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

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the quarterly period ended March 31, 2016.

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the transition period from to .

Commission file number: 001-35347

Clovis Oncology, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	90-0475355
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
5500 Flatiron Parkway, Suite 100	
Boulder, Colorado	80301
(Address of principal executive offices)	(Zip Code)

(303) 625-5000

(Registrant’s telephone number, including area code)

Not Applicable

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

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

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

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

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

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

The number of outstanding shares of the registrant’s common stock, par value $0.001 per share, as of April 29, 2016 was 38,385,660.

CLOVIS ONCOLOGY, INC.

FORM 10-Q

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS
CLOVIS ONCOLOGY, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except per share amounts)

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

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

(In thousands)

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

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except for share amounts)

	March 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$220,373	$278,756
Available-for-sale securities	225,117	249,832
Prepaid research and development expenses	10,391	3,377
Other current assets	8,090	7,736
Total current assets	463,971	539,701
Property and equipment, net	5,108	4,946
Intangible assets	105,689	101,500
Goodwill	61,775	59,327
Other assets	8,031	7,912
Total assets	$644,574	$713,386
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$14,100	$11,260
Accrued research and development expenses	52,642	53,011
Other accrued expenses	7,199	11,305
Total current liabilities	73,941	75,576
Contingent purchase consideration	25,710	24,661
Deferred income taxes, net	30,476	31,133
Convertible senior notes	280,192	279,885
Deferred rent, long-term	1,592	1,481
Total liabilities	411,911	412,736
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Preferred stock, par value $0.001 per share; 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value per share, 100,000,000 shares authorized at March 31, 2016 and December 31, 2015; 38,364,454 and 38,359,454 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	38	38
Additional paid-in capital	1,141,648	1,129,978
Accumulated other comprehensive loss	(43,717)	(47,460)
Accumulated deficit	(865,306)	(781,906)

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

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

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

See accompanying Notes to Unaudited Consolidated Financial Statements.

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CLOVIS ONCOLOGY, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Basis of Presentation

Clovis Oncology, Inc. (the "Company") is a biopharmaceutical company focused on acquiring, developing and commercializing innovative anti-cancer agents in the United States, Europe and other international markets. The Company has and intends to continue to license or acquire rights to oncology compounds in all stages of development. In exchange for the right to develop and commercialize these compounds, the Company generally expects to provide the licensor with a combination of upfront payments, milestone payments and royalties on future sales. In addition, the Company generally expects to assume the responsibility for future drug development and commercialization costs. The Company currently operates in one segment. Since inception, the Company's operations have consisted primarily of developing in-licensed compounds, evaluating new product acquisition candidates and general corporate activities.

In July 2015, the Company submitted a New Drug Application ("NDA") regulatory filing and a Marketing Authorization Application ("MAA") for rociletinib to the U.S. Food and Drug Administration ("FDA") and the European Medicines Agency ("EMA"), respectively. Both the FDA and EMA subsequently accepted the respective filings.

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

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

Basis of Presentation

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

The unaudited financial statements of Clovis Oncology, Inc. included herein reflect all adjustments, consisting only of normal recurring adjustments, which in the opinion of management are necessary to fairly state our financial position, results of operations and cash flows for the periods presented. Interim results may not be indicative of the results that may be expected for the full year. Certain information and footnote disclosures normally included in audited financial statements prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") have been condensed or omitted pursuant to the rules and regulations of the U.S. Securities and Exchange Commission ("SEC"). These financial statements should be read in conjunction with the audited consolidated financial

statements and notes thereto which are included in our Annual Report on Form 10-K for the year ended December 31, 2015 for a broader discussion of our business and the opportunities and risks inherent in such business.

Reclassifications

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

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and revenue and related disclosures. On an ongoing basis, management evaluates its estimates, including estimates related to contingent purchase consideration, the allocation of purchase consideration, intangible asset impairment, clinical trial accruals and share-based compensation expense. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

Liquidity

The Company has incurred significant net losses since inception and has relied on its ability to fund its operations through debt and equity financings. Management expects operating losses and negative cash flows to continue for the foreseeable future. As the Company continues to incur losses, transition to profitability is dependent upon the successful development, approval and commercialization of its product candidates and achieving a level of revenues adequate to support the Company's cost structure. The Company may never achieve profitability, and unless or until it does, the Company will continue to need to raise additional cash.

Management intends to fund future operations through additional private or public debt or equity offerings and may seek additional capital through arrangements with strategic partners or from other sources. Based on current estimates, management believes that existing working capital at March 31, 2016 is sufficient to meet the cash requirements to fund planned operations through at least the next 12 months, although there can be no assurance that this can, in fact, be accomplished.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2 of the Notes to the Consolidated Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

Recently Issued Accounting Standards

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

3. EOS Acquisition

On November 19, 2013, the Company acquired all of the outstanding common and preferred stock of Ethical Oncology Science, S.p.A. (“EOS”) (now known as Clovis Oncology Italy S.r.l.). The Company paid $11.8 million in cash and issued $173.7 million of common stock at the acquisition date and may make additional future cash payments if certain lucitanib regulatory and sales milestones are achieved. The potential contingent milestone payments range from a zero payment, which assumes lucitanib fails to achieve any of the regulatory milestones, to approximately $195.7 million ($65.0 million and €115.0 million) if all regulatory and sales milestones are met, utilizing the translation rate at March 31, 2016. The Company recorded a liability for the estimated fair value of these payments, which totaled $25.7 million and $24.7 million at March 31, 2016 and December 31, 2015, respectively.

