservable inputs and valuation techniques related to the contingent purchase consideration liability.

The following table identifies the Company's assets that were measured at fair value on a recurring basis (in thousands):

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

	Balance	Level 1	Level 2	Level 3
June 30, 2014				
Assets:				
Money market	\$ 258,986	\$ 258,986	\$	\$
Total assets at fair value	\$ 258,986	\$ 258,986	\$	\$
Liabilities:				
Contingent purchase consideration	\$ 57,172	\$	\$	\$ 57,172
Total liabilities at fair value	\$ 57,172	\$	\$	\$ 57,172
December 31, 2013				
Assets:				
Money market	\$ 318,886	\$ 318,886	\$	\$
Total assets at fair value	\$ 318,886	\$ 318,886	\$	\$
Liabilities:				
Contingent purchase consideration	\$ 55,754	\$	\$	\$ 55,754
Total liabilities at fair value	\$ 55,754	\$	\$	\$ 55,754

There were no security transfers between Levels 1 and 2 during the six month period ended June 30, 2014.

The following table represents a roll-forward of the fair value of Level 3 instruments (significant unobservable inputs) in thousands:

	For the Six Months Ended June 30, 2014
Liabilities:	
Balance at beginning of period	\$ 55,754
Net change in fair value	1,418
Balance at end of period	\$ 57,172

Table of Contents**5. Other Current Assets**

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

	June 30, 2014	December 31, 2013
Receivable from partner	\$ 4,228	\$ 2,921
VAT recoverable	438	950
Prepaid expenses and other	1,164	521
Other current assets	\$ 5,830	\$ 4,392

6. Other Accrued Expenses

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

	June 30, 2014	December 31, 2013
Accrued personnel costs	\$ 2,381	\$ 3,356
Accrued corporate legal fees and professional services	109	257
Accrued expenses other	784	371
Other accrued expenses	\$ 3,274	\$ 3,984

7. Intangible Assets

Intangible acquired in-process research and development assets, or intangible assets, were established as part of the purchase accounting of EOS S.p.A. in November 2013. The balance of this account at June 30, 2014 and December 31, 2013 was \$239.2 million and \$244.5 million, respectively. The decrease to the intangible asset balance was primarily attributed to a reduction in expected future milestone revenue cash flows from our lucitanib development activities due to the receipt of a lucitanib milestone payment during the first quarter of 2014 from Servier. This reduction of \$3.4 million was reported as amortization of intangible asset in the consolidated statements of operations and comprehensive loss. Recurring amortization of these assets will commence when the useful lives of the intangible assets have been determined. IPR&D intangible assets are evaluated for impairment at least annually or more frequently if impairment indicators exist and any reduction in fair value will be recognized as an expense to the statement of operations.

8. Goodwill

The acquisition of EOS S.p.A. in November 2013 generated a goodwill balance of \$74.8 million at December 31, 2013. This balance decreased to \$74.2 million at June 30, 2014 due to changes in foreign currency translation rates.

9. Accumulated Other Comprehensive Income

Other comprehensive income consists of foreign currency translation adjustments and is summarized as follows (in thousands):

	Foreign Currency Translation Adjustments	Total Accumulated Other Comprehensive Income
Balance December 31, 2013	\$ 4,696	\$ 4,696
Period change	(1,834)	(1,834)
Balance June 30, 2014	\$ 2,862	\$ 2,862
Balance December 31, 2012	\$ 53	\$ 53
Period change	(6)	(6)
Balance June 30, 2013	\$ 47	\$ 47

The period change between December 31, 2013 and June 30, 2014 is due mainly to the currency translation of the IPR&D intangible assets and goodwill associated with the acquisition of EOS in November 2013.

Table of Contents**10. Share-Based Compensation**

Share-based compensation expense for all equity based programs, including stock options and the employee stock purchase plan, for the three and six months ended June 30, 2014 and 2013, respectively, was recognized in the accompanying Consolidated Statements of Operations and Comprehensive Loss as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Research and development	\$ 2,580	\$ 1,103	\$ 5,014	\$ 1,957
General and administrative	2,633	1,005	5,135	1,915
Total share-based compensation expense	\$ 5,213	\$ 2,108	\$ 10,149	\$ 3,872

The Company did not recognize a tax benefit related to share-based compensation expense during the six months ended June 30, 2014 and 2013, respectively, as the Company maintains net operating loss carryforwards and has established a valuation allowance against the entire net deferred tax asset as of June 30, 2014. No share-based compensation expense was capitalized on our Consolidated Balance Sheets as of June 30, 2014 and December 31, 2013.

The following table summarizes the activity relating to the Company's options to purchase common stock for the six month period ended June 30, 2014:

	Option Shares Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at December 31, 2013	2,520,170	\$ 21.19		
Granted	1,107,657	68.11		
Exercised	(60,341)	8.97		
Forfeited	(13,813)	31.56		
Balance at June 30, 2014	3,553,673	\$ 35.98	8.40	\$ 54,103,280
Vested and expected to vest at June 30, 2014	3,305,508	\$ 34.46	8.33	\$ 52,796,538
Vested at June 30, 2014	1,341,676	\$ 18.69	7.46	\$ 33,339,546

The aggregate intrinsic value in the table above represents the pretax intrinsic value, based on our closing stock price of \$41.41 as of June 30, 2014, 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.

