

Clovis Oncology, Inc.
Form 10-Q
November 04, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 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	(I.R.S. Employer
incorporation or organization)	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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

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

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

The number of outstanding shares of the registrant’s common stock, par value \$0.001 per share, as of October 28, 2016 was 38,585,662.

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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues:				
License and milestone revenue	\$ —	\$ —	\$—	\$—
Operating expenses:				
Research and development	54,338	76,138	196,675	193,256
General and administrative	9,162	8,331	28,541	22,286
Acquired in-process research and development	500	12,000	800	12,000
Impairment of intangible asset	—	—	104,517	—
Change in fair value of contingent purchase consideration	—	783	(24,936)	2,271
Total expenses	64,000	97,252	305,597	229,813
Operating loss	(64,000)	(97,252)	(305,597)	(229,813)
Other income (expense):				
Interest expense	(2,108)	(2,099)	(6,318)	(6,271)
Foreign currency gains (losses)	(66)	(101)	(434)	2,004
Other income	252	179	473	252
Other expense, net	(1,922)	(2,021)	(6,279)	(4,015)
Loss before income taxes	(65,922)	(99,273)	(311,876)	(233,828)
Income tax benefit	227	628	33,467	508
Net loss	\$ (65,695)	\$ (98,645)	\$ (278,409)	\$ (233,320)
Basic and diluted net loss per common share	\$ (1.70)	\$ (2.62)	\$ (7.24)	\$ (6.62)
Basic and diluted weighted-average common shares outstanding	38,538	37,613	38,429	35,252

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	\$ (65,695)	\$ (98,645)	\$ (278,409)	\$ (233,320)
Other comprehensive income (loss)				
Foreign currency translation adjustments, net of tax	58	416	2,190	(17,186)
Net unrealized gain (loss) on available-for-sale securities, net of tax	(18)	7	260	148
Other comprehensive income (loss)	40	423	2,450	(17,038)
Comprehensive loss	\$ (65,655)	\$ (98,222)	\$ (275,959)	\$ (250,358)

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except for share amounts)

	September 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$243,724	\$278,756
Available-for-sale securities	75,054	249,832
Prepaid research and development expenses	7,376	3,377
Other current assets	5,194	7,736
Total current assets	331,348	539,701
Property and equipment, net	4,707	4,946
Intangible assets	—	101,500
Goodwill	60,748	59,327
Other assets	1,821	7,912
Total assets	\$398,624	\$713,386
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$11,076	\$11,260
Accrued research and development expenses	36,088	53,011
Other accrued expenses	11,906	11,305
Total current liabilities	59,070	75,576
Contingent purchase consideration	—	24,661
Deferred income taxes, net	266	31,133
Convertible senior notes	280,813	279,885
Deferred rent, long-term	1,437	1,481
Total liabilities	341,586	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 September 30, 2016 and December 31, 2015	—	—
Common stock, \$0.001 par value per share, 100,000,000 shares authorized at		
September 30, 2016 and December 31, 2015; 38,582,755 and 38,359,454 shares issued		
and outstanding at September 30, 2016 and December 31, 2015, respectively	39	38
Additional paid-in capital	1,162,324	1,129,978
Accumulated other comprehensive loss	(45,010)	(47,460)

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Accumulated deficit	(1,060,315)	(781,906)
Total stockholders' equity	57,038	300,650
Total liabilities and stockholders' equity	\$398,624	\$713,386

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2016	2015
Operating activities		
Net loss	\$(278,409)	\$(233,320)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	29,744	29,458
Depreciation and amortization	819	548
Amortization of premiums and discounts on available-for-sale securities	190	1,319
Amortization of debt issuance costs	928	900
Impairment of intangible asset	104,517	—
Change in fair value of contingent purchase consideration	(24,661)	(32)
Loss on disposal of property and equipment	105	—
Deferred income taxes	(33,320)	(529)
Changes in operating assets and liabilities:		
Prepaid and accrued research and development expenses	(14,877)	21,046
Other operating assets	2,358	(3,500)
Accounts payable	(322)	6,124
Other accrued expenses	923	609
Net cash used in operating activities	(212,005)	(177,377)
Investing activities		
Purchases of property and equipment	(761)	(1,175)
Proceeds from sale of property and equipment	65	-
Purchases of available-for-sale securities	—	(392,540)
Maturities of available-for-sale securities	175,000	—
Sales of available-for-sale securities	—	140,996
Net cash provided by (used in) investing activities	174,304	(252,719)
Financing activities		
Proceeds from the sale of common stock, net of issuance costs	—	298,509
Proceeds from the exercise of stock options and employee stock purchases	2,602	5,027
Net cash provided by financing activities	2,602	303,536
Effect of exchange rate changes on cash and cash equivalents	67	(674)
Decrease in cash and cash equivalents	(35,032)	(127,234)
Cash and cash equivalents at beginning of period	278,756	482,677
Cash and cash equivalents at end of period	\$243,724	\$355,443
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$7,188	\$7,307

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Basis of Presentation

Clovis Oncology, Inc. (the “Company”, “Clovis”, “we”, “our”, “us”) is a biopharmaceutical company focused on acquiring, developing and commercializing cancer treatments in the United States, Europe and other international markets. We have and intend 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, we generally expect to provide the licensor with a combination of upfront payments, milestone payments and royalties on future sales. In addition, we generally expect to assume the responsibility for future drug development and commercialization costs. We currently operate in one segment. Since inception, our operations have consisted primarily of developing in-licensed compounds, evaluating new product acquisition candidates and general corporate activities.

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, except for those discussed in the following footnotes, 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 our 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, we evaluate our estimates, including estimates 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 and other market-specific or other relevant assumptions that we believe to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

Liquidity

We have incurred significant net losses since inception and have relied on our ability to fund our operations through debt and equity financings. We expect operating losses and negative cash flows to continue for the foreseeable future. As we continue to incur losses, transition to profitability is dependent upon the successful development, approval and commercialization of our product candidates and achieving a level of revenues adequate to support our cost structure. We may never achieve profitability, and unless or until we do, we will continue to need to raise additional cash.

We intend 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 our current estimates, we believe that our cash, cash equivalents and available-for-sale securities as of September 30, 2016 will allow us to fund activities through at least the next 12 months.

2. Summary of Significant Accounting Policies

Our 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 ("2015 Form 10-K").