4. Financial Instruments and Fair Value Measurements

Cash, Cash Equivalents and Available-for-Sale Securities

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

Marketable securities are considered to be available-for-sale securities and consist of U.S. Treasury securities. Available-for-sale securities are reported at fair value on the Consolidated Balance Sheets and unrealized gains and losses are included in accumulated other comprehensive income (loss) on the Consolidated Balance Sheets. Realized gains and losses, amortization of premiums and discounts and interest and dividends earned are included in other income (expense) on the Consolidated Statements of Operations. The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Investments with maturities beyond one year are classified as short-term based on management's intent to fund current operations with these securities or to make them available for current operations.

A decline in the market value of a security below its cost that is deemed to be other than temporary is charged to earnings and results in the establishment of a new cost basis for the security. Factors evaluated to determine if an investment is other-than-temporarily impaired include significant deterioration in earnings performance, credit rating, asset quality or business prospects of the issuer; adverse changes in the general market conditions in which the issuer operates; and the Company's intent and ability to hold the security until an anticipated recovery in value occurs.

Fair Value Measurements

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

Level 1: Quoted prices in active markets for identical assets or liabilities. The Company's Level 1 assets consist of money market investments. The Company does not have Level 1 liabilities.

Level 2: Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities in active markets or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. The Company's Level 2 assets consist of U.S. treasury securities. The Company does not have Level 2 liabilities.

Level 3: Unobservable inputs that are supported by little or no market activity. The Company does not have Level 3 assets. The contingent purchase consideration related to the undeveloped lucitanib product rights acquired with the purchase of EOS is a Level 3 liability. The fair value of this liability is based on unobservable inputs and includes valuations for which there is little, if any, market activity. See Note 3 of the Company's 2015 Form 10-K for further discussion of the unobservable inputs and valuation techniques related to the contingent purchase consideration liability.

The following table identifies the Company's assets and liabilities that were measured at fair value on a recurring basis (in thousands):

	Balance	Level 1	Level 2	Level 3
March 31, 2016				
Assets:				
Money market	$201,467	$201,467	$—	$—
U.S. treasury securities	225,117	—	225,117	—
Total assets at fair value	$426,584	$201,467	$225,117	$—
Liabilities:				
Contingent purchase consideration	$25,710	$—	$—	$25,710
Total liabilities at fair value	$25,710	$—	$—	$25,710
December 31, 2015				
Assets:				

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

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

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

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

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

Financial instruments not recorded at fair value include the Company's convertible senior notes. At March 31, 2016, the carrying amount of the convertible senior notes was $287.5 million, which represents the aggregate principal amount, and the fair value was $195.5 million. The fair value was determined using Level 2 inputs based on the indicative pricing published by certain investment banks or trading levels of the Notes, which are not listed on any securities exchange or quoted on an inter-dealer automated quotation system. See Note 9 for discussion of the convertible senior notes.

5. Available-for-Sale Securities

As of March 31, 2016, available-for-sale securities consisted of the following (in thousands):

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

As of December 31, 2015, available-for-sale securities consisted of the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value
U.S. treasury securities	$ 250,215	$ —	$ (383)	$ 249,832

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

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

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

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

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

As of March 31, 2016, the amortized cost and fair value of available-for-sale securities by contractual maturity were (in thousands):

	Amortized Cost	Fair Value
Due in one year or less	$225,135	$225,117
Total	$225,135	$225,117

6. Other Current Assets

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

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

7. Intangible Assets and Goodwill

Intangible acquired in-process research and development (“IPR&D”) assets and goodwill were established as part of the purchase accounting of EOS (see Note 3) and consisted of the following (in thousands):

	March 31,	December 31,

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

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

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

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

8. Other Accrued Expenses

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

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

9. Convertible Senior Notes

On September 9, 2014, we completed a private placement of $287.5 million aggregate principal amount of 2.5% convertible senior notes due 2021 (the “Notes”) resulting in net proceeds to the Company of $278.3 million after deducting offering expenses. In accordance with the accounting guidance, the conversion feature did not meet the criteria for bifurcation, and the entire principal amount was recorded as a long-term liability on the Consolidated Balance Sheets.

The Notes are governed by the terms of the indenture between the Company, as issuer, and The Bank of New York Mellon Trust Company, N.A., as trustee. The Notes are senior unsecured obligations and bear interest at a rate of 2.5% per year, payable semi-annually in arrears on March 15 and September 15 of each year. The Notes will mature on September 15, 2021, unless earlier converted, redeemed or repurchased.

Holders may convert all or any portion of the Notes at any time prior to the close of business on the business day immediately preceding the maturity date. Upon conversion, the holders will receive shares of our common stock at an initial conversion rate of 16.1616 shares per $1,000 in principal amount of Notes, equivalent to a conversion price of approximately $61.88 per share. The conversion rate is subject to adjustment upon the occurrence of certain events described in the indenture, but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date or upon our issuance of a notice of redemption, we will increase the conversion rate for holders who elect to convert the Notes in connection with such a corporate event or during the related redemption period in certain circumstances.

On or after September 15, 2018, we may redeem the Notes, at our option, in whole or in part, if the last reported sale price of our common stock has been at least 150% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending not more than two trading days

preceding the date on which we provide written notice of redemption at a redemption price equal to 100% of the principal amount of the Notes to be redeemed plus accrued and unpaid interest to, but excluding, the redemption date. No sinking fund is provided for the Notes.

If we undergo a fundamental change, as defined in the indenture, prior to the maturity date of the Notes, holders may require us to repurchase for cash all or any portion of the Notes at a fundamental change repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The Notes rank senior in right of payment to any of our indebtedness that is expressly subordinated in right of payment to the Notes; equal in right of payment to all of our liabilities that are not so subordinated; effectively junior in right of payment to any secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all indebtedness and other liabilities (including trade payables) of our subsidiaries.