Presented in the table below are financial details associated with our stock options during the three and six months ended June 30, 2014 and 2013.

	Three Months Ended June 30,	
	2014	2013
Weighted-average grant-date fair value per share	\$ 28.50	\$ 43.22
Intrinsic value of options exercised	\$ 2,464,470	\$ 5,540,488
Cash received from stock option exercises	\$ 484,516	\$ 1,101,935

	Six Months Ended June 30,	
	2014	2013
Weighted-average grant-date fair value per share	\$ 42.61	\$ 17.61
Intrinsic value of options exercised	\$ 2,750,277	\$ 5,716,374
Cash received from stock option exercises	\$ 541,167	\$ 1,188,312

As of June 30, 2014, the unrecognized share-based compensation expense related to nonvested options, adjusted for expected forfeitures, was \$49.0 million and the estimated weighted-average remaining vesting period was 3.1 years.

11. License Agreements

Rociletinib (CO-1686)

In May 2010, the Company entered into a worldwide license agreement with Avila Therapeutics, Inc. (now part of Celgene Corporation) to discover, develop and commercialize a covalent inhibitor of mutant forms of the epidermal growth factor receptor gene product. Rociletinib was identified as the lead drug candidate to be developed under the license agreement. The Company is responsible for all preclinical, clinical, regulatory and other activities necessary to develop and commercialize rociletinib. The Company made an up-front payment of \$2.0 million upon execution of the license agreement and is obligated to pay royalties on net sales of rociletinib, based on the volume of annual net sales achieved. Celgene has the option to increase royalty rates by electing to reimburse a portion of the development expenses incurred by the Company. This option must be exercised within a limited period of time after Celgene is notified of our intent to pursue regulatory approval of rociletinib in the United States or European Union as a first line therapy. Such notice was provided to Celgene on June 4, 2014.

In January 2013, the Company entered into an exclusive license agreement with Gatekeeper Pharmaceuticals, Inc. (Gatekeeper) to acquire exclusive rights under patent applications associated with mutant epidermal growth factor receptor (EGFR) inhibitors and methods of treatment. Pursuant to the terms of the license agreement, the Company made an up-front payment of \$250,000 upon execution of the agreement, which was recognized as acquired in-process research and development expense. If rociletinib is approved for commercial sale, the Company will pay royalties to Gatekeeper on future net sales.

Table of Contents

In February, 2014, the Company initiated a Phase II study for rociletinib which resulted in a \$5.0 million milestone payment to Celgene as required by the license agreement. This payment was recognized as acquired in-process research and development expense. The Company may be required to pay up to an additional aggregate of \$110.0 million in development and regulatory milestone payments if certain clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, the Company may be required to pay up to an aggregate of \$120.0 million in sales milestones if certain annual sales targets are achieved.

Rucaparib

In June 2011, the Company entered into a worldwide license agreement with Pfizer Inc. to acquire exclusive development and commercialization rights to Pfizer's drug candidate known as rucaparib. This drug candidate is a small molecule inhibitor of poly (ADP-ribose) polymerase, or PARP, which the Company is developing for the treatment of selected solid tumors. Pursuant to the terms of the license agreement, the Company made a \$7.0 million up-front payment to Pfizer.

In April 2012, the Company 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. Pursuant to the terms of the license agreement, the Company made an up-front payment of \$250,000 upon execution of the agreement, which was recognized as acquired in-process research and development expense. The Company may be required to pay up to an aggregate of \$0.7 million in milestone payments if certain regulatory filings, acceptances and approvals are achieved. If approved, AstraZeneca will also receive royalties on any net sales of rucaparib.

In April, 2014, the Company initiated a pivotal registrational study for rucaparib, which resulted in a \$0.4 million milestone payment to Pfizer Inc. as required by the license agreement. This payment was recognized as acquired in-process research and development expense. The Company is responsible for all development and commercialization costs of rucaparib and, if approved, Pfizer will receive royalties on the net sales of the product. In addition, Pfizer is eligible to receive up to \$258.5 million of further payments, in aggregate, if certain development, regulatory and sales milestones are achieved.

Lucitanib

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

In October 2008, EOS entered into an exclusive license agreement with Advenchen Laboratories LLC (Advenchen) to develop and commercialize lucitanib on a global basis, excluding China. The Company is obligated to pay Advenchen royalties on net sales of lucitanib, based on the volume of annual net sales achieved. In addition, the Company is obligated to pay to Advenchen twenty-five percent of any consideration, excluding royalties, received pursuant to any sublicense agreements for lucitanib, including the agreement with Les Laboratoires Servier (Servier). In the first quarter of 2014, the Company recognized acquired in-process research and development expense of \$3.4 million, which represents 25% of the sublicense agreement consideration of \$13.6 million received from Servier upon the end of opposition and appeal of the lucitanib patent by the European Patent Office. In September 2012, EOS entered into a

collaboration and license agreement with Les Laboratoires Servier (Servier) whereby EOS sublicensed to Servier exclusive rights to develop and commercialize lucitanib in all countries outside of the U.S., Japan, and China. In exchange for these rights, EOS received an upfront payment and is entitled to receive additional payments on the achievement of specified development, regulatory and commercial milestones up to 90.0 million in the aggregate. In addition, the Company is entitled to receive sales milestone payments if specified annual sales targets for lucitanib are met, which, in the aggregate, could total 250.0 million. The Company is also entitled to receive royalties on net sales of lucitanib by Servier.

