Clovis Oncology, Inc.
Form 10-Q
November 06, 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 September 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 October 30, 2015 was 38,320,649.

CLOVIS ONCOLOGY, INC.

FORM 10-Q

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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,	
	2015	2014	2015	2014
Revenues:				
License and milestone revenue	$—	$—	$—	$13,625
Operating expenses:				
Research and development	76,138	34,965	193,256	87,556
General and administrative	8,331	5,267	22,286	15,852
Acquired in-process research and development	12,000	—	12,000	8,806
Amortization of intangible asset	—	—	—	3,409
Accretion of contingent purchase consideration	783	888	2,271	2,571
Total expenses	97,252	41,120	229,813	118,194
Operating loss	(97,252)	(41,120)	(229,813)	(104,569)
Other income (expense):				
Interest expense	(2,099)	(511)	(6,271)	(511)
Foreign currency gains (losses)	(101)	2,323	2,004	2,579
Other income (expense)	179	(42)	252	(134)
Other income (expense), net	(2,021)	1,770	(4,015)	1,934
Loss before income taxes	(99,273)	(39,350)	(233,828)	(102,635)
Income tax benefit (expense)	628	(292)	508	(2,489)
Net loss	$(98,645)	$(39,642)	$(233,320)	$(105,124)
Basic and diluted net loss per common share	$(2.62)	$(1.17)	$(6.62)	$(3.10)
Basic and diluted weighted average common shares outstanding	37,613	33,921	35,252	33,871
Comprehensive loss	$(98,222)	$(58,809)	$(250,358)	$(126,126)

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except for share amounts)

	September 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$355,443	$482,677
Available-for-sale securities	250,444	—
Prepaid research and development expenses	2,394	3,765
Other current assets	7,159	4,730
Total current assets	615,440	491,172
Property and equipment, net	3,303	2,718
Intangible assets	196,390	212,900
Goodwill	60,932	66,055
Other assets	15,624	13,361
Total assets	$891,689	$786,206
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$9,316	$2,917
Accrued research and development expenses	58,954	37,257
Other accrued expenses	7,667	7,598
Total current liabilities	75,937	47,772
Contingent purchase consideration	52,421	52,453
Deferred income taxes, net	61,138	66,851
Convertible senior notes	287,500	287,500
Deferred rent, long-term	371	—
Total liabilities	477,367	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 September 30, 2015 and December 31, 2014	—	—
Common stock, $0.001 par value per share, 100,000,000 shares authorized at September 30, 2015 and December 31, 2014; 38,280,996 and 33,977,187 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	38	34
Additional paid-in capital	1,118,135	785,089
Accumulated other comprehensive loss	(41,486)	(24,448)
Accumulated deficit	(662,365)	(429,045)

Total stockholders' equity	414,322	331,630
Total liabilities and stockholders' equity	$891,689	$786,206

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2015	2014
Operating activities		
Net loss	$(233,320)	$(105,124)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	548	3,700
Share-based compensation expense	29,458	15,585
Amortization of premiums and discounts on available-for-sale securities	1,319	—
Amortization of debt issuance costs	900	72
Change in value of contingent purchase consideration	(32)	(309)
Deferred income taxes	(529)	761
Changes in operating assets and liabilities:		
Prepaid and accrued research and development expenses	21,046	7,152
Other operating assets	(3,500)	(3,941)
Accounts payable	6,124	(1,889)
Other accrued expenses	609	892
Net cash used in operating activities	(177,377)	(83,101)
Investing activities		
Purchases of property and equipment	(1,175)	(2,191)
Purchases of available-for-sale securities	(392,540)	—
Sales of available-for-sale securities	140,996	—
Net cash used in investing activities	(252,719)	(2,191)
Financing activities		
Proceeds from the sale of common stock, net of issuance costs	298,509	—
Proceeds from the issuance of convertible senior notes, net of issuance costs	—	278,335
Proceeds from the exercise of stock options and employee stock purchases	5,027	763
Net cash provided by financing activities	303,536	279,098
Effect of exchange rate changes on cash and cash equivalents	(674)	(449)
(Decrease) increase in cash and cash equivalents	(127,234)	193,357
Cash and cash equivalents at beginning of period	482,677	323,228
Cash and cash equivalents at end of period	$355,443	$516,585
Supplemental disclosure of cash flow information:		
Cash paid for interest	$7,307	$—