In connection with the issuance of the Notes, the Company incurred $9.2 million of debt issuance costs. The debt issuance costs are presented as a deduction from convertible senior notes on the Consolidated Balance Sheets and are amortized as interest expense over the expected life of the Notes using the effective interest method. The Company determined the expected life of the debt was equal to the seven-year term of the Notes. As of March 31, 2016 and December 31, 2015, the balance of unamortized debt issuance costs was $7.3 million and $7.6 million, respectively.

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

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

10. Stockholders' Equity

Accumulated Other Comprehensive Income (Loss)

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

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

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

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

11. Share-Based Compensation

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

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

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

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

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

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

(a) Includes 85,000 performance-based stock options granted to executives of the Company in the first quarter of 2015. Fifty-percent of the grant vests contingent on approval by the FDA to commercially distribute, sell or market rociletinib and fifty-percent of the grant vests contingent on approval by the FDA to commercially distribute, sell or market rucaparib. Stock compensation expense will be recognized when the condition for vesting is probable of being met.

The aggregate intrinsic value in the table above represents the pretax intrinsic value, based on our closing stock price of $19.20 as of March 31, 2016, which would have been received by the option holders had all option holders with in-the-money options exercised their options as of that date.

The following table summarizes information about our stock options as of and for the three months ended March 31, 2016 and 2015:

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

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

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

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

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

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

12. License Agreements

Rucaparib

In June 2011, the Company entered into a worldwide license agreement with Pfizer Inc. to acquire exclusive development and commercialization rights to rucaparib. This drug candidate is a small molecule inhibitor of poly (ADP-ribose) polymerase, which the Company is developing for the treatment of selected solid tumors. Under the terms of the license agreement, the Company made a $7.0 million upfront payment to Pfizer. In April 2014, the Company initiated a pivotal registration study for rucaparib, which resulted in a $0.4 million milestone payment to Pfizer as required by the license agreement. This payment was recognized as acquired in-process research and development expense.

The Company is responsible for all development and commercialization costs of rucaparib. When and if commercial sales of rucaparib begin, we will pay Pfizer tiered royalties on our net sales. In addition, Pfizer is eligible to receive up to $258.5 million of further payments, in aggregate, if certain development, regulatory and sales milestones are achieved, including $20.75 million associated with the first approval of an NDA by the FDA.

Rociletinib

In May 2010, we entered into an exclusive worldwide license agreement with Avila Therapeutics, Inc. (now Celgene Avilomics Research, Inc., part of Celgene Corporation (“Celgene”)) to discover, develop and commercialize a covalent inhibitor of mutant forms of the epidermal growth factor receptor gene product. As a result of the collaboration contemplated by the agreement, rociletinib was identified as the lead inhibitor candidate, which we are developing under the terms of the license agreement. We are responsible for all non-clinical, clinical, regulatory and other activities necessary to develop and commercialize rociletinib.

We made an upfront payment of $2.0 million upon execution of the license agreement, a $4.0 million milestone payment in the first quarter of 2012 upon acceptance by the FDA of our Investigational New Drug application for rociletinib and a $5.0 million milestone payment in the first quarter of 2014 upon initiation of the Phase II study for rociletinib. In the third quarter of 2015, we made milestone payments totaling $12.0 million upon acceptance of the NDA and MAA for rociletinib by the FDA and EMA, respectively. We recognized all payments prior to commercial approval as acquired in-process research and development expense.

We are obligated to pay royalties on net sales of rociletinib based on the volume of annual net sales achieved. The Company is required to pay up to an additional aggregate of $98.0 million in development and regulatory milestone payments if certain clinical study objectives and regulatory filings, acceptances and approvals are achieved, including $15.0 million upon the first approval of an NDA by the FDA and $15.0 million upon the first approval of an MAA by the EMA. In addition, the Company is required to pay up to an aggregate of $120.0 million in sales milestone payments if certain annual sales targets are achieved.

Lucitanib

In connection with its acquisition of EOS (see Note 3), the Company gained rights to develop and commercialize lucitanib, an oral, selective tyrosine kinase inhibitor. As further described below, EOS licensed the worldwide rights, excluding China, to develop and commercialize lucitanib from Advenchen Laboratories LLC (“Advenchen”). Subsequently, rights to develop and commercialize lucitanib in markets outside the U.S. and Japan were sublicensed by EOS to Les Laboratoires Servier (“Servier”) in exchange for upfront milestone fees, royalties on sales of lucitanib in the sublicensed territories and research and development funding commitments.

In October 2008, EOS entered into an exclusive license agreement with Advenchen to develop and commercialize lucitanib on a global basis, excluding China. The Company is obligated to pay Advenchen royalties on net sales of lucitanib based on the volume of annual net sales achieved. In addition, the Company is obligated to pay to Advenchen 25% of any consideration, excluding royalties, received pursuant to any sublicense agreements for lucitanib, including the agreement with Servier. In the first quarter of 2014, the Company recognized acquired in-process research and development expense of $3.4 million, which represents 25% of the sublicense agreement consideration of $13.6 million received from Servier upon the end of opposition and appeal of the lucitanib patent by the European Patent Office.

In September 2012, EOS entered into a collaboration and license agreement with Servier whereby EOS sublicensed to Servier exclusive rights to develop and commercialize lucitanib in all countries outside of the U.S., Japan and China. In exchange for these rights, EOS received an upfront payment of €45.0 million and is entitled to receive additional payments upon achievement of specified development, regulatory and commercial milestones up to €90.0 million in the aggregate. In addition, the Company is entitled to receive sales milestone payments if specified annual sales targets for lucitanib are met, which, in the aggregate, could total €250.0 million. The Company is also entitled to receive royalties on sales of lucitanib by Servier.

