Clovis Oncology, Inc.
Form 10-Q
May 09, 2016

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 March 31, 2016.

¨ 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.)
5500 Flatiron Parkway, Suite 100	
Boulder, Colorado	80301
(Address of principal executive offices)	(Zip Code)

(303) 625-5000

(Registrant’s telephone number, including area code)

Not Applicable

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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 April 29, 2016 was 38,385,660.

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

(Unaudited)

(In thousands, except per share amounts)

	Three Months Ended March 31,	
	2016	2015
Revenues:		
License and milestone revenue	$—	$—
Operating expenses:		
Research and development	74,608	56,750
General and administrative	9,827	6,751
Change in fair value of contingent purchase consideration	516	724
Total expenses	84,951	64,225
Operating loss	(84,951)	(64,225)
Other income (expense):		
Interest expense	(2,104)	(2,075)
Foreign currency gains (losses)	(551)	3,247
Other income	25	11
Other income (expense), net	(2,630)	1,183
Loss before income taxes	(87,581)	(63,042)
Income tax benefit (expense)	4,181	(102)
Net loss	$(83,400)	$(63,144)
Basic and diluted net loss per common share	$(2.17)	$(1.86)
Basic and diluted weighted-average common shares outstanding	38,360	34,011

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

(In thousands)

	Three Months Ended March 31,	
	2016	2015
Net loss	$(83,400)	$(63,144)
Other comprehensive income (loss)		
Foreign currency translation adjustments, net of tax	3,513	(25,915)
Net unrealized gain on available-for-sale securities, net of tax	230	88
Other comprehensive income (loss)	3,743	(25,827)
Comprehensive loss	$(79,657)	$(88,971)

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except for share amounts)

	March 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$220,373	$278,756
Available-for-sale securities	225,117	249,832
Prepaid research and development expenses	10,391	3,377
Other current assets	8,090	7,736
Total current assets	463,971	539,701
Property and equipment, net	5,108	4,946
Intangible assets	105,689	101,500
Goodwill	61,775	59,327
Other assets	8,031	7,912
Total assets	$644,574	$713,386
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$14,100	$11,260
Accrued research and development expenses	52,642	53,011
Other accrued expenses	7,199	11,305
Total current liabilities	73,941	75,576
Contingent purchase consideration	25,710	24,661
Deferred income taxes, net	30,476	31,133
Convertible senior notes	280,192	279,885
Deferred rent, long-term	1,592	1,481
Total liabilities	411,911	412,736
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 March 31, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value per share, 100,000,000 shares authorized at March 31, 2016 and December 31, 2015; 38,364,454 and 38,359,454 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	38	38
Additional paid-in capital	1,141,648	1,129,978
Accumulated other comprehensive loss	(43,717)	(47,460)
Accumulated deficit	(865,306)	(781,906)

Total stockholders' equity	232,663	300,650
Total liabilities and stockholders' equity	$644,574	$713,386

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Three Months Ended March 31,	
	2016	2015
Operating activities		
Net loss	$(83,400)	$(63,144)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	10,965	8,682
Depreciation and amortization	270	169
Amortization of premiums and discounts on available-for-sale securities	80	471
Amortization of debt issuance costs	307	298
Change in fair value of contingent purchase consideration	1,049	(2,794)
Loss on disposal of property and equipment	169	—
Deferred income taxes	(4,145)	—
Changes in operating assets and liabilities:		
Prepaid and accrued research and development expenses	(7,601)	7,776
Other operating assets	(130)	(805)
Accounts payable	2,682	4,228
Other accrued expenses	(3,984)	(3,286)
Net cash used in operating activities	(83,738)	(48,405)
Investing activities		
Purchases of property and equipment	(604)	(816)
Purchases of available-for-sale securities	—	(142,216)
Maturities of available-for-sale securities	25,000	—
Net cash provided by (used in) investing activities	24,396	(143,032)
Financing activities		
Proceeds from the exercise of stock options and employee stock purchases	705	1,193
Net cash provided by financing activities	705	1,193
Effect of exchange rate changes on cash and cash equivalents	254	(891)
Decrease in cash and cash equivalents	(58,383)	(191,135)
Cash and cash equivalents at beginning of period	278,756	482,677
Cash and cash equivalents at end of period	$220,373	$291,542
Supplemental disclosure of cash flow information:		
Cash paid for interest	$3,594	$3,714

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 upfront 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.