Recently Issued Accounting Standards

In March 2016, the Financial Accounting Standards Board (“FASB”) 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. We are currently evaluating our planned method of adoption and the impact the standard may have on our consolidated financial statements and related disclosures.

3. EOS Acquisition

On November 19, 2013, we 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.). We paid \$11.8 million in cash and issued \$173.7 million of common stock at the acquisition date and are obligated to pay 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 \$193.5 million (\$65.0 million and €115.0 million) if all regulatory and sales milestones are met, utilizing the translation rate at September 30, 2016.

During the second quarter of 2016, we recorded a \$25.5 million reduction in the fair value of the contingent purchase consideration liability due to our and our development partner’s decision to discontinue the development of lucitanib for breast cancer (see Note 4). At September 30, 2016, the contingent purchase consideration liability recorded on the Consolidated Balance Sheets was zero due to the uncertainty of achieving any of the lucitanib regulatory milestones. At December 31, 2015, the liability for the estimated fair value of the payments recorded on the Consolidated Balance Sheets was \$24.7 million.

4. Financial Instruments and Fair Value Measurements

Cash, Cash Equivalents and Available-for-Sale Securities

We consider 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 our 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 our 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. Our Level 1 assets consist of money market investments. We do 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. Our Level 2 assets consist of U.S. treasury securities. We do not have Level 2 liabilities.

Level 3: Unobservable inputs that are supported by little or no market activity. We do not have Level 3 assets that are measured at fair value on a recurring basis. 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 our 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 our assets and liabilities that were measured at fair value on a recurring basis (in thousands):

	Balance	Level 1	Level 2	Level 3
September 30, 2016				
Assets:				
Money market	\$227,182	\$227,182	\$—	\$—
U.S. treasury securities	75,054	—	75,054	—
Total assets at fair value	\$302,236	\$227,182	\$75,054	\$—
Liabilities:				
Contingent purchase consideration	\$—	\$—	\$—	\$—
Total liabilities at fair value	\$—	\$—	\$—	\$—
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 nine months ended September 30, 2016.

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

	For the Nine Months Ended September 30, 2016
Liabilities:	
Balance at beginning of period	\$ 24,661

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Change in fair value (a)	(24,936)
Change in foreign currency gains and losses	275
Balance at end of period	\$ —

(a) During the second quarter of 2016, we recorded a \$25.5 million reduction in the fair value of the contingent purchase consideration due to our and our development partner's decision to discontinue the development of lucitanib for breast cancer. At September 30, 2016, the contingent purchase consideration liability recorded on the Consolidated Balance Sheets was zero due to the uncertainty of achieving any of the lucitanib regulatory milestones.

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.

Assets measured at fair value on a nonrecurring basis include our in-process research and development (“IPR&D”) intangible assets, which were recorded as part of the acquisition of EOS (see Note 3 and Note 7). The fair value of the IPR&D intangible assets 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. As the valuation is based on significant unobservable inputs, the fair value measurement is classified as Level 3. IPR&D assets are evaluated for impairment at least annually or more frequently if impairment indicators exist.

During the second quarter of 2016, we recorded a \$104.5 million impairment charge due to our and our development partner’s decision to discontinue the development of lucitanib for breast cancer. At September 30, 2016, the IPR&D intangible asset recorded on the Consolidated Balance Sheets was zero.

Financial instruments not recorded at fair value include our convertible senior notes. At September 30, 2016, the carrying amount of the convertible senior notes was \$287.5 million, which represents the aggregate principal amount, and the fair value was \$273.8 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, 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	\$ 75,024	\$ 30	\$ —	\$ 75,054

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 September 30, 2016, there were no available-for-sale securities that have been in a continuous unrealized loss position for less than 12 months.

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 September 30, 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	\$ 75,024	\$75,054
Total	\$ 75,024	\$75,054

6. Other Current Assets

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

	September 30, 2016	December 31, 2015
Receivable from partners	\$ 1,258	\$ 3,241
Prepaid expenses- other	2,613	1,023
Receivable - other	825	889
Prepaid insurance	406	1,231
Receivable from landlord	—	1,153
Other	92	199
Total	\$ 5,194	\$ 7,736

7. Intangible Assets and Goodwill

IPR&D intangible assets and goodwill were established as part of the purchase accounting of EOS (see Note 3) and consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
IPR&D intangible assets:		
Balance at beginning of period	\$ 101,500	\$ 212,900
Impairment of intangible asset (a)	(104,517)	(89,557)
Change in foreign currency gains (losses)	3,017	(21,843)
Balance at end of period	\$—	\$ 101,500
Goodwill:		
Balance at beginning of period	\$ 59,327	\$ 66,055
Change in foreign currency gains (losses)	1,421	(6,728)
Balance at end of period	\$ 60,748	\$ 59,327

(a) During the second quarter of 2016, we recorded a \$104.5 million impairment charge due to our and our development partner's decision to discontinue the development of lucitanib for breast cancer. At September 30, 2016, the IPR&D intangible asset recorded on the Consolidated Balance Sheets was zero.

During the fourth quarter of 2015, we recorded an \$89.6 million impairment charge due to our and our development partner's decision to discontinue the development of lucitanib for lung cancer, as well as updates to the probability-weighted discounted cash flow assumptions for the breast cancer indication.

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 is recorded as impairment of intangible asset on the

Consolidated Statements of Operations.

As part of the acquisition of EOS, we 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, we 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.

During the second quarter of 2016, we recognized a \$29.2 million deferred tax benefit associated with the impairment of the IPR&D intangible asset.

8. Other Accrued Expenses

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

	September 30, 2016	December 31, 2015
Accrued personnel costs	\$ 10,345	\$ 8,250
Accrued interest payable	299	2,096
Accrued expenses - other	1,262	959
Total	\$ 11,906	\$ 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 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.

Holder 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, we 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. We determined the expected life of the debt was equal to the seven-year term of the Notes. As of September 30, 2016 and December 31, 2015, the balance of unamortized debt issuance costs was \$6.7 million and \$7.6 million, respectively.