The development, regulatory and commercial milestones represent non-refundable amounts that would be paid by Servier to the Company if certain milestones are achieved in the future. These milestones, if achieved, are substantive as they relate solely to past performance, are commensurate with estimated enhancement of value associated with the achievement of each milestone as a result of the Company's performance, which are reasonable relative to the other deliverables and terms of the arrangement, and are unrelated to the delivery of any further elements under the arrangement.

The Company and Servier are developing lucitanib pursuant to a development plan agreed to between the parties. Servier is responsible for all of the initial global development costs under the agreed upon plan up to €80.0 million. Cumulative global development costs, if any, in excess of €80.0 million will be shared equally between the Company and Servier. Based on current estimates, we expect that Servier’s €80.0 million funding commitment will be fulfilled in early 2017, and thereafter, we will share with Servier in future development costs pursuant to a mutually agreed upon global development plan. Reimbursements are recorded as a reduction to research and development expense in the Consolidated Statements of Operations.

The Company recorded a $3.7 million and $3.2 million receivable at March 31, 2016 and December 31, 2015, respectively, for the reimbursable development costs incurred under the global development plan, which is included in other current assets on the Consolidated Balance Sheets. For both the three months ending March 31, 2016 and 2015, we incurred $3.6 million in research and development costs and recorded reductions in research and development expense of $3.6 million and $2.7 million, respectively, for reimbursable development costs due from Servier.

13. Net Loss Per Common Share

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

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

	Three Months Ended March 31,	
	2016	2015

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

14. Commitments and Contingencies

Royalty and License Fee Commitments

The Company has entered into certain license agreements, as identified in Note 12, with third parties that include the payment of development and regulatory milestones, as well as royalty payments, upon the achievement of pre-established development, regulatory and commercial targets. The Company's payment obligation related to these license agreements is contingent upon the successful development, regulatory approval and commercialization of the licensed products. Due to the nature of these arrangements, the future potential payments are inherently uncertain, and accordingly, no amounts have been recorded in the Company's Consolidated Balance Sheets at March 31, 2016 and December 31, 2015.

Development and Manufacturing Agreement Commitments

In February 2013, the Company entered into a development and manufacturing agreement with a third-party supplier for the production of the active ingredient for rucaparib. Under the Development and Manufacturing Agreement, the Company will provide the third-party supplier a rolling 24-month forecast that will be updated by the Company on a quarterly basis. The Company is obligated to order the quantity specified in the first 12 months of any forecast. As of March 31, 2016, $16.6 million of purchase commitments exist under this agreement.

Legal Proceedings

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15. Subsequent Events

The Company evaluated events up to the filing date of these interim financial statements and determined that no subsequent activity required disclosure.

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

Forward-Looking Information

This Quarterly Report on Form 10-Q and the information incorporated herein by reference includes statements that are, or may be deemed, "forward-looking statements." In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereo comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Quarterly Report on Form 10-Q and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned non-clinical studies and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.

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

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

You should also read carefully the factors described in the "Risk Factors" section of this Quarterly Report on Form 10-Q to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. You are advised, however, to consult any further disclosures we make on related subjects in our other reports filed with the SEC and on our website.

Overview

We are a biopharmaceutical company focused on acquiring, developing and commercializing innovative anti-cancer agents in the United States, Europe and other international markets. We generally target our development programs for the treatment of specific subsets of cancer populations and seek to simultaneously develop, with partners, companion diagnostics that direct our product candidates to the patients that are most likely to benefit from their use. We are currently developing two product candidates:

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

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

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

To date, we have devoted substantially all of our resources to identifying and in-licensing product candidates, performing development activities with respect to those product candidates and the general and administrative support of these operations. To date, we have generated $13.6 million in license and milestone revenue, but have generated no product revenues. We have principally funded our operations using the net proceeds from the sale of convertible preferred stock, the issuance of convertible promissory notes, public offerings of our common stock and our convertible senior notes offering.

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

Product License Agreements

Rucaparib

In June 2011, we entered into a license agreement with Pfizer Inc. to acquire exclusive global development and commercialization rights to rucaparib. Pursuant to the terms of the license agreement, we made a $7.0 million upfront payment to Pfizer. In April 2014, the Company initiated a pivotal registration study for rucaparib, which resulted in a $0.4 million milestone payment to Pfizer as required by the license agreement. This payment was recognized as acquired in-process research and development expense.

We are responsible for all development and commercialization costs of rucaparib. When and if commercial sales of rucaparib begin, we will pay Pfizer tiered royalties on our net sales. In addition, Pfizer is eligible to receive up to $258.5 million of further payments, in aggregate, if certain development, regulatory and sales milestones are achieved, including $20.75 million associated with the first approval of an NDA by the FDA.

Rociletinib

In May 2010, we entered into an exclusive worldwide license agreement with Avila Therapeutics, Inc. (now Celgene Avilomics Research, Inc., part of Celgene Corporation ("Celgene")) to discover, develop and commercialize a covalent inhibitor of mutant forms of the EGFR gene product. Rociletinib was identified as the lead inhibitor candidate under the license agreement. We are responsible for all non-clinical, clinical, regulatory and other activities necessary to develop and commercialize rociletinib.

We made an upfront payment of $2.0 million upon execution of the license agreement, a $4.0 million milestone payment in the first quarter of 2012 upon acceptance by the FDA of our Investigational New Drug application for rociletinib and a $5.0 million milestone payment in the first quarter of 2014 upon the initiation of the Phase II study for rociletinib. In the third quarter of 2015, we made milestone payments totaling $12.0 million upon acceptance of the NDA and MAA for rociletinib by the FDA and EMA, respectively. We recognized all payments prior to

commercial approval as acquired in-process research and development expense.

