Clovis Oncology, Inc.
Form 10-Q
November 07, 2014
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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 September 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	**90-0475355**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2525 28th Street, 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 x 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 x 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 x	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 x

The number of outstanding shares of the registrant s common stock, par value $0.001 per share, as of October 31, 2014 was 33,964,440.

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CLOVIS ONCOLOGY, INC.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CLOVIS ONCOLOGY, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

(In thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenues:				
License and milestone revenue	$	$	$ 13,625	$
Operating expenses:				
Research and development	34,965	16,063	87,556	44,001
General and administrative	5,267	4,312	15,852	11,022
Acquired in-process research and development			8,806	250
Amortization of intangible asset			3,409	
Accretion of contingent purchase consideration	888		2,571	
Total expenses	41,120	20,375	118,194	55,273
Operating loss	(41,120)	(20,375)	(104,569)	(55,273)
Other income (expense), net	1,770	55	1,934	(56)
Loss before income taxes	(39,350)	(20,320)	(102,635)	(55,329)
Income tax expense	(292)		(2,489)	
Net loss	$ (39,642)	$ (20,320)	$ (105,124)	$ (55,329)
Basic and diluted net loss per common share	$ (1.17)	$ (0.68)	$ (3.10)	$ (2.00)
Basic and diluted weighted average common shares outstanding	33,921	30,047	33,871	27,614
Comprehensive loss	$ (58,809)	$ (20,299)	$ (126,126)	$ (55,314)

See accompanying Notes to Unaudited Consolidated Financial Statements.

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CLOVIS ONCOLOGY, INC.

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except for share amounts)

	September 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 516,585	$ 323,228
Prepaid research and development expenses	2,241	976
Other current assets	7,925	4,392
Total current assets	526,751	328,596
Property and equipment, net	2,846	955
Intangible assets	220,723	244,518
Goodwill	68,482	74,811
Other assets	12,725	755
Total assets	$ 831,527	$ 649,635
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 2,428	$ 4,420
Accrued research and development expenses	23,832	12,548
Other accrued expenses	4,719	3,984
Total current liabilities	30,979	20,952
Contingent purchase consideration	55,445	55,754
Deferred income taxes, net	69,307	74,955
Convertible senior notes	287,500	
Other non-current liabilities	6	88
Total liabilities	443,237	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 September 30, 2014 and December 31, 2013		
Common stock, $0.001 par value per share, 100,000,000 shares authorized at September 30, 2014 and December 31, 2013; 33,964,065 and 33,897,321 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	34	34
Additional paid-in capital	778,700	762,170

Accumulated other comprehensive (loss) income	(16,306)	4,696
Accumulated deficit	(374,138)	(269,014)
Total stockholders equity	388,290	497,886
Total liabilities and stockholders equity	$ 831,527	$ 649,635

See accompanying Notes to Unaudited Consolidated Financial Statements.

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CLOVIS ONCOLOGY, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(Dollars in thousands)

	Nine Months Ended September 30,	
	2014	**2013**
Operating activities		
Net loss	$ (105,124)	$ (55,329)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,772	185
Share-based compensation expense	15,585	6,663
Change in value of contingent purchase consideration	(309)	
Deferred income taxes	761	
Changes in operating assets and liabilities, net of acquisition of a business:		
Prepaid and accrued research and development expenses	7,152	1,990
Other operating assets	(3,941)	(5)
Accounts payable	(1,889)	(1,463)
Other accrued expenses	892	81
Net cash used in operating activities	(83,101)	(47,878)
Investing activities		
Purchases of property and equipment	(2,191)	(80)
Net cash used in investing activities	(2,191)	(80)
Financing activities		
Proceeds from the issuance of convertible senior notes	287,500	
Proceeds from the sale of common stock, net of issuance costs		259,071
Proceeds from exercise of stock options and employee stock purchases	763	1,403
Payment of debt issuance costs	(9,165)	
Net cash provided by financing activities	279,098	260,474
Effect of exchange rate changes on cash and cash equivalents	(449)	11
Increase in cash and cash equivalents	193,357	212,527
Cash and cash equivalents at beginning of period	323,228	144,097
Cash and cash equivalents at end of period	$ 516,585	$ 356,624

See accompanying Notes to Unaudited Consolidated Financial Statements.