The following table sets forth total interest expense recognized related to the Notes during the three and nine months ended September 30, 2016 and 2015 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Contractual interest expense	\$ 1,797	\$ 1,797	\$ 5,390	\$ 5,371
Amortization of debt issuance costs	311	302	928	900
Total interest expense	\$ 2,108	\$ 2,099	\$ 6,318	\$ 6,271

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	3,526	412	3,938
Income tax expense	(1,335)	(153)	(1,488)
Balance September 30, 2016	\$ (44,886)	\$ (124)	\$ (45,010)

The period change between September 30, 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 and nine months ended September 30, 2016 and 2015 was recognized in the accompanying Consolidated Statements of Operations as follows (in thousands):

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development	\$ 7,039	\$ 9,039	\$ 20,962	\$ 19,798
General and administrative	2,164	3,367	8,782	9,660
Total share-based compensation expense	\$ 9,203	\$ 12,406	\$ 29,744	\$ 29,458

We did not recognize a tax benefit related to share-based compensation expense during the three and nine months ended September 30, 2016 and 2015, respectively, as we maintain net operating loss carryforwards and have established a valuation allowance against the entire net deferred tax asset as of September 30, 2016.

The following table summarizes the activity relating to our options to purchase common stock for the nine months ended September 30, 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	1,829,537	21.85		
Exercised	(139,396)	7.85		
Forfeited	(1,309,127)	54.27		
Outstanding at September 30, 2016 (a)	5,741,271	\$ 42.51	7.4	\$ 52,392
Vested and expected to vest at September 30, 2016	5,351,476	\$ 42.80	7.2	\$ 48,604
Exercisable at September 30, 2016	2,954,077	\$ 43.14	5.8	\$ 27,713

- (a) Includes 42,500 performance-based stock options granted to our executives in the first quarter of 2015, which vest contingent on approval by the U.S. Food and Drug Administration (“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 \$36.05 as of September 30, 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 and nine months ended September 30, 2016 and 2015:

	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Weighted-average grant date fair value per share	\$ 17.09	\$ 56.22	\$ 16.07	\$ 52.98
Intrinsic value of options exercised	\$ 930,417	\$ 5,307,365	\$ 1,555,342	\$ 15,361,206
Cash received from stock option exercises	\$ 687,332	\$ 1,953,938	\$ 1,094,855	\$ 4,534,288

As of September 30, 2016, the unrecognized share-based compensation expense related to unvested options, adjusted for expected forfeitures, was \$83.7 million and the estimated weighted-average remaining vesting period was 2.8

years.

During 2016, we 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 our 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 us on behalf of our 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 our unvested RSUs for the nine months ended September 30, 2016:

	Number of Units	Weighted- Average Grant Date Fair Value
Unvested as of December 31, 2015	—	\$ —
Granted	526,180	21.65
Vested (a)	(9,750)	19.37
Forfeited	(33,245)	19.24
Unvested as of September 30, 2016	483,185	\$ 21.86
Expected to vest after September 30, 2016	398,525	\$ 21.80

- (a) During the second quarter of 2016, we accelerated the vesting of RSUs for certain employees.

As of September 30, 2016, the unrecognized share-based compensation expense related to unvested RSUs, adjusted for expected forfeitures, was \$8.4 million and the estimated weighted-average remaining vesting period was 3.4 years.

12. License Agreements

Rucaparib

In June 2011, we 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 (PARP), which we are developing for the treatment of selected solid tumors. Under the terms of the license agreement, we made a \$7.0 million upfront payment to Pfizer. In April 2014, we initiated a pivotal registration study for rucaparib, which resulted in a \$0.4 million milestone payment to Pfizer as required by the license agreement. In September 2016, we made a milestone payment of \$0.5 million to Pfizer upon acceptance of the NDA for rucaparib by the FDA. These payments were 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 \$264.5 million of further payments, in aggregate, if certain development, regulatory and sales milestones are achieved, including \$21.25 million associated with the first filing and approval of a New Drug Application (“NDA”) by the FDA. During the second quarter of 2016, we completed the submission of our NDA with the FDA for potential accelerated approval of rucaparib in the U.S. The FDA granted the rucaparib NDA priority review status with a Prescription Drug User Fee Act action date of February 23, 2017. During the fourth quarter of 2016, we submitted a Marketing Authorization Application (“MAA”) for rucaparib to the European Medicines Agency (“EMA”).

On August 30, 2016, we entered into a first amendment to the worldwide license agreement with Pfizer, which amends the June 2011 existing worldwide license agreement to permit us to defer payment of the milestone payments payable upon (i) FDA approval of an NDA for 1st Indication in US and (ii) EMA approval of an MAA for 1st Indication in EU, to a date that is 18 months after the date of achievement of such milestones. In the event that we defer such milestone payments, we have agreed to certain higher payments related to the achievement of such milestones.

Lucitanib

In connection with its acquisition of EOS (see Note 3), we 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. We are obligated to pay Advenchen royalties on net sales of lucitanib based on the volume of annual net sales achieved. In addition, we are 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, we 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, we are entitled to receive sales milestone payments if specified annual sales targets for lucitanib are met, which, in the aggregate, could total €250.0 million. We are 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 us 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 our 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.

We 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 us and Servier. During the second quarter of 2016, we and Servier agreed to discontinue the development of lucitanib for breast cancer and are continuing to evaluate, what, if any, further development of lucitanib will be pursued. Based on current estimates, we expect to complete the committed on-going development activities in 2017 and expect full reimbursement of our development costs from Servier. Reimbursements are recorded as a reduction to research and development expense on the Consolidated Statements of Operations.

We recorded a \$1.3 million and \$3.2 million receivable at September 30, 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 the three months ending September 30, 2016 and 2015, we incurred \$1.3 million and \$3.8 million, respectively, in research and development costs and recorded reductions in research and development expense of \$1.3 million and \$3.8 million, respectively, for reimbursable development costs due from Servier. For the nine months ending September 30, 2016 and 2015, respectively, we incurred \$7.4 million and \$11.7 million, respectively, in research and development costs and recorded reductions in research and development expense of \$7.7 million and \$10.4 million, respectively, for reimbursable development costs due from Servier.

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. 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 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.

During the second quarter of 2016, we received a Complete Response Letter (“CRL”) from the FDA for the rociletinib NDA. 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, we terminated enrollment in all ongoing sponsored clinical studies, although we continue to provide drug to patients whose clinicians recommend continuing rociletinib therapy. In addition, we withdrew our MAA for rociletinib on file with the EMA. We are continuing analyses of rociletinib data to determine whether certain populations of patients may represent an opportunity for a partner committed to investing in further clinical development.

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. 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.