We are obligated to pay royalties on net sales of rociletinib based on the volume of annual net sales achieved. We are required to pay up to an additional aggregate of $98.0 million in development and regulatory milestone payments if certain clinical study objectives and regulatory filings, acceptances and approvals are achieved, including $15.0 million upon the first approval of an NDA by the FDA and $15.0 million upon the first approval of an MAA by the EMA. In addition, we are required to pay up to an aggregate of $120.0 million in sales milestone payments if certain annual sales targets are achieved.

Lucitanib

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

In October 2008, EOS entered into an exclusive license agreement with Advenchen to develop and commercialize lucitanib on a global basis, excluding China. The Company is obligated to pay Advenchen royalties on net sales of lucitanib, based on the volume of annual net sales achieved. In addition, the Company is obligated to pay to Advenchen 25% of any consideration, excluding royalties, received pursuant to any sublicense agreements for lucitanib, including the agreement with Servier. In the first quarter of 2014, the Company recognized acquired in-process research and development expense of $3.4 million, which represents 25% of the sublicense agreement consideration of $13.6 million received from Servier upon the end of opposition and appeal of the lucitanib patent by the European Patent Office.

In September 2012, EOS entered into a collaboration and license agreement with Servier whereby EOS sublicensed to Servier exclusive rights to develop and commercialize lucitanib in all countries outside of the U.S., Japan and China. In exchange for these rights, EOS received an upfront payment of €45.0 million. We are entitled to receive additional payments upon achievement of specified development, regulatory and commercial milestones up to an additional €90.0 million in the aggregate. In addition, the Company is entitled to receive sales milestone payments if specified annual sales targets for lucitanib are met, which, in the aggregate, could total €250.0 million. The Company is also entitled to receive royalties on net sales of lucitanib by Servier.

The Company and Servier are developing lucitanib pursuant to a development plan agreed to between the parties. Servier is responsible for the initial €80.0 million in global development costs under the agreed upon plan. Cumulative global development costs in excess of €80.0 million, if any, will be shared equally between the Company and Servier. Based on current estimates, we expect that Servier's €80.0 million funding commitment will be fulfilled in early 2017, and thereafter, we will share with Servier in future development costs pursuant to a mutually agreed upon global development plan.

Financial Operations Overview

Revenue

To date, we have generated $13.6 million in license and milestone revenue related to our collaboration and license agreement with Servier. In the future, we may generate revenue from the sales of product candidates that are under development by the Company, as well as from milestone payments or royalties pursuant to our sublicense agreement with Servier. If we fail to successfully complete the regulatory review and development of our product candidates and, together with our partners, companion diagnostics or obtain regulatory approval for them, our ability to generate future revenue and our results of operations and financial position will be adversely affected.

Research and Development Expenses

Research and development expenses consist of costs incurred for the development of our product candidates and companion diagnostics, which include:

- license fees and milestone payments related to the acquisition of in-licensed products, which are reported on our Consolidated Statements of Operations as acquired in-process research and development;
- employee-related expenses, including salaries, benefits, travel and share-based compensation expense;
- expenses incurred under agreements with contract research organizations and investigative sites that conduct our clinical trials;
- the cost of acquiring, developing and manufacturing clinical trial materials;
- costs associated with non-clinical activities and regulatory operations;

- market research, disease education and other commercial product planning activities, including the hiring of a U.S. sales and marketing and medical affairs organization in preparation for potential commercial launch; and
- activities associated with the development of companion diagnostics for our product candidates.

Research and development costs are expensed as incurred. License fees and milestone payments related to in-licensed products and technology are expensed if it is determined that they have no alternative future use. Costs for certain development activities, such as clinical trials and manufacturing of clinical supply, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials. We expect research and development expenses in 2016 to increase over 2015.

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

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

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

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, legal, investor relations, human resources and information technology functions. Other general and administrative expenses include facilities expenses, communication expenses, information technology costs, corporate insurance and professional fees for legal, consulting and accounting services.

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

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

Acquired In-Process Research and Development Expenses

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

Impairment of Intangible Asset

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

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

Change in Fair Value of Contingent Purchase Consideration

In connection with the acquisition of EOS, we also recorded a purchase consideration liability equal to the estimated fair value of future payments that are contingent upon the achievement of various regulatory and sales milestones. Subsequent to the acquisition date, we re-measure contingent consideration arrangements at fair value each reporting period and record changes in fair value to change in fair value of contingent purchase consideration and foreign currency gains (losses) for changes in the foreign currency translation rate on the Consolidated Statements of Operations. Changes in fair value are primarily attributed to new information about the likelihood of achieving such milestones and the passage of time. In the absence of new information, changes to fair value reflect only the passage of time as we progress towards the achievement of future milestones.

Other Income and Expense

Other income and expense is primarily comprised of foreign currency gains and losses resulting from transactions with contract research organizations, investigational sites and contract manufacturers where payments are made in currencies other than the U.S. dollar. In addition, a significant portion of the contingent purchase consideration liability will be settled in Euro-denominated payments if certain future milestones are achieved and is subject to fluctuations in foreign currency rates. Other expense also includes interest expense recognized related to the Company's convertible senior notes.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, expenses and revenue and related disclosures. On an ongoing basis, we evaluate our estimates and judgments, including those related to contingent purchase consideration, the allocation of purchase consideration, intangible asset impairment, clinical trial accruals and share-based compensation. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

2015.