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") 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. Both the FDA and EMA subsequently accepted the respective filings for review. The FDA granted the rociletinib NDA priority review status with a Prescription Drug User Fee Act action date of March 30, 2016.

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 10 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 $193.9 million ($65.0 million and €115.0 million) if all regulatory and sales milestones are met, utilizing the translation rate at September 30, 2015. The Company recorded a liability for the estimated fair value of these payments, which totaled $52.4 million and $52.5 million at September 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
September 30, 2015				
Assets:				
Money market	$325,843	$325,843	$—	$—
U.S. treasury securities	250,444	—	250,444	—
Total assets at fair value	$576,287	$325,843	$250,444	$—
Liabilities:				
Contingent purchase consideration	$52,421	$—	$—	$52,421
Total liabilities at fair value	$52,421	$—	$—	$52,421
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 Nine Months Ended September 30, 2015
Liabilities:	
Balance at beginning of period	$ 52,453
Accretion	2,271
Change in foreign currency gains and losses	(2,303)
Balance at end of period	$ 52,421

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 September 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 $480.1 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 September 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	$ 250,296	$ 148	$ —	$ 250,444

As of September 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	$175,171	$175,246
Due in one year to two years	75,125	75,198
Total	$250,296	$250,444

6. Other Current Assets

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

	September 30, 2015	December 31, 2014
Receivable from partners	$ 3,836	$ 1,991
Prepaid expenses- other	1,915	1,168
Prepaid insurance	491	1,190
Other	917	381
Total	$ 7,159	$ 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):

	September 30, 2015	December 31, 2014	
IPR&D assets:			
Balance at beginning of period	$212,900	$244,518	
Change in foreign currency gains and losses	(16,510)	(28,209)	
Amortization of intangible asset	—	(3,409)	(a)
Balance at end of period	$196,390	$212,900	
Goodwill:			
Balance at beginning of period	$66,055	$74,811	
Change in foreign currency gains and losses	(5,123)	(8,756)	

Balance at end of period	$60,932	$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):

	September 30, 2015	December 31, 2014
Accrued personnel costs	$ 6,972	$ 4,726
Accrued interest payable	299	2,236
Income tax payable	125	411
Accrued expenses - other	271	225
Total	$ 7,667	$ 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 September 30, 2015, the balance of unamortized debt issuance costs was $7.9 million.

The following table sets forth total interest expense recognized related to the Notes during the three and nine months ended September 30, 2015 and 2014 (in thousands):

	Three Months Ended September 30,		Nine Month Ended September 30,	
	2015	2014	2015	2014
Contractual interest expense	$1,797	$439	$5,371	$439
Amortization of debt issuance costs	302	72	900	72
Total interest expense	$2,099	$511	$6,271	$511

10. Stockholders' Equity

Common Stock

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 $298.5 million, after deducting underwriting discounts and commissions and offering expenses.

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	(17,186)	148	(17,038)
Balance September 30, 2015	$ (41,634)	$ 148	$ (41,486)

The period change between September 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 nine months ended September 30, 2015 and 2014 was recognized in the accompanying Consolidated Statements of Operations and Comprehensive Loss as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Research and development (a)	$9,039	$2,991	$19,798	$8,005
General and administrative	3,367	2,445	9,660	7,580
Total share-based compensation expense	$12,406	$5,436	$29,458	$15,585

(a) During the third quarter of 2015, the Company recognized $2.9 million in share-based compensation expense associated with a modification to the terms of a former executive's stock option agreement.