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 and Nine Months Ended September 30,	
	2016	2015
Convertible senior notes	4,646	4,646
Common shares under options and awards	3,772	5,232
Total potential dilutive shares	8,418	9,878

14. Commitments and Contingencies

Royalty and License Fee Commitments

We have 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. Our 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 on our Consolidated Balance Sheets at September 30, 2016 and December 31, 2015.

Development and Manufacturing Agreement Commitments

In February 2013, we 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, we will provide the third-party supplier a rolling 24-month forecast that will be updated by us on a quarterly basis. We are obligated to order the quantity specified in the first 12 months of any forecast. Currently, \$48.5 million of purchase commitments exist under this agreement.

Legal Proceedings

The Company and certain of its officers and directors 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’ 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 further agreed-upon extensions by the parties, the Arkin Plaintiffs filed a Consolidated Complaint on May 6, 2016.

The Consolidated Complaint names as defendants the Company and certain of its current and former officers (the “Clovis Defendants”), certain underwriters (the “Underwriter Defendants”) for a Company follow-on offering conducted in July 2015 (the “July 2015 Offering”) and certain Company venture capital investors (the “Venture Capital Defendants”). The Consolidated Complaint alleges that defendants violated particular sections of the Securities Exchange Act of 1934 (the “Exchange Act”) and the Securities Act of 1933 (the “Securities Act”). The purported misrepresentations and omissions concern allegedly misleading statements about rociletinib. The putative class action is purportedly brought on behalf of investors who purchased the Company’s securities between May 31, 2014 and April 7, 2016 (with respect to the Exchange Act claims) and investors who purchased the Company’s securities pursuant or traceable to the July 2015 Offering (with respect to the Securities Act claims). The Consolidated Complaint seeks unspecified compensatory and recessionary damages.

On May 23, 2016, the Medina, Kimbro, Rocco and Moran actions were consolidated for all purposes in a single proceeding in the District of Colorado.

The Clovis Defendants, along with the Underwriter Defendants and the Venture Capital Defendants, filed a Motion to Dismiss on July 27, 2016, the Arkin Plaintiffs filed their opposition on September 23, 2016, and the defendants filed their replies on October 14, 2016.

The Clovis Defendants intend 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 alleged 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 alleged claims for abuse of control, gross mismanagement and unjust enrichment. The McCall Complaint sought, among other things, an award of money damages, declaratory and injunctive relief concerning the alleged fiduciary breaches and other forms of equitable relief. On March 17, 2016, the plaintiff filed a notice of voluntary dismissal of the McCall Complaint and the action was terminated by the Court.

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. On May 5, 2016, the Northern District of California issued a written decision and order granting the Motion to Remand the case to the Superior Court, County of San Mateo and denying the Motion to Transfer as moot.

While the case was pending in the United States District Court for the Northern District of California, the parties entered into a stipulation extending the defendants' time to respond to the Electrical Workers Complaint for 30 days following the filing of an amended complaint by plaintiff or the designation by plaintiff of the Electrical Workers Complaint as the operative complaint. Following remand, Superior Court of the State of California, County of San Mateo so-ordered the stipulation on June 22, 2016.

On June 30, 2016, the Electrical Workers Plaintiffs filed an amended Complaint (the "Amended Complaint"). The Amended Complaint names as defendants the Company and certain of its current and former officers and directors, certain underwriters for the July 2015 Offering and certain Company venture capital investors. The Amended Complaint purports to assert claims under the Securities Act based upon alleged misstatements in Clovis' offering documents for the July 2015 Offering. The Amended Complaint includes new allegations about the Company's rociletinib disclosures. The Amended Complaint seeks unspecified damages.

Pursuant to a briefing schedule ordered by the court on July 28, 2016, defendants filed a motion to stay the Electrical Workers action pending resolution of the Medina, Kimbro, Moran, and Rocco actions in the District of Colorado ("Motion to Stay"), and a demurrer to the Amended Complaint, on August 15, 2016; plaintiffs filed their oppositions on August 31, 2016; and the defendants filed their reply briefs on September 15, 2016. On September 23, 2016, after hearing oral argument, the San Mateo Superior Court granted defendants' motion to stay proceedings pending resolution of the related securities class action captioned Medina v. Clovis Oncology, Inc., et. al., No. 1:15-cv-2546 (the "Colorado Action"). Per the order to stay proceedings, the San Mateo Superior Court will defer issuing a ruling on defendants' pending demurrer, and the parties' first status report as to the progress of the Colorado Action is due on March 23, 2017.

The Company intends to vigorously defend against the allegations contained in the Electrical Workers Amended 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.

We have received requests for information from governmental agencies relating to our regulatory update announcement in November 2015 that the FDA requested additional clinical data on the efficacy and safety of rociletinib. We are cooperating with the inquiries.

We received a letter dated May 31, 2016 from an alleged owner of our common stock, which purports to set forth a demand for inspection of certain of our books and records pursuant to 8 Del. C. § 220 (the "Demand Letter"). The Demand Letter was purportedly made for the purpose of investigating alleged misconduct at the Company relating to rociletinib. On June 24, 2016, we submitted a response to the Demand Letter. We believe that the Demand Letter fails to establish an entitlement to any of the requested documents, but there can be no assurance about the likelihood of an adverse outcome.

15. Subsequent Events

On October 3, 2016, we entered into a Manufacturing Services Agreement (the “Agreement”) with Lonza Ltd (“Lonza”) for the long term manufacture and supply of the active pharmaceutical ingredient (“API”) for rucaparib. The terms and conditions of the Agreement are contingent upon the approval by the FDA of the initial NDA for rucaparib, unless triggered earlier by us. Clovis and Lonza are parties to a Development and Manufacturing Agreement, dated February 8, 2013, as amended, under which Lonza has supplied rucaparib API for clinical development.

The Agreement provides that Lonza will be a non-exclusive manufacturer of the rucaparib API during the term of the Agreement, which expires on December 31, 2025, unless extended by mutual written consent of the parties. Under the Agreement, Lonza will construct, in an existing Lonza facility, a production train that will be exclusively dedicated to the manufacture of the rucaparib API. The dedicated production train will provide manufacturing capacity to meet our currently anticipated needs for commercial supply of rucaparib API.

We are obligated to make scheduled capital program fee payments towards capital equipment and other costs associated with the construction of the dedicated production train and, once the facility is operational, we are obligated to pay a fixed facility fee each quarter for the duration of the Agreement.