Recently Issued Accounting Standards

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

Results of Operations

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

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

	Three Months Ended March 31,		Change 2016 vs. 2015	
	2016	2015	$	%
Operating expenses:				
Research and development	$74,608	$56,750	$17,858	31 %
General and administrative	9,827	6,751	3,076	46 %
Change in fair value of contingent purchase consideration	516	724	(208)	(29 %)
Total expenses	84,951	64,225	20,726	32 %
Operating loss	(84,951)	(64,225)	(20,726)	32 %
Other income (expense):				
Interest expense	(2,104)	(2,075)	(29)	1 %
Foreign currency gains (losses)	(551)	3,247	(3,798)	(117 %)
Other income	25	11	14	127 %
Other income (expense), net	(2,630)	1,183	(3,813)	(322 %)
Loss before income taxes	(87,581)	(63,042)	(24,539)	39 %
Income tax benefit (expense)	4,181	(102)	4,283	(4,199 %)
Net loss	$(83,400)	$(63,144)	$(20,256)	32 %

Research and Development Expenses. Research and development expenses increased during the three months ended March 31, 2016 compared to the same period in the prior year primarily due to increased development activities for the rucaparib program. Clinical trial costs for rucaparib were $5.2 million higher than the same quarter in the prior year primarily due to higher enrollment in the ARIEL2 and ARIEL3 studies in ovarian cancer. Development costs for rucaparib were $3.0 million higher than the first quarter of 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. In addition, market research, disease education and other commercial product planning activities were $2.7 million higher than the same quarter in the prior year due to the preparation for the potential regulatory approval and commercial launch of rucaparib.

Clinical trial costs for rociletinib were $3.9 million lower than the first quarter in 2015 primarily due to the completion of enrollment for the TIGER-X study 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. In addition, clinical supply and related manufacturing development costs were $5.1 million lower than the first quarter in 2015 driven by timing of production to support our clinical studies.

Salaries, share-based compensation expense and other personnel-related costs were $14.5 million higher in the first quarter of 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 rociletinib and rucaparib.

General and Administrative Expenses. General and administrative expenses increased during the three months ended March 31, 2016 compared to the same period in the prior year primarily due to $1.5 million higher legal expense, $0.4 million higher consulting fees and $0.3 million higher personnel costs.

Other Income (Expense), net. Other expense increased during the three months ended March 31, 2016 compared to the same period in the prior year. During the first quarter of 2016, the Company recognized $0.6 million of foreign currency losses compared with $3.2 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 liabilities into U.S. dollars.

Income Taxes. Income tax benefit recognized during the first quarter of 2016 was primarily due to a reduction in the enacted corporate tax rate of a foreign jurisdiction in which the Company operates. During the first quarter of 2016, the net deferred tax items of a foreign subsidiary were adjusted to reflect the lower tax rate the Company anticipates will be realized in the future, resulting in a $3.6 million income tax benefit.

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 March 31, 2016, we had cash, cash equivalents and available-for-sale securities totaling $445.5 million.

The following table sets forth the primary sources and uses of cash for the three months ended March 31, 2016 and 2015:

	Three Months Ended March 31,	
	2016	2015
	(in thousands)	
Net cash used in operating activities	$(83,738)	$(48,405)
Net cash provided by (used in) investing activities	24,396	(143,032)
Net cash provided by financing activities	705	1,193
Effect of exchange rate changes on cash and cash equivalents	254	(891)
Net decrease in cash and cash equivalents	$(58,383)	$(191,135)

Operating Activities

Net cash used in operating activities for all periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. Net cash used in operating activities increased $35.3 million during the three months ended March 31, 2016 compared to the prior year driven by higher rucaparib research and development costs associated with the expansion of the clinical trials, as well as the preparation for the potential commercial launch of rucaparib, and higher salaries, benefits and personnel-related costs resulting from higher headcount to support the expanded development activities and commercial planning for our product candidates.

Investing Activities

Net cash provided by investing activities for the three months ended March 31, 2016 includes $25.0 million in maturities of available-for-sale securities. Net cash used in investing activities for the three months ended March 31, 2015 includes $142.2 million in purchases of available-for-sale securities.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2016 and March 31, 2015 includes $0.7 million and $1.2 million, respectively, received from employee stock option exercises and stock purchases under the employee stock purchase plan.

Operating Capital Requirements

Assuming we successfully complete clinical trials and obtain requisite regulatory approvals, we do not anticipate commercializing any of our product candidates until at least the 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 March 31, 2016, we had cash, cash equivalents and available-for-sale securities totaling $445.5 million and total current liabilities of $73.9 million. Based on current estimates, we believe that our existing cash, cash equivalents and available-for-sale securities as of March 31, 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. For further information regarding the Company’s contractual obligations and commitments, see Note 14 to our unaudited consolidated financial statements included elsewhere in this report.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of March 31, 2016, we had cash, cash equivalents and available-for-sale securities of $445.5 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 March 31, 2016 and December 31, 2015, approximately 5% 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 March 31, 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 March 31, 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 March 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

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

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

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

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

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

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

On April 1, 2016, the Arkin Plaintiffs and the defendants filed a stipulated motion to set the schedule for the filing of a consolidated complaint in the Medina, Kimbro and Rocco actions (the "Consolidated Complaint") and the responses thereto, including the defendants' anticipated motion to dismiss the Consolidated Complaint (the "Motion to Dismiss"), and to stay discovery and related proceedings until the District of Colorado issues a decision on the Motion to

Dismiss. The stipulated motion was entered by the District of Colorado on April 4, 2016. Subject to a further agreed-upon extension by the parties, the Consolidated Complaint was filed on May 6, 2016, while the Motion to Dismiss is due on July 11, 2016, the Arkin Plaintiff's opposition on August 19, 2016 and the defendants' reply on September 7, 2016. On April 15, 2016, the Arkin Plaintiffs and the defendants filed a stipulated motion to consolidate the Moran action, now pending in the District of Colorado, with the Medina, Kimbro and Rocco actions.

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

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

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

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

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

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

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 following discussion of risk factors, in its entirety, 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.