On April 12, 2016, the Oncologic Drugs Advisory Committee ("ODAC") met to discuss approval of the NDA for rociletinib. The ODAC reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products used in the treatment of cancer and makes recommendations to the FDA. The Committee recommended that the FDA wait to see results from TIGER-3, the Company's ongoing Phase III, randomized, controlled trial of rociletinib, before making a decision on approval of the treatment.

On May 5, 2016, the Company announced that it was notified by the FDA that it could expect to receive a Complete Response Letter ("CRL") for the rociletinib NDA on or before the Prescription Drug User Fee Act date of June 28, 2016. The FDA issues a CRL to indicate that their review of an application is complete and that the application is not ready for approval. In anticipation of receiving the CRL, the Company terminated enrollment in all ongoing sponsored clinical studies of rociletinib. The Company will continue to provide drug to patients whose clinicians recommend continuing rociletinib therapy. In addition, the Company has withdrawn its MAA for rociletinib currently on file with the EMA.

Basis of Presentation

All financial information presented includes the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

The unaudited financial statements of Clovis Oncology, Inc. included herein reflect all adjustments, consisting only of normal recurring adjustments, 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, 2015 for a broader discussion of our business and the opportunities and risks inherent in such business.

Reclassifications

Certain reclassifications have been made to prior year amounts to conform to the current year presentation. These reclassifications had no effect on the Company's previously reported results of operations, financial position or cash flows.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and revenue and related disclosures. On an ongoing basis, 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. Based on current estimates, management believes that existing working capital at March 31, 2016 is sufficient to meet the cash requirements to fund planned operations through at least the next 12 months, although there can be no assurance that this can, in fact, be accomplished.

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, 2015.

Recently Issued Accounting Standards

In March 2016, the Financial Accounting Standards Board issued Accounting Standards Update ("ASU") No. 2016-09, "Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting." ASU No. 2016-09 requires all income tax effects of awards to be recognized in the income statement when the awards vest or are settled. The guidance also requires the presentation of excess tax benefits as an operating activity on the statement of cash flows rather than as a financing activity. This update is effective for annual periods beginning after December 15, 2016, including interim periods within those annual periods. Early adoption is permitted. Amendments related to the timing of when excess tax benefits are recognized should be applied using a modified retrospective transition method. An entity may elect to apply the amendments related to the presentation of excess tax benefits on the statement of cash flows using either a prospective transition method or a retrospective transition method. The Company is currently evaluating its planned method of adoption and the impact the standard may have on its consolidated financial statements and related disclosures.

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 Company paid $11.8 million in cash and issued $173.7 million of common stock at the acquisition date and may make additional future cash payments 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 $195.7 million ($65.0 million and €115.0 million) if all regulatory and sales milestones are met, utilizing the translation rate at March 31, 2016. The Company recorded a liability for the estimated fair value of these payments, which totaled $25.7 million and $24.7 million at March 31, 2016 and December 31, 2015, 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 are considered to be available-for-sale securities and consist of U.S. Treasury securities. Available-for-sale securities are reported at fair value on the Consolidated Balance Sheets and unrealized gains and losses are included in accumulated other comprehensive income (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. 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 that is deemed to be other than temporary is charged to earnings and results in the establishment of a new cost basis for the security. Factors evaluated to determine if an investment is other-than-temporarily impaired include significant deterioration in earnings performance, credit rating, asset quality or business prospects of the issuer; adverse changes in the general market conditions in which the issuer operates; and the Company's intent and ability to hold the security until an anticipated recovery in value occurs.

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 consist of 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 2015 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
March 31, 2016				
Assets:				
Money market	$201,467	$201,467	$—	$—
U.S. treasury securities	225,117	—	225,117	—
Total assets at fair value	$426,584	$201,467	$225,117	$—
Liabilities:				
Contingent purchase consideration	$25,710	$—	$—	$25,710
Total liabilities at fair value	$25,710	$—	$—	$25,710
December 31, 2015				
Assets:				

Money market	$251,037	$251,037	$—	$—
U.S. treasury securities	249,832	—	249,832	—
Total assets at fair value	$500,869	$251,037	$249,832	$—
Liabilities:				
Contingent purchase consideration	$24,661	$—	$—	$24,661
Total liabilities at fair value	$24,661	$—	$—	$24,661

There were no transfers between the Level 1 and Level 2 categories or into or out of the Level 3 category during the three months ended March 31, 2016.