The development, regulatory and commercial milestones represent non-refundable amounts that would be paid by Servier to the Company if certain milestones are achieved in the future. These milestones, if achieved, are substantive as they relate solely to past performance, are commensurate with estimated enhancement of value associated with the achievement of each milestone as a result of the Company's performance, which are reasonable relative to the other deliverables and terms of the arrangement, and are unrelated to the delivery of any further elements under the arrangement.

The Company and Servier are developing lucitanib pursuant to a development plan agreed to between the parties. Servier is responsible for all of the initial global development costs under the agreed upon plan up to 80.0 million. Cumulative global development costs, if any, in excess of 80.0 million will be shared equally between the Company and Servier. At June 30, 2014, a receivable balance of \$4.2 million was recorded by the Company for reimbursement by Servier for development activities performed under the global development plan. Reimbursements for expenses incurred under the plan are recorded as a reduction to research and development expense.

12. 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, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, stock options are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

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,	
	2014	2013
Common shares under option	2,273	2,343
Total potential dilutive shares	2,273	2,343

Table of Contents

13. Income Taxes

Income tax expense of \$2.2 million was recorded during the six months ended June 30, 2014 due to taxable income earned in a foreign jurisdiction resulting from milestone revenue received during the first quarter of 2014. This expense was partially offset by a deferred tax benefit recognized upon the write down of intangible assets in the first quarter of 2014 (see Note 7). The Company maintains a valuation allowance against the majority of the net deferred tax assets held at June 30, 2014 and intends to maintain this valuation allowance until there is sufficient evidence that consistent future earnings can be achieved, which is uncertain at this time.

14. Commitments and Contingencies

Royalty and License Fee Commitments

The Company has entered into certain license agreements, as identified in Note 11, 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. The Company's payment obligation related to these license agreements is contingent upon the successful development, regulatory approval and commercialization of the licensed products. Due to the nature of these arrangements, the future potential payments are inherently uncertain, and accordingly no amounts have been recorded in the Company's accompanying Consolidated Balance Sheets at June 30, 2014 and December 31, 2013.

Development and Manufacturing Agreement Commitments

In February 2013, the Company entered into a development and manufacturing agreement with a third-party supplier for the production of the active ingredient for rucaparib. Under the Development and Manufacturing Agreement, the Company will provide the third-party supplier a rolling 24-month forecast that will be updated by the Company on a quarterly basis. The Company is obligated to order the quantity specified in the first twelve months of any forecast. As of June 30, 2014, no purchase commitments were established under this agreement.

15. Subsequent Events

The Company evaluated events up to the filing date of these interim financial statements and determined that no subsequent activity required disclosure.

Table of Contents

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

Forward-Looking Information

This Quarterly Report on Form 10-Q and the information incorporated herein by reference includes statements that are, or may be deemed, forward-looking statements. In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms believes, estimates, anticipates, expects, plans, intends, may, could, might, will, should, approximately or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Quarterly Report on Form 10-Q and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned preclinical 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 section of this Quarterly Report on Form 10-Q to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. You are advised, however, to consult any further disclosures we make on related subjects in our other reports filed with the SEC and on our website.

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 seek to simultaneously develop, with partners, companion diagnostics that direct our product candidates to the patients that are most likely to benefit from their use. We are currently developing three product candidates: rociletinib, an orally available, small molecule epidermal growth factor receptor, or EGFR, covalent inhibitor that is in Phase II clinical development for the treatment of non-small cell lung cancer, or NSCLC, in patients with activating EGFR mutations, including the initial activating mutations as well as the primary resistance mutation, T790M; rucaparib, an orally available, small molecule poly (ADP-ribose) polymerase, or PARP inhibitor, that is currently in Phase II/III clinical trials for the treatment of ovarian and pancreatic cancers; and lastly, lucitanib, an oral, selective tyrosine kinase inhibitor in Phase I/II clinical trials for the treatment of breast and lung cancers. We hold global development and commercialization rights for rociletinib and rucaparib and US and Japanese rights for lucitanib.

We were incorporated in Delaware in April 2009 and commenced operations in May 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, 2014, we have generated \$13.6 million in license and milestone revenue related to our collaboration and license agreement with Les Laboratoires Servier (Servier), but have generated no product revenues. We have principally funded our operations using the net proceeds from the sale of convertible preferred stock, the issuance of convertible promissory notes, and from public offerings of our common stock. The convertible preferred stock and convertible promissory notes converted into shares of our common stock immediately prior to the closing of our initial public offering in November 2011.

We have never been profitable and, as of June 30, 2014, we had an accumulated deficit of \$334.5 million. We expect to incur significant and increasing losses for the foreseeable future as we advance our product candidates through clinical development to seek regulatory approval and, if approved, commercialize such product candidates. We will need additional financing to support our operating activities. We will seek to fund our operations through equity or debt financings or 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 expect that research and development expenses will increase as we continue the development of our product candidates. We will need to generate significant revenues to achieve profitability and we may never do so.