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Risks Related to Our Financial Position and Capital Requirements

We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future. We are a clinical-stage company with no approved products, and no historical revenues, which makes it difficult to assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have focused primarily on in-licensing and developing our product candidates. We are not profitable and have incurred losses in each year since our inception in April 2009. We have only a limited operating history upon which you can evaluate our business and prospects. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. Two of our product candidates, CO-101 and CO-1686 (rociletinib), encountered development and regulatory setbacks after initial promising data, leading us to discontinue their development. We have not generated any revenue from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. For the years ended December 31, 2015, 2014 and 2013, we had net losses of $352.9 million, $160.0 million and $84.5 million, respectively. As of March 31, 2016, we had an accumulated deficit of $865.3 million. We expect to continue to incur losses for the foreseeable future, as we continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. As such, we are subject to all of the risks incident to the development of new biopharmaceutical products and related companion diagnostics, and we may encounter unforeseen expenses, difficulties, complications, regulatory scrutiny, delays and other unknown factors that may adversely affect our business. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if any of our product candidates, if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will require substantial additional funding which may not be available to us on acceptable terms, or at all. If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our product candidates or continue our development programs.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to advance the clinical development of our product candidates and launch and commercialize any product candidates for which we receive regulatory approval, including building our own commercial organizations to address certain markets.

Based on current estimates, we believe that our existing cash, cash equivalents and available-for-sale securities will allow us to fund our operating plan through at least the next 12 months. As of March 31, 2016, we had cash, cash equivalents and available-for-sale securities totaling $445.5 million. We do not have any material committed external source of funds or other support for our development efforts other than that portion of the costs associated with global development activities for lucitanib for which Servier is responsible pursuant to our collaboration and license agreement. Based on current cost estimates, we expect that commitment will be fulfilled in late 2016 or early 2017, and thereafter, we will share equally in future development costs with Servier pursuant to a mutually agreed upon global development plan.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs through a combination of public or private equity offerings, collaborations, strategic alliances and other similar licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. Furthermore, it may be difficult for us to raise additional funds while we are

subject to uncertainty related to litigation described under “Part II, Item 1-Legal Proceedings” in this report. 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. We may also seek collaborators for one or more of our current or future product candidates on terms that are less favorable than might otherwise be available. Any of these events could significantly harm our business, financial condition and prospects.

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

In September 2014, we completed a private placement of $287.5 million aggregate principal amount of 2.5% convertible senior notes due 2021 (the “Notes”), resulting in net proceeds to the Company of $278.3 million after deducting offering expenses. The Notes are governed by the terms of the indenture between the Company, as issuer, and The Bank of New York Mellon Trust Company, N.A., as trustee. Interest is payable on the Notes semi-annually, and the Notes mature on September 15, 2021, unless redeemed, repurchased or converted prior to that date. In addition, if, as defined by the terms of the indenture, a fundamental change occurs, holders of the Notes may require us to repurchase for cash all or any portion of their Notes at a purchase price equal to 100% of the principal amount of the Notes to be repurchased plus accrued and unpaid interest, if any, to, but excluding, the fundamental change repurchase date. As of March 31, 2016, all $287.5 million principal amount of the Notes remained outstanding.

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

We and certain of our officers and directors have been named as defendants in several lawsuits that could result in substantial costs and divert management's attention.

We and certain of our officers were named as defendants in four separate purported class action lawsuits initiated in 2015, three of which have since been consolidated, that generally allege that we and certain of our 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. An amended complaint in the consolidated action is due to be filed on May 6, 2016. Moreover, in January 2016, we and certain of our officers, directors, investors and underwriters were named as defendants in a purported class action lawsuit that alleges that the defendants violated the Securities Act because the offering documents for our July 2015 follow-on offering contained allegedly false and misleading statements regarding the progress toward FDA approval and the potential for market success of rociletinib.

We intend to engage in a vigorous defense of these lawsuits; however, we are unable to predict the outcome of these matters at this time. If we are not successful in our defense of the class action litigation, we could be forced to make significant payments to, or enter into other settlements with, our shareholders and their lawyers (and in certain circumstances reimburse costs and expenses incurred by the underwriters), and such payments or settlement arrangements could have a material adverse effect on our business, operating results and financial condition. For example, we could incur substantial costs not covered by our directors' and officers' liability insurance, suffer a significant adverse impact on our reputation and divert management's attention and resources from other priorities, any of which could have a material adverse effect on our business. In addition, any of these matters could require payments that are not covered by, or exceed the limits of, our available directors' and officers' liability insurance, which could have a material adverse effect on our operating results or financial condition.

Additional lawsuits with similar claims may be filed by other parties against us and our officers and directors. Even if such claims are not successful, these lawsuits or other future similar actions, or other regulatory inquiries or investigations, may result in substantial costs and have a significant adverse impact on our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition.

Risks Related to Our Business and Industry

We are heavily dependent on the success of our product candidates, and we cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.

To date, we have invested a significant portion of our efforts and financial resources in the acquisition and development of our product candidates. Our business depends entirely on the successful development and commercialization of our product candidates, which may never occur. Rucaparib and lucitanib are currently in clinical trials. We currently generate no revenues from sales of any drugs, and we may never be able to develop or commercialize a marketable drug.

Each of our product candidates requires clinical development, management of clinical, non-clinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization and significant marketing efforts in order to generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. In addition, our product development programs contemplate the development of companion diagnostics by third-party collaborators. Companion diagnostics are subject to regulation as medical devices and must themselves be approved for marketing by the FDA or certain other foreign regulatory agencies before our product candidates may be commercialized.