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

	For the Three Months Ended March 31, 2016
Liabilities:	
Balance at beginning of period	$ 24,661
Change in fair value	516
Change in foreign currency gains and losses	533
Balance at end of period	$ 25,710

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

Financial instruments not recorded at fair value include the Company's convertible senior notes. At March 31, 2016, the carrying amount of the convertible senior notes was $287.5 million, which represents the aggregate principal amount, and the fair value was $195.5 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 March 31, 2016, available-for-sale securities consisted of the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value
U.S. treasury securities	$ 225,135	$ 4	$ (22)	$ 225,117

As of December 31, 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	$ 250,215	$ —	$ (383)	$ 249,832

As of March 31, 2016, the fair value and gross unrealized losses of available-for-sale securities that have been in a continuous unrealized loss position for less than 12 months were as follows (in thousands):

	Aggregate Fair Value	Gross Unrealized Losses
U.S. treasury securities	$ 125,053	$ (22)

As of March 31, 2016, certain of the Company's investments have been in an unrealized loss position for between five and six months. Based upon our evaluation of all relevant factors, we believe that the decline in fair value of securities held at March 31, 2016 below cost is temporary, and we intend to retain our investment in these securities for a sufficient period of time to allow for recovery of the fair value.

As of December 31, 2015, the fair value and gross unrealized losses of available-for-sale securities that have been in a continuous unrealized loss position for less than 12 months were as follows (in thousands):

	Aggregate Fair Value	Gross Unrealized Losses
U.S. treasury securities	$249,832	$ (383)

As of March 31, 2016, 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	$225,135	$225,117
Total	$225,135	$225,117

6. Other Current Assets

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

	March 31, 2016	December 31, 2015
Receivable from partners	$3,671	$ 3,241
Receivable from landlord	1,277	1,153
Prepaid expenses - other	1,195	1,023
Prepaid insurance	919	1,231
Receivable - other	915	889
Other	113	199
Total	$8,090	$ 7,736

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 (see Note 3) and consisted of the following (in thousands):

	March 31,	December 31,

	2016	2015
IPR&D assets:		
Balance at beginning of period	$101,500	$212,900
Impairment of intangible asset (a)	—	(89,557)
Change in foreign currency gains (losses)	4,189	(21,843)
Balance at end of period	$105,689	$101,500
Goodwill:		
Balance at beginning of period	$59,327	$66,055
Change in foreign currency gains (losses)	2,448	(6,728)
Balance at end of period	$61,775	$59,327

(a) During the fourth quarter of 2015, the Company recorded an $89.6 million impairment charge due to the Company's and its development partner's decision to terminate the development of lucitanib for lung cancer, as well as updates to the probability-weighted discounted cash flow assumptions for the breast cancer indication.

Recurring amortization of the IPR&D assets will commence upon completion of the related research and development activities. IPR&D intangible assets are evaluated for impairment at least annually in the fourth quarter or more frequently if impairment indicators exist and any reduction in fair value would be recorded as impairment of intangible asset on the Consolidated Statements of Operations.

As part of the acquisition of EOS, the Company recorded a deferred tax liability to recognize the difference between the book and tax basis of the assets and liabilities acquired. During the first quarter of 2016, the Company updated the annual effective tax rate to reflect a reduction in the statutory rate of the foreign jurisdiction, resulting in the recognition of a $3.6 million income tax benefit.

8. Other Accrued Expenses

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

	March 31, 2016	December 31, 2015
Accrued personnel costs	$5,829	$ 8,250
Accrued expenses - other	1,071	959
Accrued interest payable	299	2,096
Total	$7,199	$ 11,305

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. 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. The debt issuance costs are presented as a deduction from convertible senior notes on the Consolidated Balance Sheets and are amortized as interest expense over the expected life of the Notes using the effective interest method. The Company determined the expected life of the debt was equal to the seven-year term of the Notes. As of March 31, 2016 and December 31, 2015, the balance of unamortized debt issuance costs was $7.3 million and $7.6 million, respectively.

The following table sets forth total interest expense recognized related to the Notes during the three months ended March 31, 2016 and 2015 (in thousands):

	Three Months Ended March 31,	
	2016	2015
Contractual interest expense	$1,797	$1,777
Amortization of debt issuance costs	307	298
Total interest expense	$2,104	$2,075

10. Stockholders' Equity

Accumulated Other Comprehensive Income (Loss)

Accumulated other comprehensive income (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 (Losses)	Total Accumulated Other Comprehensive Income (Loss)
Balance December 31, 2014	$ (24,448)	$ —	$ (24,448)
Period change	(22,629)	(383)	(23,012)
Balance December 31, 2015	(47,077)	(383)	(47,460)
Period change	5,580	365	5,945
Income tax expense	(2,067)	(135)	(2,202)
Balance March 31, 2016	$ (43,564)	$ (153)	$ (43,717)

The period change between March 31, 2016 and December 31, 2015 was primarily due to the currency translation of the IPR&D intangible assets, goodwill and deferred income taxes associated with the acquisition of EOS (see Note 3 and Note 7).

