Clovis Oncology, Inc.
Form 10-Q
August 07, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the quarterly period ended June 30, 2015.

¨ 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	o
Non-accelerated filer	o (Do not check if a smaller reporting company)	Smaller reporting company	o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

The number of outstanding shares of the registrant’s common stock, par value $0.001 per share, as of July 31, 2015 was 38,206,514.

CLOVIS ONCOLOGY, INC.

FORM 10-Q

TABLE OF CONTENTS

2

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS
CLOVIS ONCOLOGY, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

(In thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Revenues:				
License and milestone revenue	$—	$—	$—	$13,625
Operating expenses:				
Research and development	60,368	28,440	117,118	52,591
General and administrative	7,204	5,265	13,955	10,585
Acquired in-process research and development	—	400	—	8,806
Amortization of intangible asset	—	—	—	3,409
Accretion of contingent purchase consideration	764	861	1,488	1,683
Total expenses	68,336	34,966	132,561	77,074
Operating loss	(68,336)	(34,966)	(132,561)	(63,449)
Other income (expense):				
Interest expense	(2,097)	—	(4,172)	—
Foreign currency gains (losses)	(1,142)	316	2,105	256
Other income (expense)	62	(46)	73	(92)
Other income (expense), net	(3,177)	270	(1,994)	164
Loss before income taxes	(71,513)	(34,696)	(134,555)	(63,285)
Income tax expense	(18)	(68)	(120)	(2,197)
Net loss	$(71,531)	$(34,764)	$(134,675)	$(65,482)
Basic and diluted net loss per common share	$(2.10)	$(1.03)	$(3.96)	$(1.93)
Basic and diluted weighted average common shares outstanding	34,088	33,872	34,049	33,846
Comprehensive loss	$(63,165)	$(37,118)	$(152,136)	$(67,317)

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except for share amounts)

	June 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$236,261	$482,677
Available-for-sale securities	141,382	—
Prepaid research and development expenses	3,114	3,765
Other current assets	7,440	4,730
Total current assets	388,197	491,172
Property and equipment, net	3,333	2,718
Intangible assets	195,976	212,900
Goodwill	60,804	66,055
Other assets	14,694	13,361
Total assets	$663,004	$786,206
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$5,525	$2,917
Accrued research and development expenses	48,395	37,257
Other accrued expenses	8,508	7,598
Total current liabilities	62,428	47,772
Contingent purchase consideration	51,575	52,453
Deferred income taxes, net	61,537	66,851
Convertible senior notes	287,500	287,500
Deferred rent, long-term	290	—
Total liabilities	463,330	454,576
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Preferred stock, par value $0.001 per share; 10,000,000 shares authorized, no shares issued and outstanding at June 30, 2015 and December 31, 2014	—	—
Common stock, $0.001 par value per share, 100,000,000 shares authorized at June 30, 2015 and December 31, 2014; 34,147,119 and 33,977,187 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	34	34
Additional paid-in capital	805,269	785,089
Accumulated other comprehensive loss	(41,909)	(24,448)
Accumulated deficit	(563,720)	(429,045)

Total stockholders' equity	199,674	331,630
Total liabilities and stockholders' equity	$663,004	$786,206

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Six Months Ended June 30,	
	2015	2014
Operating activities		
Net loss	$(134,675)	$(65,482)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	949	3,557
Share-based compensation expense	17,052	10,149
Amortization of premiums and discounts on available-for-sale securities	975	—
Change in value of contingent purchase consideration	(878)	1,418
Deferred income taxes	—	761
Changes in operating assets and liabilities:		
Prepaid and accrued research and development expenses	10,029	5,023
Other operating assets	(2,758)	(1,527)
Accounts payable	2,338	(2,087)
Other accrued expenses	1,337	(691)
Net cash used in operating activities	(105,631)	(48,879)
Investing activities		
Purchases of property and equipment	(1,006)	(1,909)
Purchases of available-for-sale securities	(142,216)	—
Net cash used in investing activities	(143,222)	(1,909)
Financing activities		
Proceeds from the exercise of stock options and employee stock purchases	3,073	763
Net cash provided by financing activities	3,073	763
Effect of exchange rate changes on cash and cash equivalents	(636)	29
Decrease in cash and cash equivalents	(246,416)	(49,996)
Cash and cash equivalents at beginning of period	482,677	323,228
Cash and cash equivalents at end of period	$236,261	$273,232
Supplemental disclosure of cash flow information:		
Cash paid for interest	$3,714	$—

See accompanying Notes to Unaudited Consolidated Financial Statements.