The Company did not recognize a tax benefit related to share-based compensation expense during the three and nine months ended September 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 September 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	1,476,093 (a)	81.89		
Exercised	(239,144)	18.96		
Forfeited	(99,141)	54.89		
Outstanding at September 30, 2015	5,297,170	$ 50.53	7.9	$ 220,000
Vested and expected to vest at September 30, 2015	4,927,425	$ 49.06	7.8	$ 211,831
Exercisable at September 30, 2015	2,335,441	$ 31.51	6.5	$ 141,187

(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 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 $91.96 as of September 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 nine months ended September 30, 2015 and 2014:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Weighted-average grant date fair value per share	$56.22	$27.85	$52.98	$39.13
Intrinsic value of options exercised	$5,307,365	$4,391	$15,361,206	$2,754,669
Cash received from stock option exercises	$1,953,938	$341	$4,534,288	$541,508

As of September 30, 2015, the unrecognized share-based compensation expense related to nonvested options, adjusted for expected forfeitures, was $96.8 million and the estimated weighted-average remaining vesting period was 2.7 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. In the third quarter of 2015, we made milestone payments totaling $12.0 million upon acceptance of the NDA and MAA for rociletinib by the FDA and EMA, respectively. We recognized all payments prior to commercial approval 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 $98.0 million in development and regulatory milestone payments if certain clinical study objectives and regulatory filings, acceptances and approvals are achieved, including $15.0 million upon the first approval of an NDA by the FDA and $15.0 million upon the first approval of an MAA by the EMA. 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 $3.8 million and $2.0 million receivable at September 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 September 30, 2015 and 2014, we incurred $3.8 million and $2.2 million, respectively, in research and development costs and recorded reductions in research and development expense of $3.8 million and $4.1 million, respectively, for reimbursable development costs due from Servier. For the nine months ending September 30, 2015 and 2014, we incurred $11.7 million and $9.8 million, respectively, in research and development costs and recorded reductions in research and development expense of $10.4 million and $7.9 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 Nine Months Ended September 30,	
	2015	2014
Common shares under option	5,232	2,662
Convertible senior notes	4,646	4,646
Total potential dilutive shares	9,878	7,308

14. Commitments and Contingencies

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 September 30, 2015 and December 31, 2014.

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.

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 September 30, 2015, we had an accumulated deficit of $662.4 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 $298.5 million, after deducting underwriting discounts and commissions and offering expenses.

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. Both the FDA and EMA subsequently accepted the respective filings for review. The FDA granted the rociletinib NDA priority review status with a Prescription Drug User Fee Act action date of March 30, 2016.

Product 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 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 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. In the third quarter of 2015, we made milestone payments totaling $12.0 million upon acceptance of the NDA and MAA for rociletinib by the FDA and EMA, respectively. 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 $98.0 million in development and regulatory milestone payments if certain clinical study objectives and regulatory filings, acceptances and approvals are achieved, including $15.0 million upon the first approval of an NDA by the FDA and $15.0 million upon the first approval of an MAA by the EMA. 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands)			
Rociletinib Expenses				
Acquired in-process R&D	$12,000	$—	$12,000	$5,000
Research and development	36,371	17,905	96,365	40,983
Rociletinib Total	48,371	17,905	108,365	45,983
Rucaparib Expenses				
Acquired in-process R&D	—	—	—	400
Research and development	14,939	10,225	38,762	25,636
Rucaparib Total	14,939	10,225	38,762	26,036
Lucitanib Expenses				
Acquired in-process R&D	—	—	—	3,406
Research and development (a)	37	(1,870)	1,280	(1,518)
Lucitanib Total	37	(1,870)	1,280	1,888
Personnel and other expenses	24,791	8,705	56,849	22,455
Total	$88,138	$34,965	$205,256	$96,362

(a) This amount reflects actual costs incurred less amounts due from Servier for reimbursable development expenses pursuant to the collaboration and license agreement described in Note 12 to our unaudited consolidated financial statements included in this Quarterly Report on Form 10-Q.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, legal, investor relations, human resources 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 related disclosures. On an ongoing basis, we evaluate our estimates and judgments, including those related to contingent purchase consideration, the allocation of purchase consideration, intangible asset impairment, clinical trial accruals and share-based compensation 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, 2014. There have not been any material changes to our critical accounting policies since 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.