11. Share-Based Compensation

Share-based compensation expense for all equity based programs, including stock options, restricted stock units and the employee stock purchase plan, for the three months ended March 31, 2016 and 2015 was recognized in the

accompanying Consolidated Statements of Operations as follows (in thousands):

	Three Months Ended March 31,	
	2016	2015
Research and development	$7,309	$5,404
General and administrative	3,656	3,278
Total share-based compensation expense	$10,965	$8,682

The Company did not recognize a tax benefit related to share-based compensation expense during the three months ended March 31, 2016 and 2015, respectively, as the Company maintains net operating loss carryforwards and has established a valuation allowance against the entire net deferred tax asset as of March 31, 2016.

The following table summarizes the activity relating to the Company's options to purchase common stock for the three months ended March 31, 2016:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (Thousands)
Outstanding at December 31, 2015	5,360,257	$ 51.53		
Granted	661,640	21.51		
Exercised	(5,000)	11.02		
Forfeited	(378,852)	67.37		
Outstanding at March 31, 2016 (a)	5,638,045	$ 46.98	7.2	$ 7,440
Vested and expected to vest at March 31, 2016	5,346,922	$ 46.43	7.1	$ 7,440
Exercisable at March 31, 2016	2,845,256	$ 36.04	5.7	$ 7,438

(a) Includes 85,000 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 $19.20 as of March 31, 2016, 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 months ended March 31, 2016 and 2015:

	Three Months Ended March 31,	
	2016	2015
Weighted-average grant date fair value per share	$15.24	$49.75
Intrinsic value of options exercised	$46,400	$5,087
Cash received from stock option exercises	$55,100	$1,193

As of March 31, 2016, the unrecognized share-based compensation expense related to unvested options, adjusted for expected forfeitures, was $90.7 million and the estimated weighted-average remaining vesting period was 2.5 years.

During the first quarter of 2016, the Company issued restricted stock units ("RSUs") to certain employees under the 2011 Stock Incentive Plan. The RSUs vest over either a two-year period or over a four-year period and are payable in shares of the Company's common stock at the end of the vesting period. RSUs are measured based on the fair value of the underlying stock on the grant date. Shares issued on the vesting dates are net of the minimum statutory tax to be paid by the Company on behalf of its employees. As a result, the actual number of shares issued will be lower than the actual number of RSUs vested.

The following table summarizes the activity relating to the Company's unvested RSUs for the three months ended March 31, 2016:

	Number of Units	Weighted-Average Grant Date Fair Value
Unvested as of December 31, 2015	—	$ —
Granted	146,316	19.37
Vested	—	—
Forfeited	(4,797)	19.37
Unvested as of March 31, 2016	141,519	$ 19.37
Expected to vest after March 31, 2016	119,521	$ 19.37

As of March 31, 2016, the unrecognized share-based compensation expense related to unvested RSUs, adjusted for expected forfeitures, was $2.3 million and the estimated weighted-average remaining vesting period was 2.5 years.

12. License Agreements

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. Under the terms of the license agreement, the Company made a $7.0 million upfront 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, including $20.75 million associated with the first approval of an NDA by the FDA.

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 non-clinical, clinical, regulatory and other activities necessary to develop and commercialize rociletinib.

We made an upfront 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.

Lucitanib

In connection with its acquisition of EOS (see Note 3), 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 upfront milestone fees, royalties on sales of lucitanib in the sublicensed territories and research and development funding commitments.

In October 2008, EOS entered into an exclusive license agreement with Advenchen to develop and commercialize lucitanib on a global basis, excluding China. The Company is obligated to pay Advenchen royalties on net sales of lucitanib based on the volume of annual net sales achieved. In addition, the Company is obligated to pay to Advenchen 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 upfront payment of €45.0 million and is entitled to receive additional payments upon achievement of specified development, regulatory and commercial milestones up to €90.0 million in the aggregate. In addition, the Company is entitled to receive sales milestone payments if specified annual sales targets for lucitanib are met, which, in the aggregate, could total €250.0 million. The Company is also entitled to receive royalties on 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. Based on current estimates, we expect that Servier’s €80.0 million funding commitment will be fulfilled in early 2017, and thereafter, we will share with Servier in future development costs pursuant to a mutually agreed upon global development plan. Reimbursements are recorded as a reduction to research and development expense in the Consolidated Statements of Operations.