5

CLOVIS ONCOLOGY, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Basis of Presentation

Clovis Oncology, Inc. (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 July 2015, the Company submitted a New Drug Application ("NDA") regulatory filing and a Marketing Authorization Application ("MAA") for rociletinib to the U.S. Food and Drug Administration ("FDA") and the European Medicines Agency ("EMA"), respectively. See Note 15 for discussion of the related milestone payment.

Basis of Presentation

All financial information presented includes the accounts of the Company and its wholly-owned subsidiaries, Clovis Oncology UK Limited and Clovis Oncology Italy S.r.l. 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, 2014 for a broader discussion of our business and the opportunities and risks inherent in such business.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses, 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 asset impairment, 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. See Note 15 for discussion of our recent common stock offering.

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, 2014.

Recent Accounting Pronouncements

In April 2015, the Financial Accounting Standards Board issued Accounting Standards Update ("ASU") No. 2015-03, "Interest – Imputation of Interest (Subtopic 835-30) – Simplifying the Presentation of Debt Issuance Costs." ASU No. 2015-03 requires debt issuance costs to be presented as a deduction from the corresponding debt liability, rather than as an asset. This update is effective for fiscal years beginning after December 15, 2015, including interim periods within those years. Early adoption is permitted. Upon adoption, the guidance must be applied retrospectively to all periods presented in the financial statements. The Company has elected not to early adopt this standard. Adoption of the standard will impact the presentation of the Company's debt issuance costs on the Consolidated Balance Sheets and the related 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") (now known as Clovis Oncology Italy S.r.l.). The initial purchase consideration was comprised of an $11.8 million cash payment 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 potential contingent milestone payments range from a zero payment, which assumes lucitanib fails to achieve any of the regulatory milestones, to approximately $193.6 million ($65.0 million and €115.0 million) if all regulatory and sales milestones are met, utilizing the translation rate at June 30, 2015. The Company recorded a liability for the estimated fair value of these payments, which totaled $51.6 million and $52.5 million at June 30, 2015 and December 31, 2014, respectively.

4. Financial Instruments and Fair Value Measurements

Cash, Cash Equivalents and Available-for-Sale Securities

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

Marketable securities with original maturities greater than three months are considered to be available-for-sale securities. Available-for-sale securities are reported at fair value and unrealized gains and losses are included in accumulated other comprehensive loss 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) 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 Measurements

Fair value is defined as the exchange price that would be received to sell an asset or paid to transfer a liability (at exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The three levels of inputs that may be used to measure fair value include:

Level 1: Quoted prices in active markets for identical assets or liabilities. 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's Level 2 assets include U.S. treasury securities. The Company does not have Level 2 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 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 2014 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
June 30, 2015				
Assets:				
Money market	$225,987	$225,987	$—	$—
U.S. treasury securities	141,382	—	141,382	—
Total assets at fair value	$367,369	$225,987	$141,382	$—
Liabilities:				
Contingent purchase consideration	$51,575	$—	$—	$51,575
Total liabilities at fair value	$51,575	$—	$—	$51,575
December 31, 2014				
Assets:				
Money market	$447,994	$447,994	$—	$—
Total assets at fair value	$447,994	$447,994	$—	$—
Liabilities:				
Contingent purchase consideration	$52,453	$—	$—	$52,453
Total liabilities at fair value	$52,453	$—	$—	$52,453

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

	For the Six Months Ended June 30, 2015
Liabilities:	
Balance at beginning of period	$ 52,453
Accretion	1,488
Change in foreign currency gains and losses	(2,366)
Balance at end of period	$ 51,575

The change in the fair value of Level 3 instruments is included in accretion of contingent purchase consideration and foreign currency gains (losses) for changes in the foreign currency translation rate on the Consolidated Statements of Operations and Comprehensive Loss.

Financial instruments not recorded at fair value include the Company's convertible senior notes. At June 30, 2015, the carrying amount of the convertible senior notes was $287.5 million, which represents the aggregate principal amount, and the fair value was $458.2 million. The fair value was determined using Level 2 inputs based on the indicative pricing published by certain investment banks or trading levels of the Notes, which are not listed on any securities exchange or quoted on an inter-dealer automated quotation system. See Note 9 for discussion of the convertible senior notes.