On November 19, 2013, the Company acquired all of the outstanding common and preferred stock of Ethical Oncology Science, S.p.A. (EOS) using a combination of cash and the Company's common stock as the initial purchase consideration. EOS was a biopharmaceutical company located in Italy that focused on the development of novel medicines for the treatment of cancer. The primary reason for the business acquisition was to obtain development and commercialization rights to rociletinib. The Company paid \$11.8 million in cash and issued \$173.7 million of common stock at the acquisition date and may make additional contingent future cash payments of \$65.0 million and 115.0 million if certain regulatory and sales milestones are achieved.

The Company received notice on July 30, 2014 that the nonproprietary name *rociletinib* was adopted for our drug candidate CO-1686 by the United States Adopted Names Council. All future references to this drug candidate will now be presented as rociletinib.

Product License Agreements

Rociletinib (CO-1686)

In May 2010, we entered into a worldwide license agreement with Avila (now part of Celgene Corporation) to discover, develop and commercialize a covalent inhibitor of mutant forms of the EGFR gene product. Rociletinib was identified as the lead inhibitor candidate under the license agreement. We are responsible for all preclinical, clinical, regulatory and other activities necessary to develop and commercialize rociletinib. We made an up-front payment of \$2.0 million upon execution of the license agreement, a \$4.0 million milestone payment in the first quarter of 2012 upon the acceptance by the U.S. Food and Drug Administration, or FDA, of our investigational new drug, or IND, application for rociletinib, and a \$5.0 million milestone payment in the first quarter of 2014 upon the initiation of the Phase II study for rociletinib. We recognized all payments as acquired in-process research and development expense. We are obligated to pay royalties on net sales of rociletinib, based on the volume of annual net sales achieved. Celgene has the option to increase royalty rates by electing to reimburse a portion of our development expenses. This option must be exercised within a limited period of time after Celgene is notified by us of our intent to pursue regulatory approval of rociletinib in the United States or the European Union as a first-line treatment. Such notice was provided to Celgene on June 4, 2014. We may be required to pay up to an additional aggregate of \$110.0 million in additional development and regulatory milestone payments if certain clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, we may be required to pay up to an aggregate of \$120.0 million

in sales milestone payments if certain annual sales targets are achieved.

In January 2013, the Company entered into an exclusive license agreement with Gatekeeper Pharmaceuticals, Inc. (Gatekeeper) to acquire exclusive rights under patent applications associated with mutant EGFR inhibitors and methods of treatment. Pursuant to the terms of the license agreement, the Company made an up-front payment of \$250,000 upon execution of the agreement, which was recognized as acquired in-process research and development expense. If rociletinib is approved for commercial sale, the Company will pay royalties to Gatekeeper on future net sales.

Table of Contents

Rucaparib

In June 2011, we entered into a license agreement with Pfizer to acquire exclusive global development and commercialization rights to Pfizer's drug candidate known as rucaparib. This drug candidate is a small molecule PARP inhibitor which we are developing for the treatment of ovarian and pancreatic cancers. Pursuant to the terms of the license agreement, we made an up-front payment of \$7.0 million. In April, 2014, the Company initiated a pivotal registrational study for rucaparib, which resulted in a \$0.4 million milestone payment to Pfizer Inc. as required by the license agreement. We recognized all payments as acquired in-process research and development expense. We are responsible for all development and commercialization costs of rucaparib and, if approved, we will be required to pay Pfizer royalties on sales of the product. In addition, we may be required to pay Pfizer up to an aggregate of \$258.5 million in milestone payments if certain development, regulatory and sales milestones are achieved.

In April 2012, the Company 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. Pursuant to the terms of the license agreement, the Company made an up-front payment of \$250,000 upon execution of the agreement, which was recognized as acquired in-process research and development expense. The Company may be required to pay up to an aggregate of \$0.7 million in milestone payments if certain regulatory filings, acceptances and approvals are achieved. If approved, AstraZeneca will also receive royalties on any sales of rucaparib.

Lucitanib

On November 19, 2013, the Company acquired all of the issued and outstanding capital stock of EOS and gained rights to develop and commercialize lucitanib, an oral, selective tyrosine kinase inhibitor. As further described below, EOS licensed the worldwide rights, excluding China, to develop and commercialize lucitanib from Advenchen Laboratories LLC (Advenchen). Subsequently, rights to develop and commercialize lucitanib in markets outside the U.S. and Japan were sublicensed by EOS to Les Laboratoires Servier (Servier) in exchange for upfront milestone fees, royalties on sales of lucitanib in the sublicensed territories, and research and development funding commitments.

In October 2008, EOS entered into an exclusive license agreement with Advenchen to develop and commercialize lucitanib on a global basis, excluding China. The Company is obligated to pay Advenchen royalties on net sales of lucitanib, based on the volume of annual net sales achieved. In addition, the Company is obligated to pay to Advenchen twenty-five percent of any consideration, excluding royalties, received pursuant to any sublicense agreements for lucitanib, including the agreement with Les Laboratoires Servier. In the first quarter of 2014, the Company recognized acquired in-process research and development expense of \$3.4 million, which represents 25% of the sublicense agreement consideration of \$13.6 million received from Servier upon the end of opposition and appeal of the lucitanib patent by the European Patent Office.