Results of Operations

Comparison of Three Months Ended September 30, 2015 and 2014:

The following table summarizes the results of our operations for the three months ended September 30, 2015 and 2014 (in thousands):

	Three Months Ended September 30,		Change 2015 vs. 2014	
	2015	2014	$	%
Operating expenses:				
Research and development	$76,138	$34,965	$41,173	118 %
General and administrative	8,331	5,267	3,064	58 %
Acquired in-process research and development	12,000	—	12,000	n/a
Accretion of contingent purchase consideration	783	888	(105)	(12 %)
Total expenses	97,252	41,120	56,132	137 %
Operating loss	(97,252)	(41,120)	(56,132)	137 %

Other income (expense):				
Interest expense	(2,099)	(511)	(1,588)	311 %
Foreign currency gains (losses)	(101)	2,323	(2,424)	(104%)
Other income (expense)	179	(42)	221	(526%)
Other income (expense), net	(2,021)	1,770	(3,791)	(214%)
Loss before income taxes	(99,273)	(39,350)	(59,923)	152 %
Income tax benefit (expense)	628	(292)	920	(315%)
Net loss	$(98,645)	$(39,642)	$(59,003)	149 %

Research and Development Expenses. Research and development expenses increased during the three months ended September 30, 2015 compared to the same period in the prior year primarily due to increased development activities for the rociletinib and rucaparib programs. Costs associated with non-clinical and clinical development activities for rociletinib were $10.3 million higher than the third quarter in 2014 driven by increased patient enrollment in the TIGER program of studies in non-small cell lung cancer. In addition, market research, disease education and other commercial product planning activities for rociletinib were $7.0 million higher in the third quarter of 2015 due to the preparation for the planned commercial launch.

Clinical supply and related manufacturing costs for rucaparib were $1.6 million higher than the third quarter of 2014, as we increased production to support expanded clinical studies. Clinical trial costs for rucaparib were $1.5 million higher than the same quarter in the prior year primarily due to higher enrollment in the ARIEL-3 study in ovarian cancer. In addition, development costs for rucaparib were $0.9 million higher than the third quarter of 2014 due to the advancement of our collaboration with Foundation Medicine, Inc. to develop a novel companion diagnostic test to identify patients most likely to respond to rucaparib.

Salaries, share-based compensation expense and other personnel-related costs were $15.6 million higher in the third quarter of 2015 driven by higher headcount to support our expanded development and commercial planning activities. In addition, during the third quarter of 2015, the Company recognized $2.9 million of share-based compensation expense associated with a modification to the terms of a former executive’s stock option agreement.

General and Administrative Expenses. General and administrative expenses increased during the three months ended September 30, 2015 compared to the same period in the prior year primarily due to $0.9 million higher share-based compensation expense, $0.9 million higher professional service fees, $0.6 million higher personnel costs and $0.4 million higher facilities expense.

Acquired In-Process Research and Development Expenses. Acquired in-process research and development expenses increased during the three months ended September 30, 2015 compared to the same period in the prior year. During the third quarter of 2015, we made milestone payments totaling $12.0 million to Celgene upon acceptance of the NDA and MAA for rociletinib by the FDA and EMA, respectively. We did not recognize any acquired in-process research and development expense during the third quarter of 2014.