5. Available-for-Sale Securities

As of June 30, 2015, available-for-sale securities consisted of the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value
U.S. treasury securities	$ 141,241	$ 141	$ —	$ 141,382

As of June 30, 2015, the amortized cost and fair value of available-for-sale securities by contractual maturity were (in thousands):

	Amortized Cost	Fair Value
Due in one year or less	$ 141,241	$ 141,382
Total	$ 141,241	$ 141,382

6. Other Current Assets

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

	June 30, 2015	December 31, 2014
Receivable from partners	$ 3,936	$ 1,991
Prepaid expenses- other	1,453	1,168
Interest receivable	973	—
Prepaid insurance	819	1,190
VAT recoverable	152	231
Other	107	150
Total	$ 7,440	$ 4,730

7. Intangible Assets and Goodwill

Intangible acquired in-process research and development ("IPR&D") assets and goodwill were established as part of the purchase accounting of EOS in November 2013.

IPR&D assets and goodwill consisted of the following (in thousands):

	June 30, 2015	December 31, 2014	
IPR&D assets:			
Balance at beginning of period	$ 212,900	$ 244,518	
Change in foreign currency gains and losses	(16,924)	(28,209)	
Amortization of intangible asset	—	(3,409)	(a)
Balance at end of period	$ 195,976	$ 212,900	
Goodwill:			
Balance at beginning of period	$ 66,055	$ 74,811	

Change in foreign currency gains and losses	(5,251)	(8,756)
Balance at end of period	$60,804	$66,055

(a) During the first quarter of 2014, the Company recorded a $3.4 million reduction in the intangible assets driven by lower expected future milestone revenue from the lucitanib development activities due to the receipt of a lucitanib milestone payment from Servier (see Note 12). This reduction was reported as amortization of intangible asset on the Consolidated Statements of Operations and Comprehensive Loss.

Recurring amortization of the IPR&D 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.

8. Other Accrued Expenses

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

	June 30, 2015	December 31, 2014
Accrued personnel costs	$5,450	$ 4,726
Accrued interest payable	2,096	2,236
Income tax payable	542	411
Accrued corporate legal fees and professional services	257	77
Accrued expenses - other	163	148
Total	$8,508	$ 7,598

9. Convertible Senior Notes

On September 9, 2014, we completed a private placement of $287.5 million aggregate principal amount of 2.5% convertible senior notes due 2021 (the “Notes”) resulting in net proceeds 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 June 30, 2015, the balance of unamortized debt issuance costs was $8.2 million.

The following table sets forth total interest expense recognized related to the Notes during the three and six months ended June 30, 2015 (in thousands):

	For the Three Months Ended June 30, 2015	For the Six Months Ended June 30, 2015
Contractual interest expense	$ 1,797	$ 3,574
Amortization of debt issuance costs	300	598
Total interest expense	$ 2,097	$ 4,172

10. Stockholders' Equity

Accumulated Other Comprehensive Loss

Accumulated other comprehensive loss consists of changes in foreign currency translation adjustments, which includes changes in a subsidiary's functional currency, and unrealized gains and losses on available-for-sale securities.

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

	Foreign Currency Translation Adjustments	Unrealized Gains	Total Accumulated Other Comprehensive Income (Loss)
Balance December 31, 2013	$ 4,696	$ —	$ 4,696
Period change	(29,144)	—	(29,144)
Balance December 31, 2014	(24,448)	—	(24,448)
Period change	(17,602)	141	(17,461)
Balance June 30, 2015	$ (42,050)	$ 141	$ (41,909)

The period change between June 30, 2015 and December 31, 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 (see Notes 3 and 7).

11. Share-Based Compensation

Share-based compensation expense for all equity based programs, including stock options and the employee stock purchase plan, for the three and six months ended June 30, 2015 and 2014 was recognized in the accompanying Consolidated Statements of Operations and Comprehensive Loss as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Research and development	$5,355	$2,580	$10,759	$5,014
General and administrative	3,015	2,633	6,293	5,135
Total share-based compensation expense	$8,370	$5,213	$17,052	$10,149

The Company did not recognize a tax benefit related to share-based compensation expense during the three and six months ended June 30, 2015 and 2014, respectively, as the Company maintains net operating loss carryforwards and has established a valuation allowance against the entire net deferred tax asset as of June 30, 2015.