The Company recorded a $3.7 million and $3.2 million receivable at March 31, 2016 and December 31, 2015, 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 both the three months ending March 31, 2016 and 2015, we incurred $3.6 million in research and development costs and recorded reductions in research and development expense of $3.6 million and $2.7 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 RSUs and the if-converted method for the Notes. As a result of our net losses for the periods presented, all potentially dilutive common share equivalents were considered anti-dilutive and were excluded from the computation of diluted net loss per share.

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

	Three Months Ended March 31,	
	2016	2015

Common shares under option	539	4,005
Convertible senior notes	4,646	4,646
Total potential dilutive shares	5,185	8,651

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 March 31, 2016 and December 31, 2015.

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 March 31, 2016, $16.6 million of purchase commitments exist under this agreement.

Legal Proceedings

The Company and certain of its officers were named as defendants in several lawsuits, as described below. We cannot reasonably predict the outcome of these legal proceedings, nor can we estimate the amount of loss or range of loss, if any, that may result. An adverse outcome in these proceedings could have a material adverse effect on our results of operations, cash flows or financial condition.

On November 19, 2015, Steve Kimbro, a purported shareholder of Clovis, filed a purported class action complaint (the "Kimbro Complaint") against Clovis and certain of its officers in the United States District Court for the District of Colorado. The Kimbro Complaint purports to be asserted on behalf of a class of persons who purchased Clovis stock between October 31, 2013 and November 15, 2015. The Kimbro Complaint generally alleges that Clovis and certain of its officers violated federal securities laws by making allegedly false and misleading statements regarding the progress toward FDA approval and the potential for market success of rociletinib. The Kimbro Complaint seeks unspecified damages.

Also on November 19, 2015, a second purported shareholder class action complaint was filed by Sonny P. Medina, another purported Clovis shareholder, containing similar allegations to those set forth in the Kimbro Complaint, also in the United States District Court for the District of Colorado (the "Medina Complaint"). The Medina Complaint purports to be asserted on behalf of a class of persons who purchased Clovis stock between May 20, 2014 and November 13, 2015. On November 20, 2015, a third complaint was filed by John Moran in the United States District Court for the Northern District of California (the "Moran Complaint"). The Moran Complaint contains similar allegations to those asserted in the Kimbro and Medina Complaints and purports to be asserted on behalf of a plaintiff class who purchased Clovis stock between October 31, 2013 and November 13, 2015.

On December 14, 2015, Ralph P. Rocco, a fourth purported shareholder of Clovis, filed a complaint in the United States District Court for the District of Colorado (the "Rocco Complaint"). The Rocco Complaint contains similar allegations to those set forth in the previous complaints and purports to be asserted on behalf of a plaintiff class who purchased Clovis stock between October 31, 2013 and November 15, 2015.

On January 19, 2016, a number of motions were filed in both the District of Colorado and the Northern District of California seeking to consolidate the shareholder class actions into one matter and for appointment of a lead plaintiff. All lead plaintiff movants other than M. Arkin (1999) LTD and Arkin Communications LTD (the "Arkin Plaintiffs") subsequently filed notices of non-opposition to the Arkin Plaintiffs' application.

On February 2, 2016, the Arkin Plaintiffs filed a motion to transfer the Moran Complaint to the District of Colorado (the "Motion to Transfer"). Also on February 2, 2016, the defendants filed a statement in the Northern District of California supporting the consolidation of all actions in a single court, the District of Colorado. On February 3, 2016, the Northern District of California court denied without prejudice the lead plaintiff motions filed in that court pending a decision on the Motion to Transfer.

On February 16, 2016, the defendants filed a memorandum in support of the Motion to Transfer, and plaintiff Moran filed a notice of non-opposition to the Motion to Transfer. On February 17, 2016, the Northern District of California court granted the Motion to Transfer.

On February 18, 2016, the Medina court issued an opinion and order addressing the various motions for consolidation and appointment of lead plaintiff and lead counsel in the District of Colorado actions. By this ruling, the court consolidated the Medina, Kimbro and Rocco actions into a single proceeding. The court also appointed the Arkin Plaintiffs as the lead plaintiffs and Bernstein Litowitz Berger & Grossman as lead counsel for the putative class.