Other Income (Expense), net. Other expense increased during the three months ended September 30, 2015 compared to the same period in the prior year. During the third quarter of 2015, the Company recognized $0.1 million of foreign currency losses compared with $2.3 million of foreign currency gains during the same period in 2014. The change in the foreign currency gains and losses was driven by fluctuations in the foreign currency rate utilized to translate our Euro-denominated contingent purchase consideration liabilities into U.S. dollars. In addition, we recognized $1.6 million higher interest expense related to the Company’s convertible senior notes issued in September 2014.

Comparison of Nine Months Ended September 30, 2015 and 2014:

The following table summarizes the results of our operations for the nine months ended September 30, 2015 and 2014 (in thousands):

	Nine Months Ended September 30,		Change 2015 vs. 2014	
	2015	2014	$	%
Revenues:				
License and milestone revenue	$—	$13,625	$(13,625)	(100%)
Operating expenses:				
Research and development	193,256	87,556	105,700	121%
General and administrative	22,286	15,852	6,434	41%
Acquired in-process research and development	12,000	8,806	3,194	36%
Amortization of intangible asset	—	3,409	(3,409)	(100%)
Accretion of contingent purchase consideration	2,271	2,571	(300)	(12%)
Total expenses	229,813	118,194	111,619	94%
Operating loss	(229,813)	(104,569)	(125,244)	120%
Other income (expense):				
Interest expense	(6,271)	(511)	(5,760)	1,127%
Foreign currency gains	2,004	2,579	(575)	(22%)
Other income (expense)	252	(134)	386	(288%)
Other income (expense), net	(4,015)	1,934	(5,949)	(308%)
Loss before income taxes	(233,828)	(102,635)	(131,193)	128%
Income tax benefit (expense)	508	(2,489)	2,997	(120%)
Net loss	$(233,320)	$(105,124)	$(128,196)	122%

License and Milestone Revenue. License and milestone revenue decreased during the nine months ended September 30, 2015 compared to the same period in the prior year. During the first quarter of 2014, we recognized $13.6 million of milestone revenue from Servier upon the end of opposition and appeal of the lucitanib patent by the European Patent Office. We did not recognize any revenue during the nine months ended September 30, 2015.

Research and Development Expenses. Research and development expenses increased during the nine months ended September 30, 2015 compared to the same period in the prior year primarily due to increased development activities for the rociletinib and rucaparib programs. Costs associated with non-clinical and clinical development activities for rociletinib were $37.2 million higher than 2014 driven by increased patient enrollment in the TIGER program of studies in non-small cell lung cancer. In addition, market research, disease education and other commercial product planning activities for rociletinib were $14.8 million higher in 2015 due to the preparation for the planned commercial launch.

Clinical trial costs for rucaparib were $5.4 million higher than the same period in the prior year primarily due to higher enrollment in the ARIEL-2 and ARIEL-3 studies in ovarian cancer. Development costs for rucaparib were also

$3.7 million higher than 2014 due to the advancement of our collaboration with Foundation Medicine, Inc. to develop a novel companion diagnostic test to identify patients most likely to respond to rucaparib.

Clinical supply and related manufacturing development costs for both programs were $5.5 million higher than 2014, as we increased production to support the expanded clinical studies.

Salaries, share-based compensation expense and other personnel-related costs were $33.3 million higher in 2015 driven by higher headcount to support our expanded development and commercial planning activities. In addition, during the third quarter of 2015, the Company recognized $2.9 million of share-based compensation expense associated with a modification to the terms of a former executive’s stock option agreement.

General and Administrative Expenses. General and administrative expenses increased during the nine months ended September 30, 2015 compared to the same period in the prior year primarily due to $2.1 million higher share-based compensation expense, $1.4 million higher professional services, $1.1 million higher personnel costs, $1.0 million higher facilities expense and $0.4 million higher information technology expense.