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CLOVIS ONCOLOGY, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Basis of Presentation

Clovis Oncology, Inc. (the Company) 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.

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 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, 2013 for a broader discussion of our business and the opportunities and risks inherent in such business.

Use of Estimates

The preparation of these financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses, revenue 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. Management expects operating losses and negative cash flows to continue for the

foreseeable future. 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 Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606). 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 an entity s contracts with customers. This update is effective 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 its planned method of adoption and the impact the standard may have on its consolidated financial statements and related disclosures.

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties About an Entity s Ability to Continue as a Going Concern, which requires management to evaluate whether there are conditions or events that raise substantial doubt about an entity s ability to continue as a going concern and to provide disclosures when certain criteria are met. The guidance is effective for annual periods beginning in 2016 and interim reporting periods starting in the first quarter of 2017. Early application is permitted. The Company does not expect the standard will have an impact on its disclosures.

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 the 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 and 115.0 million. The Company recorded a liability for the estimated fair value of these payments, which totaled $55.4 million and $55.8 million at September 30, 2014 and December 31, 2013, respectively.

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4. Financial Instruments and Fair Value Measurement

Cash, Cash Equivalents and Marketable 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 value and unrealized gains and losses are included in accumulated other comprehensive income on the Consolidated Balance Sheets. Realized gains and losses, amortization of premiums and discounts and interest and dividends earned are included in other income (expense), net on the Consolidated Statements of Operations and Comprehensive Loss. 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 consist of money market investments. The Company does 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. The Company does not have Level 2 assets or 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 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 and liabilities that were measured at fair value on a recurring basis (in thousands):

	Balance	Level 1	Level 2	Level 3

September 30, 2014				
Assets:				
Money market	$ 447,986	$ 447,986	$	$
Total assets at fair value	$ 447,986	$ 447,986	$	$
Liabilities:				
Contingent purchase consideration	$ 55,445	$	$	$ 55,445
Total liabilities at fair value	$ 55,445	$	$	$ 55,445
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 transfers between Level 1 and Level 2 during the nine months ended September 30, 2014.

The following table rolls forward the fair value of Level 3 instruments (significant unobservable inputs) in thousands:

	For the Nine Months Ended September 30, 2014
Liabilities:	
Balance at beginning of period	$ 55,754
Accretion	2,571
Change in foreign currency gains and losses	(2,880)
Balance at end of period	$ 55,445

The change in the fair value of Level 3 instruments is included in accretion of contingent purchase consideration and other income (expense), net for the change in foreign currency gains and losses on the Consolidated Statements of Operations and Comprehensive Loss.

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5. Other Current Assets

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

	September 30, 2014	December 31, 2013
Receivable from partners	$ 6,544	$ 2,921
VAT recoverable	45	950
Prepaid expenses and other	1,336	521
Other current assets	$ 7,925	$ 4,392

6. Intangible Assets and Goodwill

Intangible acquired in-process research and development (IPR&D) assets were established as part of the purchase accounting of EOS in November 2013. The intangible asset balance at September 30, 2014 and December 31, 2013 was $220.7 million and $244.5 million, respectively. The balance decreased $20.4 million over the prior year due to changes in foreign currency translation rates. In addition, the Company recorded a $3.4 million reduction in the intangible assets driven by lower expected future milestone revenue cash flows from our lucitanib development activities due to the receipt of a lucitanib milestone payment from Servier during the first quarter of 2014. This reduction was reported as amortization of intangible asset on 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 in the Consolidated Statements of Operations and Comprehensive Loss.

The acquisition of EOS in November 2013 generated a goodwill balance of $74.8 million at December 31, 2013. This balance decreased to $68.5 million at September 30, 2014 due to changes in foreign currency translation rates.

7. Other Accrued Expenses

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

	September 30, 2014	December 31, 2013
Accrued personnel costs	$ 3,404	$ 3,356
Accrued corporate legal fees and professional services	132	257
Accrued expenses other	1,183	371
Other accrued expenses	$ 4,719	$ 3,984

8. 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 to the Company 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, beginning March 15, 2015. 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, the Company incurred $9.2 million of debt issuance costs, which is included in other assets on the Consolidated Balance Sheets. The debt issuance costs are amortized as interest expense over the expected life of the Notes using the effective interest method. The Company determined the expected life of the debt was equal to the seven-year term of the Notes. As of September 30, 2014, the balance of unamortized debt issuance costs was $9.1 million.