On April 1, 2016, the Arkin Plaintiffs and the defendants filed a stipulated motion to set the schedule for the filing of a consolidated complaint in the Medina, Kimbro and Rocco actions (the "Consolidated Complaint") and the responses thereto, including the defendants' anticipated motion to dismiss the Consolidated Complaint (the "Motion to Dismiss"), and to stay discovery and related proceedings until the District of Colorado issues a decision on the Motion to Dismiss. The stipulated motion was entered by the District of Colorado on April 4, 2016. Subject to a further agreed-upon extension by the parties, the Consolidated Complaint was filed on May 6, 2016, while the Motion to Dismiss is due on July 11, 2016, the Arkin Plaintiff's opposition on August 19, 2016 and the defendants' reply on September 7, 2016. On April 15, 2016, the Arkin Plaintiffs and the defendants filed a stipulated motion to consolidate the Moran action, now pending in the District of Colorado, with the Medina, Kimbro and Rocco actions.

The Company intends to vigorously defend against the allegations contained in the Kimbro, Medina, Moran and Rocco Complaints, but there can be no assurance that the defense will be successful.

On December 30, 2015, Jamie McCall, a purported shareholder of Clovis, filed a shareholder derivative complaint (the "McCall Complaint") against certain officers and directors of Clovis in the Colorado District Court, County of Boulder. The McCall Complaint generally alleges that the defendants breached their fiduciary duties owed to Clovis by participating in misrepresentation of the Company's business operations and prospects. The McCall Complaint also alleges claims for abuse of control, gross mismanagement and unjust enrichment. The McCall Complaint seeks, among other things, an award of money damages, declaratory and injunctive relief concerning the alleged fiduciary breaches and other forms of equitable relief. The Company intends to vigorously defend against the allegations contained in the McCall Complaint, but there can be no assurance that the defense will be successful.

On January 22, 2016, the Electrical Workers Local #357 Pension and Health & Welfare Trusts, a purported shareholder of Clovis, filed a purported class action complaint (the "Electrical Workers Complaint") against Clovis and certain of its officers, directors, investors and underwriters in the Superior Court of the State of California, County of San Mateo. The Electrical Workers Complaint purports to be asserted on behalf of a class of persons who purchased stock in Clovis' July 8, 2015 follow-on offering. The Electrical Workers Complaint generally alleges that the defendants violated the Securities Act because the offering documents for the July 8, 2015 follow-on offering contained allegedly false and misleading statements regarding the progress toward FDA approval and the potential for market success of rociletinib. The Electrical Workers Complaint seeks unspecified damages.

On February 25, 2016, the defendants removed the case to the United States District Court for the Northern District of California and thereafter moved to transfer the case to the District of Colorado ("Motion to Transfer"). On March 2, 2016, the plaintiff filed a motion to remand the case to San Mateo County Superior Court ("Motion to Remand"). Following briefing on the Motion to Transfer and the Motion to Remand, the Northern District of California held a hearing on April 18, 2016 concerning the Motion to Remand, at the conclusion of which the court granted to the Motion to Remand. We expect that the court will deny the Motion to Transfer as moot. The Company intends to vigorously defend against the allegations contained in the Electrical Workers Complaint, but there can be no assurance that the defense will be successful.

On February 19, 2016, Maris Sanchez, a purported shareholder of Clovis, filed a shareholder derivative complaint (the "Sanchez Complaint") against certain officers and directors of Clovis in the United States District Court for the District of Colorado. The Sanchez Complaint generally alleged that the defendants breached their fiduciary duties owed to Clovis by participating in misrepresentation of the Company's business operations and prospects. The Sanchez Complaint also alleged claims for abuse of control and gross mismanagement. The Sanchez Complaint sought, among other things, an award of money damages. On March 11, 2016, the plaintiff filed a notice of voluntary dismissal of the Sanchez Complaint without prejudice. On March 14, 2016, the Sanchez action was terminated by the District of Colorado.

The Company has received requests for information from governmental agencies relating to the Company's regulatory update announcement in November 2015 that the FDA requested additional clinical data on the efficacy and safety of rociletinib. The Company is cooperating with the inquiries.

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 non-clinical studies and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity and the development of the industry in which we operate may differ materially from the forward-looking statements contained herein.

Any forward-looking statements that we make in this Quarterly Report on Form 10-Q speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect the occurrence of unanticipated events.