Acquired In-Process Research and Development Expenses. Acquired in-process research and development expenses increased during the nine months ended September 30, 2015 compared to the same period in the prior year. During the third quarter of 2015, we made milestone payments totaling $12.0 million to Celgene upon acceptance of the NDA and MAA for rociletinib by the FDA and EMA, respectively. During the first quarter of 2014, we made a $5.0 million milestone payment to Celgene upon initiation of the Phase II study for rociletinib, and we recorded a $3.4 million charge for a milestone payment to Advenchen, representing 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. During the second quarter of 2014, we also made a $0.4 million milestone payment to Pfizer upon initiation of a pivotal registration study for rucaparib.

Amortization of Intangible Asset. Amortization of intangible asset decreased during the nine months ended September 30, 2015 compared to the same period in the prior year. During the first quarter of 2014, the fair value of the acquired in-process research and development intangible assets was reduced by $3.4 million due to a fair value adjustment to an asset's expected future cash flows resulting from the receipt of the lucitanib milestone payment. We did not record a fair value adjustment during the nine months ended September 30, 2015.

Other Income (Expense), net. Other expense increased during the nine months ended September 30, 2015 compared to the same period in the prior year driven by $5.8 million higher interest expense related to the Company's convertible senior notes issued in September 2014.

Income Taxes. Income tax expense decreased during the nine months ended September 30, 2015 compared to the same period in the prior year. During the first quarter of 2014, we recorded foreign tax provisions related to the milestone revenue recognized under the Servier license agreement, partially offset by a deferred tax benefit recognized upon reduction of the carrying value of the IPR&D assets.

Liquidity and Capital Resources

To date, we have funded our operations through the sale of equity and convertible debt securities. At September 30, 2015, we had cash, cash equivalents and available-for-sale securities totaling $605.9 million.

The following table sets forth the primary sources and uses of cash for the nine months ended September 30, 2015 and 2014:

	Nine Months Ended September 30,	
	2015	2014
	(in thousands)	
Net cash used in operating activities	$(177,377)	$(83,101)
Net cash used in investing activities	(252,719)	(2,191)
Net cash provided by financing activities	303,536	279,098
Effect of exchange rate changes on cash and cash equivalents	(674)	(449)
Net (decrease) increase in cash and cash equivalents	$(127,234)	$193,357

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 $94.3 million during the nine months ended September 30, 2015 compared to the prior year driven by higher rociletinib and

rucaparib research and development costs associated with the expansion of the clinical trials, as well as the preparation for the planned commercial launch of rociletinib, and higher salaries, benefits and personnel-related costs resulting from higher headcount to support the expanded development activities of our product candidates. During the third quarter of 2015, we made milestone payments totaling $12.0 million to Celgene upon acceptance of the NDA and MAA for rociletinib by the FDA and EMA, respectively. During the nine months ended September 30, 2015, we also paid $7.3 million in interest related to the convertible senior notes. The net loss for the nine months ended September 30, 2014 was partially offset by a $13.6 million milestone revenue payment received from Servier.

Investing Activities

Net cash used in investing activities increased $250.5 million during the nine months ended September 30, 2015 compared to the prior year primarily due to the purchase of available-for-sale securities.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2015 includes $298.5 million in net proceeds received from our recent common stock offering and $5.0 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, 2014 includes $278.3 million in net proceeds received from our convertible senior notes offering in September 2014 and $0.8 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 may not be sufficient to fund our operations through successful development and commercialization of our product candidates. As a result, we may 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.

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 2014 Annual Report on Form 10-K. There have not been any material changes to such contractual obligations or potential milestone payments since December 31, 2014. 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.

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, 2015, we had cash, cash equivalents and available-for-sale securities of $605.9 million, consisting of bank demand deposits, money market funds and U.S. treasury securities. The primary objectives of our investment policy are to preserve principal and maintain proper liquidity to meet operating needs. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Our available-for-sale securities are subject to interest rate risk and will decline in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair value of our portfolio.