Pursuant to the terms of the Agreement, Lonza will manufacture and store an advanced intermediate to be used in the subsequent production of the rucaparib API. We will pay fixed fees on a per kilogram basis for quantities of the advanced intermediate and the rucaparib API ordered by us under the Agreement, subject to certain adjustments. Until the dedicated facility is completed and operationally qualified, Lonza will manufacture the rucaparib API in existing Lonza facilities at pricing established in the Agreement.

Either party may terminate the Agreement due to a material breach of the Agreement by the other party, subject to prior written notice and a cure period. We may terminate the Agreement, subject to 90 days' prior written notice, in the event rucaparib is withdrawn from the market for certain reasons. In the event of such a termination by us, or termination by Lonza due to material breach by us, we are obligated to compensate Lonza for any services rendered, or for which costs have been incurred by Lonza in anticipation of services to be provided to us, and to pay to Lonza the remaining amount of any capital program fees and quarterly fixed facility fees for the remainder of the term of the Agreement. In the event the Agreement is terminated by us due to material breach by Lonza, Lonza is obligated to repay all or a portion of the capital program fees previously paid by us.

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 thereof or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Quarterly Report on Form 10-Q and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned 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 cancer treatments in the United States, Europe and other international markets. Our product development programs generally target specific subsets of cancer, and we seek to simultaneously develop, with partners, companion diagnostics that direct our product candidates to the patients most likely to benefit from their use.

Our lead product candidate under active development is rucaparib, which is an oral inhibitor of poly (ADP-ribose) polymerase (PARP) currently in advanced clinical development for the treatment of ovarian cancer. During the second quarter of 2016, we completed the submission of our New Drug Application (“NDA”) with the U.S. Food and Drug Administration (“FDA”) for potential accelerated approval of rucaparib in the U.S. We submitted our first E.U. regulatory application in the fourth quarter of 2016. The FDA granted the rucaparib NDA priority review status with a Prescription Drug User Fee Act action date of February 23, 2017. We hold global development and commercialization rights for rucaparib.

In addition, we have two other product candidates: lucitanib and rociletinib. Lucitanib is 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. Lucitanib was previously evaluated in breast and lung cancers. Development in those indications has ceased and we continue to provide drug to patients whose clinicians recommend continuing lucitanib therapy. Along with our development partner, Servier, we are continuing to evaluate development options 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 Servier.

Rociletinib is an oral mutant-selective inhibitor of epidermal growth factor receptor (“EGFR”). During the second quarter of 2016, we received a Complete Response Letter (“CRL”) from the FDA for the rociletinib NDA, which was submitted during the third quarter of 2015. 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, we terminated enrollment in all ongoing sponsored clinical studies, although we continue to provide drug to patients whose clinicians recommend continuing rociletinib therapy. In addition, we withdrew our Marketing Authorization Application (“MAA”) for rociletinib on file with the European Medicines Agency (“EMA”). We hold global development and commercialization rights for rociletinib.

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 September 30, 2016, we had an accumulated deficit of \$1,060.3 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 September 30, 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, we initiated a pivotal registration study for rucaparib, which resulted in a \$0.4 million milestone payment to Pfizer as required by the license agreement. In September 2016, we made a milestone payment of \$0.5 million to Pfizer upon acceptance of the NDA for rucaparib by the FDA. These payments were 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 \$264.5 million of further payments, in aggregate, if certain development, regulatory and sales milestones are achieved, including \$21.25 million associated with the first filing and approval of an NDA by the FDA. During the second quarter of 2016, we completed the submission of our NDA with the FDA for potential accelerated approval of rucaparib in the U.S. The FDA granted the rucaparib NDA priority review status with a Prescription Drug User Fee Act action date of February 23, 2017. During the fourth quarter of 2016, we submitted an MAA for rucaparib to the EMA.

On August 30, 2016, we entered into a first amendment to the worldwide license agreement with Pfizer, which amends the June 2011 existing worldwide license agreement to permit us to defer payment of the milestone payments payable upon (i) FDA approval of an NDA for 1st Indication in US and (ii) EMA approval of an MAA for 1st Indication in EU, to a date that is 18 months after the date of achievement of such milestones. In the event that we defer such milestone payments, we have agreed to certain higher payments related to the achievement of such milestones.

Lucitanib

On November 19, 2013, we 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 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. We are obligated to pay Advenchen royalties on net sales of lucitanib, based on the volume of annual net sales achieved. In addition, we are 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, we 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, we are entitled to receive sales milestone payments if specified annual sales targets for lucitanib are met, which, in the aggregate, could total €250.0 million. We are also entitled to receive royalties on net sales of lucitanib by Servier.

We 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 us and Servier. During the second quarter of 2016, we and Servier agreed to discontinue the development of lucitanib for breast cancer and are continuing to evaluate what, if any, further development of lucitanib will be pursued. Based on current estimates, we expect to complete the committed on-going development activities in 2017 and expect full reimbursement of our development costs from Servier. Reimbursements are recorded as a reduction to research and development expense on

the Consolidated Statements of Operations.

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 as acquired in-process research and development expense.

During the second quarter of 2016, we received a Complete Response Letter (“CRL”) from the FDA for the rociletinib NDA. 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, we terminated enrollment in all ongoing sponsored clinical studies, although we continue to provide drug to patients whose clinicians recommend continuing rociletinib therapy. In addition, we withdrew our MAA for rociletinib on file with the EMA. We are continuing analyses of rociletinib data to determine whether certain populations of patients may represent an opportunity for a partner committed to investing in further clinical development.

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. 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.

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 us, 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 of rucaparib; 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. We expect research and development expenses in 2016 to decrease compared to 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 September 30,		Three Months Ended September 30,	
	2016	2015	2016	2015
	(in thousands)			
Rucaparib Expenses				
Research and development	\$25,773	\$14,939	\$74,709	\$38,762
Acquired in-process research and development	500	—	800	—
Rucaparib Total	26,273	14,939	75,509	38,762
Lucitanib Expenses				
Research and development (a)	3	37	(211)	1,280
Lucitanib Total	3	37	(211)	1,280
Rociletinib Expenses				
Research and development	3,040	36,371	40,455	96,365
Acquired in-process research and development	—	12,000	—	12,000
Rociletinib Total	3,040	48,371	40,455	108,365
Personnel and other expenses	25,522	24,791	81,722	56,849
Total	\$54,838	\$88,138	\$197,475	\$205,256

(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 us 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. During the second quarter of 2016, we recorded a \$104.5 million impairment charge due to our and our development partner’s decision to discontinue the development of lucitanib for breast cancer. At September 30, 2016, the IPR&D intangible asset recorded on the Consolidated Balance Sheets was zero.