The fair value of the Notes was $297.3 million at September 30, 2014 and 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.

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The following table sets forth total interest expense, included in other income (expense), net on the Consolidated Statements of Operations and Comprehensive Loss, recognized related to the Notes during the three and nine months ended September 30, 2014 (in thousands):

	Three Months Ended September 30, 2014	Nine Months Ended September 30, 2014
Contractual interest expense	$ 439	$ 439
Amortization of debt issuance costs	72	72
Total interest expense	$ 511	$ 511

9. Stockholders Equity

Common Stock

In June 2013, the Company sold 3,819,444 shares of its common stock in a public offering at $72.00 per share. The net offering proceeds realized after deducting offering expenses and underwriters discounts and commissions were $259.1 million.

Accumulated Other Comprehensive Income (Loss)

The accumulated balances related to each component of other comprehensive income (loss) are summarized as follows (in thousands):

	Foreign Currency Translation Adjustments	Total Accumulated Other Comprehensive Income (Loss)
Balance December 31, 2013	$ 4,696	$ 4,696
Period change	(21,002)	(21,002)
Balance September 30, 2014	$ (16,306)	$ (16,306)
Balance December 31, 2012	$ 53	$ 53
Period change	4,643	4,643
Balance December 31, 2013	$ 4,696	$ 4,696

The period change between December 31, 2013 and September 30, 2014 was primarily due to the currency translation of the IPR&D intangible assets, goodwill and deferred income taxes associated with the acquisition of EOS in November 2013.

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 nine months ended September 30, 2014 and 2013, respectively, was recognized in the accompanying Consolidated Statements of Operations and Comprehensive Loss as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development	$ 2,991	$ 1,138	$ 8,005	$ 3,095
General and administrative	2,445	1,653	7,580	3,568
Total share-based compensation expense	$ 5,436	$ 2,791	$ 15,585	$ 6,663

The Company did not recognize a tax benefit related to share-based compensation expense during the three and nine months ended September 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 September 30, 2014. No share-based compensation expense was capitalized on our Consolidated Balance Sheets as of September 30, 2014 and December 31, 2013.

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

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2013	2,520,170	$ 21.19		
Granted	1,449,457	62.00		
Exercised	(60,449)	8.96		
Forfeited	(23,813)	34.96		
Outstanding at September 30, 2014	3,885,365	$ 36.52	8.29	$ 64,790,012
Vested and expected to vest at September 30, 2014	3,620,712	$ 35.23	8.22	$ 63,341,213
Vested at September 30, 2014	1,503,631	$ 19.47	7.30	$ 41,643,182

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The aggregate intrinsic value in the table above represents the pretax intrinsic value, based on our closing stock price of $45.36 as of September 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 nine months ended September 30, 2014 and 2013:

	Three Months Ended September 30,	
	2014	2013
Weighted-average grant-date fair value per share	$ 27.85	$ 43.43
Intrinsic value of options exercised	$ 4,391	$ 85,589
Cash received from stock option exercises	$ 341	$ 34,711

	Nine Months Ended September 30,	
	2014	2013
Weighted-average grant-date fair value per share	$ 39.13	$ 18.43
Intrinsic value of options exercised	$ 2,754,669	$ 5,801,963
Cash received from stock option exercises	$ 541,508	$ 1,223,023

As of September 30, 2014, the unrecognized share-based compensation expense related to nonvested options, adjusted for expected forfeitures, was $51.6 million and the estimated weighted-average remaining vesting period was 3.0 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 (EGFR) 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 U.S. or European Union as a first line therapy. Such notice was provided to Celgene on June 4, 2014, and on September 2, 2014, we received notification from Celgene that the company elected not to exercise this option.

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.

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 (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 2014, the Company initiated a pivotal registrational study for rucaparib, which resulted in a $0.4 million milestone payment to Pfizer 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.

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.

Lucitanib

In connection with its November 2013 acquisition of 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 (Advenchen). Subsequently, rights to develop and commercialize lucitanib in markets outside the U.S. and Japan were sublicensed by EOS to Servier in exchange for up-front 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 25% of any consideration, excluding royalties, received pursuant to any sublicense agreements for lucitanib, including the agreement with 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.