The following table summarizes the activity relating to the Company's options to purchase common stock:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (Thousands)
Outstanding at December 31, 2014	4,159,362	$ 37.69		
Granted	1,011,193 (a)	79.88		
Exercised	(159,754)	16.15		
Forfeited	(80,985)	51.64		
Outstanding at June 30, 2015	4,929,816	$ 46.82	8.1	$ 202,569
Vested and expected to vest at June 30, 2015	4,637,933	$ 45.57	8.0	$ 196,336
Exercisable at June 30, 2015	2,138,822	$ 29.58	7.1	$ 124,691

(a) Includes 120,000 performance-based stock options granted to executives of the Company in the first quarter of 2015. Fifty-percent of the grant vests contingent on approval by the U.S. Food and Drug Administration ("FDA") to commercially distribute, sell or market rociletinib and fifty-percent of the grant vests contingent on approval by the FDA to commercially distribute, sell or market rucaparib. Stock compensation expense will be recognized when the condition for vesting is probable of being met.

The aggregate intrinsic value in the table above represents the pretax intrinsic value, based on our closing stock price of $87.88 as of June 30, 2015, which would have been received by the option holders had all option holders with in-the-money options exercised their options as of that date.

The following table summarizes information about our stock options as of and for the three and six months ended June 30, 2015 and 2014:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Weighted-average grant date fair value per share	$55.35	$28.50	$51.49	$42.61
Intrinsic value of options exercised	$4,966,707	$2,464,470	$10,053,841	$2,750,277
Cash received from stock option exercises	$1,387,060	$484,516	$2,580,350	$541,167

As of June 30, 2015, the unrecognized share-based compensation expense related to nonvested options, adjusted for expected forfeitures, was $84.2 million and the estimated weighted-average remaining vesting period was 2.8 years.

12. License Agreements

Rociletinib

In May 2010, we entered into an exclusive worldwide license agreement with Avila Therapeutics, Inc. (now Celgene Avilomics Research, Inc., part of Celgene Corporation ("Celgene")) to discover, develop and commercialize a covalent inhibitor of mutant forms of the epidermal growth factor receptor gene product. As a result of the collaboration contemplated by the agreement, rociletinib was identified as the lead inhibitor candidate, which we are developing under the terms of 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 acceptance by the FDA of our Investigational New Drug application for rociletinib and a $5.0 million milestone payment in the first quarter of 2014 upon 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. The Company is 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 is required to pay up to an aggregate of $120.0 million in sales milestone payments 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 rucaparib. This drug candidate is a small molecule inhibitor of poly ADP-ribose polymerase, 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 registration 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. When and if commercial sales of rucaparib begin, we will pay Pfizer tiered royalties on our net sales. In addition, Pfizer is eligible to receive up to $258.5 million of further payments, in aggregate, if certain development, regulatory and sales milestones are achieved.

Lucitanib

In connection with its November 2013 acquisition of 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 Les Laboratoires Servier (“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 upon achievement of specified development, regulatory and commercial milestones up to an additional €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 $3.9 million and $2.0 million receivable at June 30, 2015 and December 31, 2014, respectively, for the reimbursable development costs incurred under the global development plan, which is included in other current assets on the Consolidated Balance Sheets. For the three months ending June 30, 2015 and 2014, we incurred $4.2 million and $2.4 million, respectively, in research and development costs and recorded reductions in research and development expense of $3.9 million and $2.2 million, respectively, for reimbursable development costs due from Servier. For the six months ending June 30, 2015 and 2014, we incurred $7.8 million and $4.2 million, respectively, in research and development costs and recorded reductions in research and development expense of $6.6 million and $3.8 million, respectively, for reimbursable development costs due from Servier.

13. Net Loss Per Common Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common share equivalents outstanding using the treasury-stock method for the stock options and the if-converted method for the Notes. As a result of our net losses for the periods presented, all potentially dilutive common share equivalents were considered anti-dilutive and were excluded from the computation of diluted net loss per share.

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

	Three and Six Months Ended June 30,	
	2015	2014
Common shares under option	4,898	2,273
Convertible senior notes	4,646	—
Total potential dilutive shares	9,544	2,273

14. Commitments and Contingencies

Royalty and License Fee Commitments

The Company has entered into certain license agreements, as identified in Note 12, 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 June 30, 2015 and December 31, 2014.