You should also read carefully the factors described in the "Risk Factors" 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 other international markets. We generally 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 two product candidates:

- Rucaparib, an oral inhibitor of poly (ADP-ribose) polymerase that is currently in advanced clinical development for the treatment of ovarian cancer. We filed the first component of our rolling New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") for potential accelerated approval of rucaparib in the the U.S., and we intend to complete the NDA submission by the second quarter of 2016. We intend to submit our first E.U. regulatory application in the fourth quarter of 2016.
- Lucitanib, an oral inhibitor of the tyrosine kinase activity of vascular endothelial growth factor receptors (VEGFR) 1-3, platelet-derived growth factor receptors (PDGFR) alpha and beta and fibroblast growth factor receptors (FGFR) 1-3, which is in Phase II development for the treatment of breast cancer.

In addition, we have a third product candidate, rociletinib. Rociletinib is an oral epidermal growth factor receptor ("EGFR"), mutant-selective covalent inhibitor for the treatment of advanced non-small cell lung cancer in patients with activating EGFR mutations, as well as the dominant resistance mutation, T790M. On May 5, 2016, the Company announced that it was notified by the FDA that it could expect to receive a Complete Response Letter ("CRL") for the rociletinib NDA on or before the Prescription Drug User Fee Act date of June 28, 2016. The FDA issues a CRL to indicate that their review of an application is complete and that the application is not ready for approval. In anticipation of receiving the CRL, the Company terminated enrollment in all ongoing sponsored clinical studies of rociletinib. The Company will continue to provide drug to patients whose clinicians recommend continuing rociletinib therapy. In addition, the Company has withdrawn its Marketing Authorization Application for rociletinib currently on file with the European Medicines Agency.

We hold global development and commercialization rights for rucaparib and rociletinib. For lucitanib, we hold development and commercialization rights in the U.S. and Japan and have sublicensed rights to Europe and rest of world markets, excluding China, to Les Laboratoires ("Servier").

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 sale of convertible preferred stock, the issuance of convertible promissory notes, public offerings of our common stock and our convertible senior notes offering.

We have never been profitable and, as of March 31, 2016, we had an accumulated deficit of $865.3 million. We expect to incur significant 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. Based on our current estimates, we believe that our cash, cash equivalents and available-for-sale securities as of March 31, 2016 will allow us to fund activities through at least the next 12 months. We expect to finance future cash needs through a combination of public or private equity or debt offerings, collaborations, strategic alliances or other similar licensing arrangements. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

Product License Agreements

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 upfront 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, including $20.75 million associated with the first approval of an NDA by the FDA.

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 non-clinical, clinical, regulatory and other activities necessary to develop and commercialize rociletinib.

We made an upfront 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 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. 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.

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 upfront milestone fees, royalties on sales of lucitanib in the sublicensed territories and research and development funding commitments.

In October 2008, EOS entered into an exclusive license agreement with Advenchen to develop and commercialize lucitanib on a global basis, excluding China. The Company is obligated to pay Advenchen royalties on net sales of lucitanib, based on the volume of annual net sales achieved. In addition, the Company is obligated to pay to Advenchen 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 upfront payment of €45.0 million. We are 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 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 in excess of €80.0 million, if any, will be shared equally between the Company and Servier. Based on current estimates, we expect that Servier's €80.0 million funding commitment will be fulfilled in early 2017, and thereafter, we will share with Servier in future development costs pursuant to a mutually agreed upon global development plan.

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 under development by the Company, as well as from milestone payments or royalties pursuant to our sublicense agreement with Servier. If we fail to successfully complete the regulatory review and development of our product candidates and, together with our partners, companion diagnostics 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 as acquired in-process research and development;
- employee-related expenses, including salaries, benefits, travel and share-based compensation expense;
- expenses incurred under agreements with contract research organizations and investigative sites that conduct our clinical trials;
- the cost of acquiring, developing and manufacturing clinical trial materials;
- costs associated with non-clinical activities and regulatory operations;

- market research, disease education and other commercial product planning activities, including the hiring of a U.S. sales and marketing and medical affairs organization in preparation for potential commercial launch; 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 expect research and development expenses in 2016 to increase over 2015.

The following table identifies research and development and acquired in-process research and development costs on a program-specific basis for our products under development. Personnel-related costs, depreciation and share-based compensation are not allocated to specific programs, as they are deployed across multiple projects under development and, as such, are separately classified as personnel and other expenses in the table below.

	Three Months Ended March 31,	
	2016	2015
	(in thousands)	
Rucaparib Expenses		
Research and development	$24,557	$12,296
Rucaparib Total	24,557	12,296
Rociletinib Expenses		
Research and development	20,594	28,845
Rociletinib Total	20,594	28,845
Lucitanib Expenses		
Research and development (a)	(20)	935
Lucitanib Total	(20)	935
Personnel and other expenses	29,477	14,674
Total	$74,608	$56,750

(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 facilities expenses, communication expenses, information technology costs, corporate insurance and professional fees for legal, consulting and accounting services.