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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 up-front payment and is entitled to receive additional payments upon 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. Beginning in the third quarter of 2014, depending on the expense type, reimbursements are determined using a standard rate approved by the Company and Servier or actual costs incurred. Previously, reimbursements were determined based on actual costs. Reimbursements are recorded as a reduction to research and development expense in the Consolidated Statements of Operations and Comprehensive Loss.

The Company recorded a $6.5 million and $2.9 million receivable at September 30, 2014 and December 31, 2013, 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 and nine months ending September 30, 2014, we recorded reductions in research and development expense of $4.1 million and $7.9 million, respectively, for reimbursable development costs due from Servier.

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. 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 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.

13. Income Taxes

Income tax expense of $2.5 million was recorded during the nine months ended September 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 an intangible asset in the first quarter of 2014 (see Note 6). The Company maintains a valuation allowance against the majority of the net deferred tax assets held at September 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 Consolidated Balance Sheets at September 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 12 months of any forecast. As of September 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.

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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 (EGFR) covalent inhibitor that is in Phase II clinical trials for the treatment of non-small cell lung cancer (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 (PARP) inhibitor, that is currently in Phase II/III clinical trials for the treatment of ovarian and pancreatic cancers; and

Lucitanib, an oral, selective tyrosine kinase inhibitor in Phase II clinical trials for the treatment of breast and lung cancers.

We hold global development and commercialization rights for rociletinib and rucaparib and U.S. and Japanese rights for lucitanib.

We 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 September 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, public offerings of our common stock and our recent convertible senior notes offering. 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 September 30, 2014, we had an accumulated deficit of $374.1 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 lucitanib. 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.

On September 9, 2014, we completed a private placement of $287.5 million aggregate principal amount of our 2.5% convertible senior notes due 2021 (the Notes) resulting in net proceeds to the Company of $278.3 million after deducting offering expenses. 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 December 15 of each year, beginning March 15, 2015. The Notes will mature on September 15, 2021, unless earlier converted, redeemed or repurchased. For additional information regarding the Notes, see Note 8 to our unaudited consolidated financial statements included in this quarterly report.

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Product License Agreements

Rociletinib (CO-1686)

In May 2010, we 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 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 of our investigational new drug 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 U.S. or the European Union as a first-line treatment. Such notice was provided to Celgene on June 4, 2014, and on September 2, 2014, we received notification from Celgene that the company elected not to exercise this option.

We 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, 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.

Rucaparib

In June 2011, we entered into a license agreement with Pfizer Inc. 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 Servier in exchange for up-front 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 25% of any consideration, excluding royalties, received pursuant to any sublicense agreements for lucitanib, including the agreement with 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 up-front 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.

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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 cKIT 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 Consolidated Statements of Operations and Comprehensive Loss 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 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 expense 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.

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
CO-101 Expenses				
Research and development	$	$ (20)	$	$ 946
CO-101 Total		(20)		946
Rociletinib Expenses				
Acquired in-process R&D			5,000	250
Research and development	17,905	4,133	40,983	11,509
Rociletinib Total	17,905	4,133	45,983	11,759
Rucaparib Expenses				
Acquired in-process R&D			400	
Research and development	10,225	6,441	25,636	13,746
Rucaparib Total	10,225	6,441	26,036	13,746
cKIT Inhibitor Expenses				
Research and development		1,135		3,398
cKIT Inhibitor Total		1,135		3,398
Lucitanib Expenses				
Acquired in-process R&D			3,406	
Research and development	(1,870)a		(1,518)a	
Lucitanib Total	(1,870)		1,888	
Personnel and other expenses	8,705	4,374	22,455	14,402
Total	$ 34,965	$ 16,063	$ 96,362	$ 44,251

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 11 to our unaudited consolidated financial statements included in this quarterly report.