In September 2012, EOS entered into a collaboration and license agreement with Servier whereby EOS sublicensed to Servier exclusive rights to develop and commercialize lucitanib in all countries outside of the U.S., Japan, and China. In exchange for these rights, EOS received an upfront payment and is entitled to receive additional payments on the achievement of specified development, regulatory and commercial milestones up to \$90.0 million in the aggregate. In addition, the Company is entitled to receive sales milestone payments if specified annual sales targets for lucitanib are met, which, in the aggregate, could total \$250.0 million. The Company is also entitled to receive royalties on net sales of lucitanib by Servier.

The Company and Servier are developing lucitanib pursuant to a development plan agreed to between the parties. Servier is responsible for the initial 80 million in global development costs under the agreed upon plan. Cumulative global development costs, if any, in excess of 80.0 million will be shared equally between the Company and Servier.

CO-101

In November 2009, we entered into a license agreement with Clavis Pharma ASA to develop and commercialize CO-101. In November 2012, the Company reported results from a pivotal study of CO-101 in metastatic pancreatic cancer, which failed to demonstrate a difference in overall survival between the two study arms. Based on the results of the study, the Company ceased development of CO-101 and terminated the license agreement.

Drug Discovery Collaboration Agreement

In July 2012, the Company entered into a drug discovery collaboration agreement with Array BioPharma Inc. for the discovery of a novel KIT inhibitor targeting resistance mutations for the treatment of GIST, a gastrointestinal cancer. Under the terms of the agreement, the Company was responsible to fund all costs of the discovery program, as well as costs to develop and commercialize any clinical candidates discovered. This drug discovery program did not identify a compound to be used in further development activities and the program was terminated in the fourth quarter of 2013.

Financial Operations Overview

Revenue

To date, we have generated \$13.6 million in license and milestone revenue related to our collaboration and license agreement with Servier. In the future, we may generate revenue from the sales of product candidates that are currently under development, as well as from milestone payments or royalties pursuant to our sublicense agreement with Servier. If we fail to successfully complete the development of our product candidates or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, will be adversely affected.

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 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;

Table of Contents

costs associated with preclinical activities and regulatory operations; 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.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials. We plan to increase our research and development expenses for the foreseeable future as we seek to expand our clinical and companion diagnostic development activities for our rociletinib, rucaparib and lucitanib product candidates.

The following table identifies research and development costs 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.

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2014	2013	2014	2013
CO-101 Expenses				
Research and development	\$	\$ 342	\$	\$ 966
CO-101 Total		342		966
Rociletinib Expenses				
Acquired in-process R&D			5,000	250
Research and development	13,407	3,740	23,078	7,376
Rociletinib Total	13,407	3,740	28,078	7,626
Rucaparib Expenses				
Acquired in-process R&D	400		400	
Research and development	7,629	4,668	15,411	7,305
Rucaparib Total	8,029	4,668	15,811	7,305
cKIT Inhibitor Expenses				
Research and development		1,136		2,263
cKIT Inhibitor Total		1,136		2,263
Lucitanib Expenses				
Acquired in-process R&D			3,406	
Research and development	180		352	

Lucitanib Total	180		3,758	
Personnel and other expenses	7,224	5,930	13,750	10,028
Total	\$ 28,840	\$ 15,816	\$ 61,397	\$ 28,188

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, business development, legal, investor relations and information technology functions. Other general and administrative expenses include facility costs, communication expenses, corporate insurance, and professional fees for legal, consulting and accounting services.

Accretion of Contingent Purchase Consideration

In connection with the acquisition of EOS in November 2013, we recorded an additional purchase consideration liability equal to the estimated fair value of future payments that are contingent upon the achievement of various regulatory and sales milestones. We re-measure the fair value of contingent consideration arrangements on a periodic basis and record changes in fair value as an operating expense in the statement of operations. Changes in fair value are primarily attributed to new information about the likelihood of achieving such milestones and increases to the liability associated with the passage of time. In the absence of new information, the changes to fair value represent the passage of time as we progress towards the achievement of future milestones.

Other Income and Expense

Other income is comprised of interest income earned on cash and cash equivalents. We also hold cash balances at financial institutions denominated in currencies other than the U.S. dollar to fund research and development activities performed by various third-party vendors. The translation of these currencies into U.S. dollars results in foreign currency gains or losses, depending on the change in value of these currencies in relation to the U.S. dollar.

Table of Contents**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, revenue and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses 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, 2013. There have not been any material changes to our critical accounting policies since December 31, 2013.

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update Revenue from Contracts with Customers (Topic 606) (ASU 2014-09). ASU 2014-09 specifies the accounting for revenue from contracts with customers and establishes disclosure requirements relating to the nature, timing and uncertainty of revenue and cash flows arising from the entity's contracts with customers. This update is effective for public entities for annual and interim periods beginning after December 15, 2016 and allows for either full retrospective or modified retrospective adoption. Early adoption is not permitted. The Company is currently evaluating the planned method of adoption and if this update will have a material impact on our financial position or results of operations.