Effective May 9, 2016, at Mr. Mahaffy's request, the Compensation Committee of the Board of Directors approved his waiver of any annual base salary in excess of $1.00, plus the cost of the employee portion of any premiums to be paid

pursuant to any health and welfare benefit plans maintained by the Company and any tax withholdings related to health and welfare benefits. Such waiver shall continue in effect until the earliest to occur of (i) the Company entering into a definitive agreement with respect to a transaction that if consummated would constitute a Change in Control (as defined in his Employment Agreement) or the public announcement of a proposal or transaction that if consummated would constitute a Change of Control, (ii) approval by the FDA to commercially distribute, sell or market rucaparib, and (iii) termination of his employment by the Company without Just Cause or by Mr. Mahaffy for Good Reason (each as defined in his Employment Agreement).

Acquired In-Process Research and Development Expenses

Acquired in-process research and development expenses consist of upfront payments to acquire a new drug compound, as well as subsequent milestone payments. Acquired in-process research and development payments are immediately expensed provided that the drug has not achieved regulatory approval for marketing and, absent obtaining such, approval, has no alternative future use.

Impairment of Intangible Asset

In connection with the acquisition of EOS, we recorded intangible assets to reflect the fair value of acquired in-process research and development ("IPR&D") as of the acquisition date. The fair value was established based upon discounted cash flow models using assumptions related to the timing of development, probability of development and regulatory success, sales and commercialization factors and estimated product life.

The IPR&D intangible assets are treated as indefinite-lived intangible assets and are not amortized. Amortization of these assets will commence upon completion of the related research and development activities. IPR&D intangible assets are evaluated for impairment at least annually or more frequently if impairment indicators exist and any reduction in fair value would be recorded as impairment of intangible asset on the Consolidated Statements of Operations.

Change in Fair Value of Contingent Purchase Consideration

In connection with the acquisition of EOS, we also recorded a purchase consideration liability equal to the estimated fair value of future payments that are contingent upon the achievement of various regulatory and sales milestones. Subsequent to the acquisition date, we re-measure contingent consideration arrangements at fair value each reporting period and record changes in fair value to change in fair value of contingent purchase consideration and foreign currency gains (losses) for changes in the foreign currency translation rate on the Consolidated Statements of Operations. Changes in fair value are primarily attributed to new information about the likelihood of achieving such milestones and the passage of time. In the absence of new information, changes to fair value reflect only 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 and revenue and related disclosures. On an ongoing basis, we evaluate our estimates and judgments, including those related to contingent purchase consideration, the allocation of purchase consideration, intangible asset impairment, clinical trial accruals and share-based compensation. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

For a description of our critical accounting policies, please see Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015. There have not been any material changes to our critical accounting policies since December 31,

2015.

Recently Issued Accounting Standards

In March 2016, the Financial Accounting Standards Board issued Accounting Standards Update ("ASU") No. 2016-09, "Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting." ASU No. 2016-09 requires all income tax effects of awards to be recognized in the income statement when the awards vest or are settled. The guidance also requires the presentation of excess tax benefits as an operating activity on the statement of cash flows rather than as a financing activity. This update is effective for annual periods beginning after December 15, 2016, including interim periods within those annual periods. Early adoption is permitted. Amendments related to the timing of when excess tax benefits are recognized should be applied using a modified retrospective transition method. An entity may elect to apply the amendments related to the presentation of excess tax benefits on the statement of cash flows using either a prospective transition method or a retrospective transition method. The Company is currently evaluating its planned method of adoption and the impact the standard may have on its consolidated financial statements and related disclosures.

Results of Operations

Comparison of Three Months Ended March 31, 2016 and 2015:

The following table summarizes the results of our operations for the three months ended March 31, 2016 and 2015 (in thousands):

	Three Months Ended March 31,		Change 2016 vs. 2015	
	2016	2015	$	%
Operating expenses:				
Research and development	$74,608	$56,750	$17,858	31 %
General and administrative	9,827	6,751	3,076	46 %
Change in fair value of contingent purchase consideration	516	724	(208)	(29 %)
Total expenses	84,951	64,225	20,726	32 %
Operating loss	(84,951)	(64,225)	(20,726)	32 %
Other income (expense):				
Interest expense	(2,104)	(2,075)	(29)	1 %
Foreign currency gains (losses)	(551)	3,247	(3,798)	(117%)
Other income	25			