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 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. We re-measure the fair value of contingent consideration arrangements on a periodic basis and record

changes in fair value as accretion of contingent purchase consideration on the Consolidated Statements of Operations and Comprehensive Loss. 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 and expense is primarily comprised of foreign currency gains and losses resulting from transactions with contract research organizations, investigational sites and contract manufacturers where payments are made in currencies other than the U.S. dollar. In addition, a significant portion of the contingent purchase consideration liability will be settled in Euro-denominated payments if certain future milestones are achieved and is subject to fluctuations in foreign currency rates. Other expense also includes interest expense recognized related to the Company s 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, 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 contingent purchase consideration, the allocation of purchase consideration, intangible assets, clinical trial accruals and share-based compensation expense. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

For a description of our critical accounting policies, please see Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013. There have not been any material changes to our critical accounting policies since December 31, 2013.

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Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606). 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 an entity s contracts with customers. This update is effective 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 its planned method of adoption and the impact the standard may have on its consolidated financial statements and related disclosures.

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties About an Entity s Ability to Continue as a Going Concern, which requires management to evaluate whether there are conditions or events that raise substantial doubt about an entity s ability to continue as a going concern and to provide disclosures when certain criteria are met. The guidance is effective for annual periods beginning in 2016 and interim reporting periods starting in the first quarter of 2017. Early application is permitted. The Company does not expect the standard will have an impact on its disclosures.

Results of Operations

Comparison of Three Months Ended September 30, 2014 and 2013:

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

	Three Months Ended September 30,			
	2014	2013	Change	Percent Change
	(in thousands)			
Revenues:				
License and milestone revenue	$	$	$	
Operating expenses:				
Research and development	34,965	16,063	18,902	117.7%
General and administrative	5,267	4,312	955	22.1%
Accretion of contingent purchase consideration	888		888	100.0%
Total expenses	41,120	20,375	20,745	101.8%
Operating loss	(41,120)	(20,375)	(20,745)	101.8%
Other income, net	1,770	55	1,715	3118.2%
Loss before income taxes	(39,350)	(20,320)	(19,030)	93.7%
Income tax expense	(292)		(292)	(100.0%)
Net loss	$ (39,642)	$ (20,320)	$ (19,322)	95.1%

Research and Development Expenses. Research and development expenses increased during the three months ended September 30, 2014 compared to the same period in the prior year primarily due to expanded development activities for the rociletinib and rucaparib programs. Costs associated with clinical and nonclinical development activities for rociletinib were $8.4 million higher than the third quarter in 2013 driven by higher enrollment in the ongoing Phase I/II study in NSCLC, as well as the initiation of the TIGER1, TIGER2 and Japanese Phase I studies in 2014. Clinical trial costs for rucaparib were $5.0 million higher than the same quarter in the prior year primarily due to the initiation of the ARIEL2 and ARIEL3 studies in ovarian cancer. Our development costs for rucaparib were also $1.3 million higher than the third quarter of 2013 due to the expansion of our collaboration with Foundation Medicine, Inc. to incorporate a coordinated regulatory strategy for the development of a novel companion diagnostic test. Clinical supply and related manufacturing development costs for both programs were $1.2 million higher than the third quarter in 2013, as we increased production to support expanded clinical studies. In addition, salaries, share-based compensation expense and other personnel related costs were $4.4 million higher in the third quarter of 2014 driven by higher headcount to support our expanded development activities. These increases were partially offset by $1.1 million lower costs due to the termination of the cKIT program in late 2013.

General and Administrative Expenses. General and administrative expenses increased during the three months ended September 30, 2014 compared to the same period in the prior year driven by $0.8 million higher share-based compensation expense.

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

Other Income, net. Other income, net increased during the three months ended September 30, 2014 compared to the same period in the prior year driven by $2.2 million net currency gains primarily due to the translation of our Euro-based contingent purchase consideration liabilities into U.S. dollars. The contingent purchase liabilities originated from the November 2013 EOS acquisition and did not exist in the third quarter of 2013. The net currency gains were partially offset by $0.5 million interest expense recognized in Q3 2014 related to the Company s convertible senior notes issued in September 2014.