Results of Operations***Comparison of Three Months Ended June 30, 2014 and 2013:***

The following table summarizes the results of our operations for the three months ended June 30, 2014 and 2013:

	Three Months Ended			
	June 30, 2014	2013	Change	Percent Change
	(in thousands)			
Revenues:				
License and milestone revenue	\$	\$	\$	0.0%
Operating expenses:				
Research and development	28,440	15,816	12,624	79.8%
General and administrative	5,265	3,492	1,773	50.8%
Acquired in-process research and development	400		400	100.0%
	861		861	100.0%

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

Accretion of contingent purchase consideration				
Total expenses	34,966	19,308	15,658	81.1%
Operating loss	(34,966)	(19,308)	(15,658)	81.1%
Other income (expense), net	270	(33)	303	(918.2%)
Loss before income taxes	(34,696)	(19,341)	(15,355)	79.4%
Income taxes	(68)		(68)	(100.0%)
Net loss	\$ (34,764)	\$ (19,341)	\$ (15,423)	79.7%

Table of Contents

Research and Development Expenses. The increase in research and development expenses for the three months ended June 30, 2014 as compared to the three months ended June 30, 2013 was due primarily to expanded development activities for the rociletinib and rucaparib programs. Clinical supply and related manufacturing development costs for both programs increased by a combined \$5.9 million as we increased production to support expanded clinical studies. Costs associated with clinical and nonclinical development activities for rociletinib increased by \$4.0 million in the second quarter of 2014 due primarily to the increased enrollment in the ongoing Phase I/II study in non small cell lung cancer as well as the initiation of the TIGER 1, TIGER 2 and Japanese Phase I studies in 2014. Clinical trial costs for rucaparib increased by \$1.7 million in the second quarter of 2014 due primarily to the initiation of the ARIEL2 and ARIEL3 studies in ovarian cancer and a Phase II study in patients with pancreatic cancer and a known BRCA mutation. In addition, salaries, share-based compensation expense and other personnel related costs increased by \$2.4 million in the second quarter of 2014 as we increased our headcount to support our expanded development activities. These increases in expense were partially offset by a \$1.4 million decline in costs associated with the termination of the CO-101 and cKIT programs in late 2012 and 2013, respectively.

General and Administrative Expenses. The increase in general and administrative expenses for the three months ended June 30, 2014 compared to the three months ended June 30, 2013 was primarily attributable to an increase in share-based compensation expense of \$1.6 million. The increase was also due to larger professional services, facilities and information technology costs in the second quarter of 2014 to support our expanded development activities and the operation of our EOS subsidiary acquired in November 2013.

Acquired In-Process Research and Development Expenses. The increase in acquired in-process research and development for the three months ended June 30, 2014 compared to the three months ended June 30, 2013 related to a \$0.4 million milestone payment made to Pfizer in the second quarter of 2014 upon the initiation of a pivotal registrational study for rucaparib.

Accretion of Contingent Purchase Consideration. Accretion of the contingent purchase consideration totaled \$0.9 million for the three months ended June 30, 2014 and there was no similar liability for the three months ended June 30, 2013. This amount relates to the increase of the contingent purchase consideration liability associated with the passage of time.

Other Income (Expense), net. The increase in other income (expense), net for the three months ended June 30, 2014 compared to the three months ended June 30, 2013 was primarily due to currency gains resulting from the translation of our euro based contingent purchase consideration liabilities into US dollars. The contingent purchase liabilities originated from the November 2013 EOS acquisition and did not exist in the second quarter of 2013.

Comparison of Six Months Ended June 30, 2014 and 2013:

The following table summarizes the results of our operations for the six months ended June 30, 2014 and 2013:

	Six Months Ended			
	June 30,			
	2014	2013	Change	Percent Change
	(in thousands)			
Revenues:				
License and milestone revenue	\$ 13,625	\$	\$ 13,625	100.0%

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

Operating expenses:				
Research and development	52,591	27,938	24,653	88.2%
General and administrative	10,585	6,710	3,875	57.7%
Acquired in-process research and development	8,806	250	8,556	3422.4%
Amortization of intangible asset	3,409		3,409	100.0%
Accretion of contingent purchase consideration	1,683		1,683	100.0%
Total expenses	77,074	34,898	42,176	120.9%
Operating loss	(63,449)	(34,898)	(28,551)	81.8%
Other income (expense), net	164	(111)	275	(247.7%)
Loss before income taxes	(63,285)	(35,009)	(28,276)	80.8%
Income taxes	(2,197)		(2,197)	(100.0%)
Net loss	\$ (65,482)	\$ (35,009)	\$ (30,473)	87.0%

Table of Contents

License and Milestone Revenue. The increase in license and milestone revenue for the six months ended June 30, 2014 compared to the six months ended June 30, 2013 was due to the recording of \$13.6 million of milestone revenue from Servier upon the end of opposition and appeal of the lucitanib patent by the European Patent Office in the first quarter of 2014.

Research and Development Expenses. The increase in research and development expenses for the six months ended June 30, 2014 as compared to the six months ended June 30, 2013 was due primarily to expanded development activities for the rociletinib and rucaparib programs. Clinical supply and related manufacturing development costs for both programs increased by a combined \$10.4 million as we increased production to support expanded clinical studies. Costs associated with clinical and nonclinical development activities for rociletinib increased by \$6.1 million in 2014 due primarily to the increased enrollment in the ongoing Phase I/II study in non small cell lung cancer as well as the initiation of the TIGER 1, TIGER 2 and Japanese Phase I studies in 2014. Clinical trial costs for rucaparib increased by \$5.0 million in 2014 due primarily to the initiation of the ARIEL2 and ARIEL3 studies in ovarian cancer and a Phase II study in patients with pancreatic cancer and a known BRCA mutation. Our development costs for rucaparib also increased by \$1.1 million in the first six months of 2014 as we expanded our collaboration with Foundation Medicine, Inc. to incorporate a coordinated regulatory strategy for the development of a novel companion diagnostic test. In addition, salaries, share-based compensation expense and other personnel related costs increased by \$3.7 million in the first six months of 2014 as we increased our headcount to support our expanded development activities. These increases in expense were partially offset by a \$3.2 million decline in costs associated with the termination of the CO-101 and cKIT programs in late 2012 and 2013, respectively.