The IPR&D intangible assets are treated as indefinite-lived intangible assets and are not amortized. IPR&D intangible assets are evaluated for impairment at least annually or more frequently if impairment indicators exist and any reduction in fair value is 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 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 in fair value reflect only the passage of time as we progress towards the achievement of future milestones. During the second quarter of 2016, we recorded a \$25.5 million reduction in the fair value of the contingent purchase consideration liability due to our and our development partner's decision to discontinue the development of lucitanib for breast cancer. At September 30, 2016, the contingent purchase consideration liability recorded on the Consolidated Balance Sheets was zero due to the uncertainty of achieving any of the lucitanib regulatory 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 our 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. We are currently evaluating our planned method of adoption and the impact the standard may have on our consolidated financial statements and related disclosures.

Results of Operations

Comparison of Three Months Ended September 30, 2016 and 2015:

The following table summarizes the results of our operations for the three months ended September 30, 2016 and 2015 (in thousands):

	Three Months Ended September 30,		Change 2016 vs. 2015	
	2016	2015	\$	%
Operating expenses:				
Research and development	\$ 54,338	\$ 76,138	\$(21,800)	(29 %)
General and administrative	9,162	8,331	831	10 %
Acquired in-process research and development	500	12,000	(11,500)	(96 %)
Change in fair value of contingent purchase consideration	—	783	(783)	(100%)
Total expenses	64,000	97,252	(33,252)	(34 %)
Operating loss	(64,000)	(97,252)	33,252	(34 %)
Other income (expense):				
Interest expense	(2,108)	(2,099)	(9)	0 %
Foreign currency gains (losses)	(66)	(101)	35	(35 %)
Other income	252	179	73	41 %
Other income (expense), net	(1,922)	(2,021)	99	(5 %)
Loss before income taxes	(65,922)	(99,273)	33,351	(34 %)
Income tax benefit (expense)	227	628	(401)	(64 %)
Net loss	\$ (65,695)	\$ (98,645)	\$32,950	(33 %)

Research and Development Expenses. Research and development expenses decreased during the three months ended September 30, 2016 compared to the same period in the prior year primarily due to decreased development activities for the rociletinib program, partially offset by higher expenses related to the rucaparib program.

Clinical trial costs for rucaparib were \$3.3 million higher than the same quarter in the prior year primarily due to higher enrollment in the ARIEL2 and ARIEL3 studies in ovarian cancer. Market research, disease education and other commercial product planning activities were \$3.6 million higher than the same quarter in the prior year due to the preparation for the potential regulatory approval and commercial launch of rucaparib. In addition, clinical supply and related manufacturing development costs were \$3.9 million higher than the third quarter of 2015, as we increased production to support the expanded clinical studies.

Clinical trial costs for rociletinib were \$15.4 million lower than the third quarter in 2015 primarily due to the completion of patient enrollment for all of the TIGER studies in non-small cell lung cancer. Market research, disease education and other commercial product planning activities were \$9.6 million lower than the same quarter in the prior year. We incurred higher costs during the third quarter of 2015 due to the preparation for the potential regulatory approval and commercial launch of rociletinib. In addition, clinical supply and related manufacturing development

costs were \$6.3 million lower than the third quarter in 2015 driven by timing of production to support our clinical studies.

General and Administrative Expenses. General and administrative expenses increased during the three months ended September 30, 2016 compared to the same period in the prior year primarily due to \$2.2 million of higher legal expense, partially offset by \$1.2 million lower share-based compensation expense.

Acquired In-Process Research and Development Expenses. Acquired in-process research and development expenses decreased during the three months ended September 30, 2016 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 third quarter of 2016, we made a milestone payment of \$0.5 million to Pfizer upon acceptance of the NDA for rucaparib by the FDA.

Change in Fair Value of Contingent Purchase Consideration. During the second quarter of 2016, we recorded a \$25.5 million reduction in the fair value of the contingent purchase consideration liability due to our and our development partner's decision to discontinue the development of lucitanib for breast cancer. At September 30, 2016, the contingent purchase consideration liability recorded on the Consolidated Balance Sheets was zero due to the uncertainty of achieving any of the lucitanib regulatory milestones.

Comparison of Nine Months Ended September 30, 2016 and 2015:

The following table summarizes the results of our operations for the nine months ended September 30, 2016 and 2015 (in thousands):

	Nine Months Ended September 30,		Change 2016 vs. 2015	
	2016	2015	\$	%
Operating expenses:				
Research and development	\$ 196,675	\$ 193,256	\$3,419	2 %
General and administrative	28,541	22,286	6,255	28 %
Acquired in-process research and development	800	12,000	(11,200)	(93 %)
Impairment of intangible asset	104,517	—	104,517	n/a
Change in fair value of contingent purchase consideration	(24,936)	2,271	(27,207)	(1,198 %)
Total expenses	305,597	229,813	75,784	33 %
Operating loss	(305,597)	(229,813)	(75,784)	33 %
Other income (expense):				
Interest expense	(6,318)	(6,271)	(47)	1 %
Foreign currency gains (losses)	(434)	2,004	(2,438)	(122 %)
Other income	473	252	221	88 %
Other expense, net	(6,279)	(4,015)	(2,264)	56 %
Loss before income taxes	(311,876)	(233,828)	(78,048)	33 %
Income tax benefit (expense)	33,467	508	32,959	6,488 %
Net loss	\$ (278,409)	\$ (233,320)	\$ (45,089)	19 %

Research and Development Expenses. Research and development expenses increased during the nine months ended September 30, 2016 compared to the same period in the prior year primarily due to increased development activities for the rucaparib program and higher salaries, share-based compensation and other personnel-related costs, partially offset by lower expenses related to the rociletinib program.