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Comparison of Nine Months Ended September 30, 2014 and 2013:

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

	Nine Months Ended September 30,			
	2014	2013	Change	Percent Change
	(in thousands)			
Revenues:				
License and milestone revenue	$ 13,625	$	$ 13,625	100.0%
Operating expenses:				
Research and development	87,556	44,001	43,555	99.0%
General and administrative	15,852	11,022	4,830	43.8%
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	2,571		2,571	100.0%
Total expenses	118,194	55,273	62,921	113.8%
Operating loss	(104,569)	(55,273)	(49,296)	89.2%
Other income (expense), net	1,934	(56)	1,990	(3553.6%)
Loss before income taxes	(102,635)	(55,329)	(47,306)	85.5%
Income tax expense	(2,489)		(2,489)	(100.0%)
Net loss	$ (105,124)	$ (55,329)	$ (49,795)	90.0%

License and Milestone Revenue. License and milestone revenue increased during the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013 due to the recognition 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. Research and development expenses increased during the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013 primarily due to expanded development activities for the rociletinib and rucaparib programs. Costs associated with clinical and nonclinical development activities for rociletinib were $14.5 million higher in 2014 driven by higher enrollment in the ongoing Phase I/II study in NSCLC, as well as the initiation of the TIGER 1, TIGER 2 and Japanese Phase I studies in 2014. Clinical trial costs for rucaparib were $9.9 million higher in 2014 primarily due 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 were $2.3 million higher in the first nine months of 2014 due to the expansion of our collaboration with Foundation Medicine, Inc. to incorporate a coordinated regulatory strategy for the development of a novel companion diagnostic test. Clinical supply and related manufacturing development costs for both programs were $11.6 million higher in 2014, as we increased production to support expanded clinical studies. In addition, salaries, share-based compensation expense and other personnel related costs were $8.0 million higher in the first nine months

of 2014 driven by higher headcount to support our expanded development activities. These increases were partially offset by $4.3 million lower costs due to the termination of the CO-101 and cKIT programs in late 2012 and 2013, respectively.

General and Administrative Expenses. General and administrative expenses increased during the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013 driven by $4.0 million higher share-based compensation expense. In addition, we incurred $0.5 million higher facilities and information technology costs during the first nine 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. Acquired in-process research and development expenses increased during the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013 primarily due 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 was reduced by $3.4 million during the nine months ended September 30, 2014 due to a fair value adjustment in the first quarter of 2014 to an asset s expected future cash flows resulting from the receipt of the lucitanib milestone payment.

Accretion of Contingent Purchase Consideration. Accretion of contingent purchase consideration totaled $2.6 million for the nine months ended September 30, 2014, and there was no similar liability for the nine months ended September 30, 2013. This amount relates to the increase of the contingent purchase consideration liability associated with the passage of time.

Other Income (Expense), net. Other income (expense), net increased during the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013 driven by $2.5 million net currency gains primarily due to the translation of our Euro-based contingent purchase consideration liabilities into U.S. dollars. The contingent purchase liabilities originated from the November 2013 EOS acquisition and did not exist in the first nine months of 2013. The net currency gains were partially offset by $0.5 million interest expense recognized in Q3 2014 related to the Company s convertible senior notes issued in September 2014.

Income Tax Expense. Income tax expense increased during the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013 primarily due to recording foreign tax provisions during the first quarter of 2014 related to milestone revenue recognized under the Servier license agreement, partially offset by a deferred tax benefit recognized upon the reduction of the carrying value of the IPR&D intangible assets in the first quarter of 2014.

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Liquidity and Capital Resources

Through September 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 September 30, 2014, we had cash and cash equivalents totaling $516.6 million.

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

	Nine Months Ended September 30,	
	2014	2013
	(in thousands)	
Net cash used in operating activities	$ (83,101)	$ (47,878)
Net cash used in investing activities	(2,191)	(80)
Net cash provided by financing activities	279,098	260,474
Effect of exchange rate changes on cash and cash equivalents	(449)	11
Increase in cash and cash equivalents	$ 193,357	$ 212,527

Operating Activities

Net 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. Net cash used in operating activities increased $35.2 million during the nine months ended September 30, 2014 driven by higher rociletinib and rucaparib research and development costs associated with the expansion of clinical trials, drug formulation and manufacturing costs and higher salaries, benefits and personnel-related costs resulting from higher headcount to support the expanding development activities of our product candidates, partially offset by the milestone revenue payment received from Servier.

Investing Activities

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

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2014 includes $278.3 million in net proceeds received from our recent convertible senior notes offering and $0.8 million received from employee stock option exercises and stock purchases under the employee stock purchase plan. Net cash provided by financing activities for the nine months ended September 30, 2013 includes $259.1 million in net proceeds received from the sale of our common stock in June 2013 and $1.4 million received from employee stock option exercises and stock purchases under the employee stock purchase plan.