General and Administrative Expenses. The increase in general and administrative expenses for the six months ended June 30, 2014 compared to the six months ended June 30, 2013 was primarily attributable to an increase in share-based compensation expense of \$3.2 million. The increase was also due to larger professional services, facilities and information technology costs in the first six months of 2014 to support our expanded development activities and the operation of our EOS subsidiary acquired in November 2013.

Acquired In-Process Research and Development Expenses. The increase in acquired in-process research and development for the six months ended June 30, 2014 compared to the six months ended June 30, 2013 related to a \$5.0 million milestone payment made to Celgene in the first quarter of 2014 upon the initiation of the Phase II study for rociletinib, a \$3.4 million payment due to Advenchen recorded in the first quarter of 2014 pursuant to terms defined in our license agreement and a \$0.4 million payment due to Pfizer recorded in the second quarter of 2014 upon the initiation of a pivotal registrational study for rucaparib.

Amortization of Intangible Asset. The fair value of the IPR&D intangible assets were reduced by \$3.4 million during the six months ended June 30, 2014 due to a fair value adjustment in the first quarter of 2014 to the asset's expected future cash flows resulting from the receipt of a lucitanib milestone payment.

Accretion of Contingent Purchase Consideration. Accretion of the contingent purchase consideration totaled \$1.7 million for the six months ended June 30, 2014 and there was no similar liability for the six months ended June 30, 2013. This amount relates to the increase of the contingent purchase consideration liability associated with the passage of time.

Other Income (Expense), net. The increase in other income (expense), net for the six months ended June 30, 2014 compared to the six months ended June 30, 2013 was primarily due to currency gains resulting from the translation of our euro based contingent purchase consideration liabilities into US dollars. The contingent purchase liabilities originated from the November 2013 EOS acquisition and did not exist in the first six months of 2013.

Income Taxes. The increase in income taxes for the six months ended June 30, 2014 compared to the six months ended June 30, 2013 was due mainly to the recording of foreign tax provisions during the first quarter of 2014 related to milestone revenue recognized under the Servier license agreement, offset by a deferred tax benefit recognized upon the reduction of the carrying value of the IPR&D intangible asset in the first quarter of 2014.

Liquidity and Capital Resources

Through June 30, 2014, we funded our operations through the private placement of preferred stock and convertible debt securities and the public offering of our common stock. As of June 30, 2014, we had cash and cash equivalents totaling \$273.2 million.

The following table sets forth the primary sources and uses of cash for the six months ended June 30, 2014 and 2013:

	Six Months Ended June 30,	
	2014	2013
	(in thousands)	
Net cash used in operating activities	\$ (48,879)	\$ (32,287)
Net cash used in investing activities	(1,909)	(66)
Net cash provided by financing activities	763	260,514
Effect of exchange rate changes on cash and cash equivalents	29	(18)
Net increase (decrease) in cash and cash equivalents	\$ (49,996)	\$ 228,143

Operating Activities

The cash used in operating activities for all periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. The increase of \$16.6 million to cash used in operating activities for the six months ended June 30, 2014 in comparison to prior period was primarily due to the growth in rociletinib and rucaparib research and development costs associated with the expansion of clinical trials, drug formulation and manufacturing costs and increased internal salaries, benefits and personnel-related costs resulting from additional headcount hired to support the expanding development activities of our product candidates, partially offset by the milestone revenue payment received from Servier.

Investing Activities

The net cash used in investing activities for all periods reflects the purchase of property and equipment.

Table of Contents

Financing Activities

The cash provided by financing activities for the six months ended June 30, 2014 and 2013 represents the receipt of proceeds from the exercise of stock options and the employee stock purchase plan. The six month period ended June 30, 2013 also includes the receipt of \$259.1 million in net proceeds from the sale of our common stock in June 2013.

Operating Capital Requirements

Assuming we successfully complete clinical trials and obtain requisite regulatory approvals, we do not anticipate commercializing any of our product candidates until at least the end of 2015. As such, we anticipate that we will continue to generate significant losses for the foreseeable future as we incur expenses to complete our development activities for each of our programs, including clinical trial activities, companion diagnostic development, drug development, establishing our commercial capabilities, and expanding our general and administrative functions to support the growth in our research and development and commercial organizations.

The net proceeds raised from the sale of securities to date will not be sufficient to fund our operations through successful development and commercialization of our product candidates. As a result, we will need to raise additional capital to fund our operations and continue to conduct clinical trials to support additional development and potential regulatory approval, make milestone payments to our licensors and commercialize our product candidates.

We believe that our existing cash and cash equivalents, will allow us to fund our operating plan through at least the next 12 months. If our available cash and cash equivalents are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or obtain a credit facility. The sale of additional equity and debt securities may result in additional dilution to our shareholders.