We contract with contract research organizations, investigational sites and contract manufacturers globally where payments are made in currencies other than the U.S. dollar. In addition, 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, 2015 and December 31, 2014, approximately 6% and 7%, 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, 2015 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, 2015, 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, 2015 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, 2014 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, 2014. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial also may negatively impact our business.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS
None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES
None.

ITEM 4. MINE SAFETY DISCLOSURES
Not Applicable.

ITEM 5. OTHER INFORMATION
None.

ITEM 6. EXHIBITS

INDEX TO EXHIBITS

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.
4.3(8)	Indenture dated as of September 9, 2014, by and between Clovis Oncology, Inc. and The Bank of New York Mellon Trust Company, N.A.
10.1*(4)	Amended and Restated Strategic License Agreement, dated as of June 16, 2011, by and between Clovis Oncology, Inc. and Avila Therapeutics, Inc.
10.2*(4)	License Agreement, dated as of June 2, 2011, by and between Clovis Oncology, Inc. and Pfizer Inc.
10.3+(1)	Clovis Oncology, Inc. 2009 Equity Incentive Plan.
10.4+(4)	Clovis Oncology, Inc. 2011 Stock Incentive Plan.
10.5+(1)	Form of Clovis Oncology, Inc. 2009 Equity Incentive Plan Stock Option Agreement.
10.6+(4)	Form of Clovis Oncology, Inc. 2011 Stock Incentive Plan Stock Option Agreement.
10.7+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Patrick J. Mahaffy.
10.8+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Erle T. Mast.
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.
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+(4)	Clovis Oncology, Inc. 2011 Employee Stock Purchase Plan.
10.22+(4)	Clovis Oncology, Inc. 2011 Cash Bonus Plan.
10.23+(6)	Employment Agreement, dated as of March 22, 2012, by and between Clovis Oncology, Inc. and Steven L. Hoerter.
10.24+(6)	Indemnification Agreement, dated as of March 22, 2012, by and between Clovis Oncology, Inc. and Steven L. Hoerter.
10.25+(2)	Indemnification Agreement, dated as of June 13, 2013, between Clovis Oncology, Inc. and Ginger L. Graham.
10.26+(2)	Indemnification Agreement, dated as of June 13, 2013, between Clovis Oncology, Inc. and Keith Flaherty.
10.27(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.

10.28*(7)	Development and Commercialization Agreement, dated as of October 24, 2008, by and between Advenchen Laboratories LLC and Ethical Oncology Science S.p.A., as amended by the First Amendment, dated as of April 13, 2010 and the Second Amendment, dated as of July 30, 2012.
10.29*(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.
10.30(9)	Consulting Agreement, dated August 6, 2015, by and between Andrew Allen and Clovis Oncology, Inc.
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from Clovis Oncology, Inc.'s Quarterly Report on Form 10-Q for the period ended September 30, 2015, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Statements of Operations and Comprehensive Loss, (ii) the Consolidated Balance Sheets, (iii) the Consolidated Statements of Cash Flows and (iv) Notes to Unaudited Consolidated Financial Statements.

(1) Filed as an exhibit with the Registrant's Registration Statement on Form S-1 (File No. 333-175080) on June 23, 2011.
(2) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on June 14, 2013.
(3) Filed as an exhibit with Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (File No. 333-175080) on August 31, 2011.
(4) Filed as an exhibit with Amendment No. 3 to the Registrant's Registration Statement on Form S-1 (File No. 333-175080) on October 31, 2011.
(5) Filed as an exhibit with the Registrant's Annual Report on Form 10-K on March 15, 2012.
(6) Filed as an exhibit with the Registrant's Registration Statement on Form S-1 (File No. 333-180293) on March 23, 2012.
(7) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on November 19, 2013.
(8) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on September 9, 2014.
(9) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on August 12, 2015.
+ 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 6, 2015 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