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 to date from the sale of equity securities and issuance of debt 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 the outcome of such litigation; and

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

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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. For further information regarding the Company s contractual obligations and commitments, see Note 14 to our unaudited consolidated financial statements included elsewhere in this report.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of September 30, 2014, we had cash and cash equivalents of $516.6 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 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, a significant portion of the contingent purchase consideration 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 September 30, 2014 and December 31, 2013, approximately 8% 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 (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 September 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 September 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 September 30, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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, except as described below. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial also may negatively impact our business.

Risks Related to Our Financial Position and Capital Requirements

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

In September 2014, we completed a private placement of $287.5 million aggregate principal amount of 2.5% convertible senior notes due 2021 (the Notes), resulting in net proceeds to the Company of $278.3 million after deducting offering expenses. 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. Interest is payable on the Notes semi-annually, and the Notes mature on September 15, 2021, unless redeemed, repurchased, or converted prior to that date. In addition, if, as defined by the terms of the indenture, a fundamental change occurs, holders of the Notes may require us to repurchase for cash all or any portion of their Notes at a purchase price equal to 100% of the principal amount of the Convertible Notes to be repurchased plus accrued and unpaid interest, if any, to, but excluding, the fundamental change repurchase date. As of September 30, 2014, all $287.5 million principal amount of the Notes remained outstanding.

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

Risks Related to Our Business and Industry

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. In addition, the competition in the oncology market is intense. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. For example, Tarceva®, Iressa® and GilotrifTM are currently approved drugs that are used to treat EGFR mutant NSCLC, and in addition, we are aware of a number of products in development targeting EGFR for the treatment of NSCLC, including Pfizer s PF-299804 (dacomitinib), AstraZeneca s AZD9291, Astellas Pharma s ASP8273, HEC Pharma s Z650 (larotinib), Novartis EGF816 and Hanmi Pharmaceutical s HM61713 and HM781-36B. Also, we believe the products in development targeting the PARP pathway include AbbVie s veliparib, Tesaro, Inc. s niraparib, Eisai s E-7016, Teva s CEP-9722, Biomarin s BMN-673 and Astra Zeneca s olaparib. AstraZeneca has filed a Marketing Authorization Application with the European Medicines Agency (EMA) for olaparib for the maintenance treatment of BRCA mutated platinum-sensitive relapsed serous ovarian cancer, for which AstraZeneca has received from the EMA s Committee for Medicinal Products for Human Use a positive opinion recommending approval. No currently approved drugs specifically target each of FGFR1, VEGF and PDGF, as does lucitanib, however, there are a number of FGFR inhibitors in development including Novartis dovitinib and BGJ 398, AstraZeneca s AZD4547, Johnson and Johnson s JNJ-42756493, Eli Lilly s LY 2874455, Debiopharm s Debio 1347 and GlaxoSmithKline s GSK3052230.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products that are more effective or less costly than any drug candidate that we are currently developing or that we may develop. If approved, our product candidates will face competition from commercially available drugs, as well as drugs that are in the development pipelines of our competitors and later enter the market.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA, EMA or other regulatory approval or discovering, developing and commercializing medicines before we do, which would have a material adverse effect on our business.

Risks Related to Our Intellectual Property

Third-party claims of intellectual property infringement may prevent or delay our drug discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including interference and reexamination proceedings before the U.S. PTO or oppositions and other comparable proceedings in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are

developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

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Third parties may assert that we are employing their proprietary technology without authorization. There are or may be third-party patents with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications, which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license, limit our uses, or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys fees for willful infringement, obtain one or more licenses from third parties, limit our uses, pay royalties or redesign our infringing product candidates, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

Risks Related to Ownership of Our Common Stock and Convertible Senior Notes

The price of our stock has been, and may continue to be, volatile, and you could lose all or part of your investment.