In addition, if we raise additional funds through the issuance of debt securities or preferred stock, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations. Furthermore, any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay, or eliminate some or all of our planned development and commercialization activities, which could harm our business.

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 preclinical trials;

the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates and companion diagnostics;

the cost of commercialization activities, if any, assuming our product candidates are approved for sale, including marketing and distribution costs;

the cost of manufacturing any of our product candidates we successfully commercialize;

the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and outcome of such litigation; and

the timing, receipt and amount of sales, if any, of our product candidates.

Contractual Obligations and Commitments

For a discussion of our contractual obligations, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our 2013 Annual Report on Form 10-K. There have not been any material changes to such contractual obligations or potential milestone payments since December 31, 2013 aside from those disclosed in Note 14 to the Notes to Unaudited Consolidated Financial Statements included elsewhere in this report.

Table of Contents

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, 2014, we had cash and cash equivalents of \$273.2 million, consisting of bank demand deposits and money market funds that primarily invest in U.S. government obligations. 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. 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 market value of our portfolio.

We contract with contract research organizations, investigational sites, and contract manufacturers globally in which payments are performed in currencies other than the U.S. dollar. In addition, we have recorded a contingent purchase consideration liability resulting from the acquisition of EOS in November 2013. A significant portion of this liability will be settled with Euro denominated payments if certain future milestones are achieved. We may be subject to fluctuations in foreign currency rates in connection with these agreements and future contingent payments. 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 June 30, 2014 and December 31, 2013, approximately 22% and 24%, respectively, of our total liabilities were denominated in currencies other than the functional currency.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Securities Exchange Act of 1934, as amended, or 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 Chief Financial 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 Chief Financial Officer, management performed an evaluation as of June 30, 2014 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 Chief Financial Officer concluded that, as of June 30, 2014, 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, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

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 carefully consider the risk factors described under the heading Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013 and in 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, 2013. 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.

Table of Contents

ITEM 6. EXHIBITS

INDEX TO EXHIBITS

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(1)	Clovis Oncology Inc. Investor Rights Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and certain investors named therein.
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.
10.9+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Gillian C. Ivers-Read.
10.10+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Andrew R. Allen.
10.11+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Paul Klingenstein.
10.12+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and James C. Blair.
10.13+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Edward J. McKinley.

Table of Contents

10.14+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Thorlef Spickschen.
10.15+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and M. James Barrett.
10.16+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Brian G. Atwood.
10.17+(1)	Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Patrick J. Mahaffy.
10.18+(1)	Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Erle T. Mast.
10.19+(1)	Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Gillian C. Ivers-Read.
10.20+(1)	Indemnification Agreement, dated as of May 13, 2009, between Clovis Oncology, Inc. and Andrew R. Allen.
10.21+(1)	Restricted Stock Purchase Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Patrick J. Mahaffy.
10.22+(1)	Restricted Stock Purchase Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Erle T. Mast.
10.23+(1)	Restricted Stock Purchase Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Gillian C. Ivers-Read.
10.24+(1)	Restricted Stock Purchase Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Andrew R. Allen.
10.25+(4)	Clovis Oncology, Inc. 2011 Employee Stock Purchase Plan.
10.26+(4)	Clovis Oncology, Inc. 2011 Cash Bonus Plan.
10.27+(6)	Employment Agreement, dated as of March 22, 2012, by and between Clovis Oncology, Inc. and Steven L. Hoerter.
10.28+(6)	Indemnification Agreement, dated as of March 22, 2012, by and between Clovis Oncology, Inc. and Steven L. Hoerter.
10.29+(2)	Indemnification Agreement, dated as of June 13, 2013, between Clovis Oncology, Inc. and Ginger L. Graham.
10.30+(2)	Indemnification Agreement, dated as of June 13, 2013, between Clovis Oncology, Inc. and Keith Flaherty.
10.31(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.
10.32(7)	Registration Rights Agreement, dated as of November 19, 2013, by and between the Company and the Sellers signatory thereto.

Table of Contents

- 10.33*(7) Development and Commercialization Agreement, dated as of October 24, 2008, by and between Advenchen Laboratories LLC and Ethical Oncology Science S.p.A., as amended by the First Amendment, dated as of April 13, 2010 and the Second Amendment, dated as of July 30, 2012.
- 10.34*(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.
- 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, 2014, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Statements of Operations, (ii) the Consolidated Balance Sheets, (iii) the Consolidated Statements of Cash Flows and (iv) Notes to Unaudited Consolidated Financial Statements.
- (1) Filed as an exhibit with the Registrant's Registration Statement on Form S-1 (File No. 333-175080) on June 23, 2011.
- (2) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on June 14, 2013.
- (3) Filed as an exhibit with Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (File No. 333-175080) on August 31, 2011.
- (4) Filed as an exhibit with Amendment No. 3 to the Registrant's Registration Statement on Form S-1 (File No. 333-175080) on October 31, 2011.
- (5) Filed as an exhibit with the Registrant's Annual Report on Form 10-K on March 15, 2012.
- (6) Filed as an exhibit with the Registrant's Registration Statement on Form S-1 (File No. 333-180293) on March 23, 2012.
- (7) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on November 19, 2013.
- + 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 8, 2014

CLOVIS ONCOLOGY, INC.

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

By: /s/ Erle T. Mast
Erle T. Mast
Executive Vice President and Chief Financial
Officer