Clinical trial costs for rucaparib were \$13.8 million higher than the same period in the prior year primarily due to higher enrollment in the ARIEL2 and ARIEL3 studies in ovarian cancer. Market research, disease education and other commercial product planning activities were \$10.6 million higher than the same period in the prior year due to the preparation for the potential regulatory approval and commercial launch of rucaparib. Clinical supply and related manufacturing development costs were \$6.8 million higher than 2015, as we increased production to support the expanded clinical studies. In addition, diagnostic development costs for rucaparib were \$3.2 million higher than 2015 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 \$24.4 million higher in 2016 driven by increased headcount to support our expanded development and commercial planning activities. During the third quarter of 2015, we completed the hiring of our U.S. sales and marketing and medical affairs organizations in

preparation for the potential regulatory approval and commercial launch of rucaparib.

Clinical trial costs for rociletinib were \$29.1 million lower than 2015 primarily due to the completion of patient enrollment in the TIGER-1, TIGER-2 and TIGER-X studies in non-small cell lung cancer. This decrease was partially offset by higher clinical trial costs for the TIGER-3 study, which began enrolling patients during the second quarter of 2015. Market research, disease education and other commercial product planning activities were \$14.2 million lower than the prior year. We incurred higher costs during 2015 due to the preparation for the potential regulatory approval and commercial launch of rociletinib. In addition, clinical supply and related manufacturing development costs were \$12.6 million lower than 2015 driven by timing of production to support our clinical studies.

General and Administrative Expenses. General and administrative expenses increased during the nine months ended September 30, 2016 compared to the same period in the prior year primarily due to \$5.4 million higher legal expense and \$0.8 million higher personnel costs.

Acquired In-Process Research and Development Expenses. Acquired in-process research and development expenses decreased during the nine months ended September 30, 2016 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 second quarter of 2016, we made a milestone payment of \$0.3 million to AstraZeneca upon the NDA submission for rucaparib and during the third quarter of 2016, we made a milestone payment of \$0.5 million to Pfizer upon acceptance of the NDA for rucaparib by the FDA.

Impairment of Intangible Asset. During the second quarter of 2016, we recorded a \$104.5 million impairment charge to the IPR&D intangible asset relating to our lucitanib product candidate. This reduction in the estimated fair value of lucitanib was the result of our and our development partner's decision to discontinue the development of lucitanib for breast cancer.

Change in Fair Value of Contingent Purchase Consideration. Change in fair value of contingent purchase consideration totaled (\$24.9) million for the nine months ended September 30, 2016 compared to \$2.3 million for the same period in the prior year. During the second quarter of 2016, we recorded a \$25.5 million reduction in the fair value of the contingent purchase consideration liability due to our and our development partner's decision to discontinue the development of lucitanib for breast cancer.

Other Income (Expense), net. Other expense increased during the nine months ended September 30, 2016 compared to the same period in the prior year. During the nine months ended September 30, 2016, we recognized \$0.4 million of foreign currency losses compared with \$2.0 million of foreign currency gains during the same period in 2015. 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 liability into U.S. dollars.

Income Tax Benefit (Expense). During the nine months ended September 30, 2016, we recognized a \$29.2 million deferred tax benefit associated with the impairment of the IPR&D intangible asset recorded in the second quarter of 2016. In addition, during the first quarter of 2016, we recognized a \$3.6 million deferred tax benefit due to a reduction in the enacted corporate tax rate of a foreign jurisdiction in which we operate.

Liquidity and Capital Resources

To date, we have funded our operations through the public offering of our common stock and the private placement of convertible debt securities and preferred stock. At September 30, 2016, we had cash, cash equivalents and available-for-sale securities totaling \$318.8 million.

The following table sets forth the primary sources and uses of cash for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,	
	2016	2015
	(in thousands)	
Net cash used in operating activities	\$ (212,005)	\$ (177,377)
Net cash provided by (used in) investing activities	174,304	(252,719)
Net cash provided by financing activities	2,602	303,536
Effect of exchange rate changes on cash and cash equivalents	67	(674)
Net decrease in cash and cash equivalents	\$ (35,032)	\$ (127,234)

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 \$34.6 million during the nine months ended September 30, 2016 compared to same period in the prior year, primarily driven by an increase in payments for accrued research and development costs.

Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2016 includes \$175.0 million in maturities of available-for-sale securities compared to net purchases of \$251.5 million for the same period in the prior year.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2016 and 2015 includes \$2.6 million and \$5.0 million, respectively, received from employee stock option exercises and stock purchases under the employee stock purchase plan. In addition, we completed the sale of \$298.5 million of common stock during the nine months ended September 30, 2015.

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 fourth quarter of 2016. 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 our programs, prepare for the potential commercial launch of our products and expand our general and administrative functions to support the growth in our research and development and commercial organizations.

As of September 30, 2016, we had cash, cash equivalents and available-for-sale securities totaling \$318.8 million and total current liabilities of \$59.1 million. Based on current estimates, we believe that our existing cash, cash equivalents and available-for-sale securities as of September 30, 2016 will allow us to fund our operating plan through at least the next 12 months. We expect to finance future cash flow needs through the public or private sale of equity or debt securities, collaborations, strategic alliances or other similar licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. 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 non-clinical 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 2015 Annual Report on Form 10-K. There have not been any material changes to such contractual obligations or potential milestone payments since December 31, 2015, except as discussed in Note 12 and Note 15. For further information regarding our 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, 2016, we had cash, cash equivalents and available-for-sale securities of \$318.8 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 pounds 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, 2016 and December 31, 2015, approximately 1% and 3%, 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 Principal Financial and Accounting 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 Principal Financial and Accounting Officer, management performed an evaluation as of September 30, 2016 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 Principal Financial and Accounting Officer concluded that, as of September 30, 2016, 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, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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’ 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 further agreed-upon extensions by the parties, the Arkin Plaintiffs filed a Consolidated Complaint on May 6, 2016.

The Consolidated Complaint names as defendants the Company and certain of its current and former officers (the “Clovis Defendants”), certain underwriters (the “Underwriter Defendants”) for a Company follow-on offering conducted in July 2015 (the “July 2015 Offering”) and certain Company venture capital investors (the “Venture Capital Defendants”). The Consolidated Complaint alleges that defendants violated particular sections of the Securities Exchange Act of 1934 (the “Exchange Act”) and the Securities Act of 1933 (the “Securities Act”). The purported misrepresentations and omissions concern allegedly misleading statements about rociletinib. The consolidated action is purportedly brought on behalf of investors who purchased the Company’s securities between May 31, 2014 and April 7, 2016 (with respect to the Exchange Act claims) and investors who purchased the Company’s securities pursuant or traceable to the July 2015 Offering (with respect to the Securities Act claims). The Consolidated Complaint seeks unspecified compensatory and recessionary damages.