The trading price of our common stock has been, and may continue to be, volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. During calendar year 2013, the price of our common stock on the NASDAQ Global Select Market has ranged from $15.96 per share to $86.29 per share. In addition to the factors discussed in this Risk Factors section and elsewhere in this report, these factors include:

- our failure to commercialize our product candidates, if approved;
- actual or anticipated adverse results or delays in our clinical trials;
- unanticipated serious safety concerns related to the use of any of our product candidates;

adverse regulatory decisions;

changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approvals;

disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates;

our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;

our dependence on third parties, including CROs as well as our partners that provide us with companion diagnostic products;

additions or departures of key scientific or management personnel;

failure to meet or exceed any financial guidance or expectations regarding development milestones that we may provide to the public;

actual or anticipated variations in quarterly operating results;

failure to meet or exceed the estimates and projections of the investment community;

overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;

conditions or trends in the biotechnology and biopharmaceutical industries;

introduction of new products offered by us or our competitors;

announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

issuances of debt or equity securities;

significant lawsuits, including patent or stockholder litigation;

sales of our common stock by us or our stockholders in the future;

trading volume of our common stock;

publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;

ineffectiveness of our internal controls;

general political and economic conditions;

effects of natural or man-made catastrophic events; and

other events or factors, many of which are beyond our control.

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In addition, the stock market in general, and the NASDAQ Global Select Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in these Risk Factors, could have a dramatic and material adverse effect on the market price of our common stock.

Because our outstanding Notes are convertible into shares of our common stock, volatility or depressed prices of our common stock could have a similar effect on the trading price of our Notes. In addition, the existence of the Notes may encourage short selling in our common stock by market participants because the conversion of the Notes could depress the price of our common stock.

The conversion of some or all of the Notes may dilute the ownership interest of existing stockholders. Holders of the outstanding Notes will be able to convert them at any time prior to the close of business on the business day immediately preceding September 15, 2021. Upon conversion, holders of the Notes will receive shares of common stock. Any sales in the public market of shares of common stock issued upon conversion of such Notes could adversely affect the trading price of our common stock. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price of our common stock. The issuance and sale of substantial amounts of common stock, or the perception that such issuances and sales may occur, could adversely affect the market price of our common stock and impair our ability to raise capital through the sale of additional equity or convertible debt securities.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

Pursuant to our equity incentive plan(s), our compensation committee (or its designee) is authorized to grant equity-based incentive awards to our employees, directors and consultants. As of December 31, 2013, the number of shares of our common stock available for future grant under our 2011 Stock Incentive Plan, or the 2011 Plan, is 1,661,642. The number of shares of our common stock reserved for issuance under our 2011 Plan will be increased (i) from time to time by the number of shares of our common stock forfeited upon the expiration, cancellation, forfeiture, cash settlement or other termination of awards under our 2009 Equity Incentive Plan, and (ii) at the discretion of our board of directors, on the date of each annual meeting of our stockholders, by up to the lesser of (x) a number of additional shares of our common stock representing 4% of our then-outstanding shares of common stock on such date and (y) 2,758,621 shares of our common stock. Future option grants and issuances of common stock under our 2011 Plan may have an adverse effect on the market price of our common stock. In addition, a substantial number of shares of our common stock are reserved for issuance upon conversion of the Notes.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third-party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management. These provisions include:

- authorizing the issuance of blank check preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders;
- permitting our board of directors to accelerate the vesting of outstanding option grants upon certain transactions that result in a change of control; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our certificate of incorporation or bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock. Additionally, certain provisions of our outstanding Notes could make it more difficult or more expensive for a third party to acquire us. The repurchase price of the Notes must be paid in cash, and this obligation may have the effect of discouraging, delaying or preventing an acquisition of the Company that would otherwise be beneficial to our security holders.

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

If we undergo a fundamental change, as defined in the indenture, prior to the maturity date of the Notes, holders may require us to repurchase for cash all or any portion of the Notes at a fundamental change repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. We may not have or be able to borrow the funds required to repurchase the

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

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

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

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

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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.
10.14+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Thorlef Spickschen.

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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.
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.

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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.
10.35(8)	Indenture, dated as of September 9, 2014, by and between the Company and The Bank of New York Mellon Trust Company, N.A.
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from Clovis Oncology, Inc. s Quarterly Report on Form 10-Q for the period ended September 30, 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.
(8) Filed as an exhibit with the Registrant s Current Report on Form 8-K (File No. 001-35347) on September 9, 2014.
+ Indicates management contract or compensatory plan.
* Confidential treatment has been granted with respect to portions of this exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: November 7, 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