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 June 30, 2015, $2.0 million of purchase commitments were established under this agreement.

15. Subsequent Events

In July 2015, the Company sold 4,054,487 shares of its common stock in a public offering at $78.00 per share. The net proceeds to the Company from the offering were approximately $298 million, after deducting underwriting discounts

and commissions and estimated offering expenses payable.

In July 2015, the Company submitted a NDA and a MAA for rociletinib to the FDA and the EMA, respectively. Under the terms of the license agreement, the Company will make a $12.0 million milestone payment to Celgene within 10 days of acceptance of the filings by the respective agencies, which will be recorded as acquired in-process research and development expense.

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

Forward-Looking Information

This Quarterly Report on Form 10-Q and the information incorporated herein by reference includes statements that are, or may be deemed, "forward-looking statements." In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereo comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Quarterly Report on Form 10-Q and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned 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 oral, epidermal growth factor receptor ("EGFR") mutant-selective covalent inhibitor that is in advanced clinical development for the treatment of non-small cell lung cancer in patients with activating EGFR mutations, as well as the primary resistance mutation, T790M;
- Rucaparib, an oral, small molecule poly ADP-ribose polymerase inhibitor that is currently in advanced clinical development for the treatment of ovarian cancer; and
- Lucitanib, an oral, selective tyrosine kinase inhibitor that is currently in Phase II clinical development 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.

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. To date, we have generated $13.6 million in license and milestone revenue, but have generated no product revenues. We have principally funded our operations using the net proceeds from the sales of convertible preferred stock and common stock and a convertible senior notes offering.

We have never been profitable and, as of June 30, 2015, we had an accumulated deficit of $563.7 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.

In July 2015, the Company sold 4,054,487 shares of its common stock in a public offering at $78.00 per share. The net proceeds to the Company from the offering were approximately $298 million, after deducting underwriting discounts and commissions and estimated offering expenses payable.

In July 2015, the Company submitted a New Drug Application regulatory filing and a Marketing Authorization Application for rociletinib to the U.S. Food and Drug Administration ("FDA") and the European Medicines Agency, respectively. Under the terms of the license agreement, the Company will make a $12.0 million milestone payment to Celgene Avilomics Research Inc., part of Celgene Corporation ("Celgene"), within 10 days of acceptance of the filings by the respective agencies, which will be recorded as acquired in-process research and development expense.

Product License Agreements

Rociletinib

In May 2010, we entered into an exclusive worldwide license agreement with Avila Therapeutics, Inc. (now Celgene) 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 FDA 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. We are 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 are required to pay up to an aggregate of $120.0 million in sales milestone payments if certain annual sales targets are achieved.

Rucaparib

In June 2011, we entered into a license agreement with Pfizer Inc. to acquire exclusive global development and commercialization rights to rucaparib. Pursuant to the terms of the license agreement, we made a $7.0 million up-front payment to Pfizer. In April 2014, the Company initiated a pivotal registration 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.

We are responsible for all development and commercialization costs of rucaparib. When and if commercial sales of rucaparib begin, we will pay Pfizer tiered royalties on our net sales. In addition, Pfizer is eligible to receive up to

$258.5 million of further payments, in aggregate, if certain development, regulatory and sales milestones are achieved.

Lucitanib

On November 19, 2013, the Company acquired all of the issued and outstanding capital stock of Ethical Oncology Science, S.p.A. ("EOS") (now known as Clovis Oncology Italy S.r.l.) and gained rights to develop and commercialize lucitanib, an oral, selective tyrosine kinase inhibitor. As further described below, EOS licensed the worldwide rights, excluding China, to develop and commercialize lucitanib from Advenchen Laboratories LLC ("Advenchen"). Subsequently, rights to develop and commercialize lucitanib in markets outside the U.S. and Japan were sublicensed by EOS to Les Laboratoires Servier ("Servier") in exchange for 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 an additional €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 €80.0 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.

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 pre-clinical activities and regulatory operations;
- market research, disease education and other commercial product planning activities; 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.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
	(in thousands)			
Rociletinib Expenses				
Acquired in-process R&D	$—	$—	$—	$5,000
Research and development	31,149	13,407	59,994	23,078
Rociletinib Total	31,149	13,407	59,994	28,078
Rucaparib Expenses				
Acquired in-process R&D	—	400	—	