On May 23, 2016, the Medina, Kimbro, Rocco, and Moran actions were consolidated for all purposes in a single proceeding in the District of Colorado.

The Clovis Defendants, the Underwriter Defendants and the Venture Capital Defendants filed a Motion to Dismiss on July 27, 2016, the Arkin Plaintiffs opposition is due on September 23, 2016, and the defendants filed their replies on October 14, 2016.

The Clovis Defendants intend 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 alleged 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 alleged claims for abuse of control, gross mismanagement and unjust enrichment. The McCall Complaint sought, among other things, an award of money damages, declaratory and injunctive relief concerning the alleged fiduciary breaches and other forms of equitable relief. On March 17, 2016, the plaintiff filed a notice of voluntary dismissal of the McCall Complaint and the action was terminated by the Court.

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. On May 5, 2016, the Northern District of California issued a written decision and order granting the Motion to Remand the case to the Superior Court, County of San Mateo and denying the Motion to Transfer as moot.

While the case was pending in the United States District Court for the Northern District of California, the parties entered into a stipulation extending the defendants' time to respond to the Electrical Workers Complaint for 30 days following the filing of an amended complaint by plaintiff or the designation by plaintiff of the Electrical Workers Complaint as the operative complaint. Following remand, Superior Court of the State of California, County of San Mateo so-ordered the stipulation on June 22, 2016.

On June 30, 2016, the Electrical Workers Plaintiffs filed an amended Complaint (the "Amended Complaint"). The Amended Complaint names as defendants the Company and certain of its current and former officers and directors, certain underwriters for the July 2015 Offering and certain Company venture capital investors. The Amended Complaint purports to assert claims under the Securities Act based upon alleged misstatements in Clovis' offering documents for the July 2015 Offering. The Amended Complaint includes new allegations about the Company's rociletinib disclosures. The Amended Complaint seeks unspecified damages.

Pursuant to a briefing schedule ordered by the court on July 28, 2016, defendants filed a motion to stay the Electrical Workers action pending resolution of the Medina, Kimbro, Moran, and Rocco actions in the District of Colorado (“Motion to Stay”), and a demurrer to the Amended Complaint, on August 15, 2016; plaintiffs filed their oppositions on August 31, 2016; and the defendants filed their reply briefs on September 15, 2016. On September 23, 2016, after hearing oral argument, the San Mateo Superior Court granted defendants’ motion to stay proceedings pending resolution of the related securities class action captioned Medina v. Clovis Oncology, Inc., et. al., No. 1:15-cv-2546 (the “Colorado Action”). Per the order to stay proceedings, the San Mateo Superior Court will defer issuing a ruling on defendants’ pending demurrer, and the parties’ first status report as to the progress of the Colorado Action is due on March 23, 2017.

The Company intends to vigorously defend against the allegations contained in the Electrical Workers Amended 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.

We have received requests for information from governmental agencies relating to our regulatory update announcement in November 2015 that the FDA requested additional clinical data on the efficacy and safety of rociletinib. We are cooperating with the inquiries.

We received a letter dated May 31, 2016 from an alleged owner of our common stock, which purports to set forth a demand for inspection of certain of our books and records pursuant to 8 Del. C. § 220 (the “Demand Letter”). The Demand Letter was purportedly made for the purposes of investigating alleged misconduct at the Company relating to rociletinib. On June 24, 2016, we submitted a response to the Demand Letter. We believe that the Demand Letter fails to establish an entitlement to any of the requested documents, but there can be no assurance about the likelihood of an adverse outcome.

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 consider the risk factors described under the heading “Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, in addition to other information contained in or incorporated by reference into this Quarterly Report on Form 10-Q and 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2016. 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.

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ITEM 6. EXHIBITS

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INDEX TO EXHIBITS

Exhibit

Number	Exhibit Description
3.1(5)	Amended and Restated Certificate of Incorporation of Clovis Oncology, Inc.
3.2(5)	Amended and Restated Bylaws of Clovis Oncology, Inc.
4.1(3)	Form of Common Stock Certificate of Clovis Oncology, Inc.
4.2(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.

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- 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.
- 10.31+(10) Indemnification Agreement, dated as of January 29, 2016, by and between Clovis Oncology, Inc. and Lindsey Rolfe.
- 10.32+(10) Employment Agreement, dated as of February 25, 2016, by and between Clovis Oncology, Inc. and Lindsey Rolfe.
- 10.33+(10) Indemnification Agreement, dated as of January 26, 2016, by and between Clovis Oncology, Inc. and Dale Hooks.
- 10.34+(10) Employment Agreement, dated as of January 26, 2016, by and between Clovis Oncology, Inc. and Dale Hooks.
- 10.35+(11) Indemnification Agreement, dated as of February 17, 2016, by and between Clovis Oncology, Inc. and Daniel W. Muehl.
- 10.36+(12) Offer Letter, dated as of May 27, 2015, by and between Clovis Oncology, Inc. and Daniel W. Muehl.
- 10.37+(12) Salary Waiver Letter, dated as of May 9, 2016, by and between Clovis Oncology, Inc. and Patrick J. Mahaffy.
- 10.38* First Amendment to License Agreement, by and between Clovis Oncology, Inc. and Pfizer Inc., dated as of August 30, 2016.
- 31.1 Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
- 31.2 Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
- 32.1 Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101 The following materials from Clovis Oncology, Inc.'s Quarterly Report on Form 10-Q for the period ended June 30, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Statements of Operations, (ii) the Consolidated Statements of Comprehensive Loss, (iii) the Consolidated Balance Sheets, (iv) the Consolidated Statements of Cash Flows and (v) 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.
- (10) Filed as an exhibit with the Registrant's Annual Report on Form 10-K on February 29, 2016.
- (11) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on April 1, 2016.
- (12) Filed as an exhibit with the Registrant's Quarterly Report on Form 10-Q on May 9, 2016.

+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.

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 4, 2016 CLOVIS ONCOLOGY, INC.

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

By: /s/ DANIEL W. MUEHL
Daniel W. Muehl
Senior Vice President of Finance and Principal Financial and Accounting Officer