We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. Two of our product candidates, CO-101 and CO-1686 (rociletinib), encountered development and regulatory setbacks after initial promising data, leading us to discontinue their development. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon our diagnostic collaborators' ability to obtain regulatory approval of the companion diagnostics to be used with our product candidates, as well as the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our product candidates in the United States, the European Union and in additional foreign countries. While the scope of regulatory approval is similar in other countries, obtaining separate regulatory approval in many other countries requires compliance with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of non-clinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through non-clinical studies and initial clinical trials. It is not uncommon for companies in the biopharmaceutical industry to suffer significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Indeed, based on the negative results of a pivotal study, we ceased further development of our previous product candidate CO-101, and we decided to discontinue ongoing development of rociletinib in anticipation of the issuance of a Complete Response Letter by FDA. Additionally, our future clinical trial results may not be successful.

Although we have clinical trials ongoing, we may experience delays in our ongoing clinical trials, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations (“CROs”) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board (“IRB”) approval at each site;
- recruiting suitable patients to participate in a trial;
- developing and validating companion diagnostics on a timely basis;
- having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians’ and patients’ perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may impose a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical

trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Although our product candidates rociletinib and rucaparib have been granted Breakthrough Therapy designation by the FDA, which allows for greater interaction with, and expedited review by, the FDA, the designation does not guarantee a faster development or review time as compared to other drugs, nor does it ensure that the drugs will obtain ultimate marketing approval by the FDA. Indeed, in anticipation of the issuance of a Complete Response Letter by FDA with respect to the rociletinib NDA, we decided to discontinue further development of rociletinib. In addition, the FDA may withdraw this designation at any time.

Our product candidates could fail to receive regulatory approval or approval may be delayed for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from non-clinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with partners; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing and clinical trials and surveillance to monitor the safety and

efficacy of the product candidate. In addition, if the FDA or comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, pricing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices and good clinical practices for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;

- fines, warning letters or holds on clinical trials;
- refusal by the FDA and comparable foreign authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

We may seek approval from U.S. and foreign regulatory authorities for one or more product candidates on a conditional basis with full approval conditioned upon fulfilling the requirements of regulators. For example, we are seeking accelerated approval from the FDA for rucaparib and plan to seek conditional marketing authorization from the E.U. for rucaparib. Each of these approval pathways has certain conditions to approval, some of which may be post-approval, such as the conduct of a post-approval, or confirmatory, trial using due diligence. If we are unable to fulfill the requirements of regulators that are conditions of a product's accelerated or conditional approval, if the confirmatory trial shows unfavorable results or increased or additional undesirable side effects, or if regulators re-evaluate the data or risk-benefit profile of our product candidate, the availability of accelerated or conditional approval may be withdrawn or our conditional approval may not result in full approval or may be revoked or not renewed. Alternatively, we may be required to change a product candidate's labeled indications or even withdraw the product, if approved, from the market.

The FDA's and comparable foreign authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability, which would adversely affect our business. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any.

Adverse events ("AEs") attributable to our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Clinical studies conducted to date have generated AEs related to our product candidates, some of which have been serious. Patients treated with rucaparib have commonly experienced anemia/decreased hemoglobin and fatigue/asthenia. In studies of lucitanib, hypertension, proteinuria and subclinical hypothyroidism requiring supplementation are the most common AEs observed. The most notable AEs experienced by patients treated with rociletinib include hyperglycemia and QTc prolongation. As is the case with all oncology drugs, it is possible that there may be other potentially harmful characteristics associated with their use in future trials, including larger and lengthier Phase III clinical trials. As we evaluate the use of our product candidates in combination with other active agents, we may encounter safety issues as a result of the combined safety profiles of each agent, which could pose a substantial challenge to that development strategy.

Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related AEs could affect patient recruitment or the ability of enrolled patients to complete the

trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics could harm our drug development strategy.

As one of the key elements of our clinical development strategy, we seek to identify patient subsets within a disease category who may derive selective and meaningful benefit from the product candidates we are developing. In collaboration with partners, we plan to develop companion diagnostics to help us to more accurately identify patients within a particular subset, both during our clinical trials and in connection with the commercialization of our product candidates. Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate regulatory approval prior to commercialization. We do not develop companion diagnostics internally and thus we are dependent on the sustained cooperation and effort of our third-party collaborators in developing and obtaining approval for these companion diagnostics. We and our collaborators may encounter difficulties in developing and obtaining approval for the companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility, or clinical validation. Any delay or failure by our collaborators to develop or obtain regulatory approval of the companion diagnostics could delay or prevent approval of our product candidates. In addition, our collaborators may encounter production difficulties that could constrain the supply of the companion diagnostics, and both they and we may have difficulties gaining acceptance of the use of the companion diagnostics in the clinical community. If such companion diagnostics fail to gain market acceptance, it would have an adverse effect on our ability to derive revenues from sales of our products. In addition, the diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

The failure to maintain our collaboration with Servier, or the failure of Servier to perform its obligations under the collaboration, could negatively affect our business.

Pursuant to the terms of our collaboration and license agreement with Servier, Servier was granted exclusive rights to develop and commercialize lucitanib in markets outside of the United States and Japan (excluding China). Consequently, our ability to realize any revenues from lucitanib in the Servier territory depends on our success in maintaining our collaboration with Servier and Servier's ability to obtain regulatory approvals for, and to successfully commercialize, lucitanib in its licensed territory. Although we collaborate with Servier to carry out a global development plan for lucitanib, we have limited control over the amount and timing of resources that Servier will dedicate to these efforts.

Based on current cost estimates, we expect Servier's funding commitment will be fulfilled in late 2016 or early 2017, and thereafter, we will share equally with Servier in future development costs pursuant to a mutually agreed upon global development plan.

We are subject to a number of other risks associated with our collaboration and license agreement with Servier, including:

- Servier may not comply with applicable regulatory requirements with respect to developing or commercializing lucitanib, which could adversely affect future development or sales of lucitanib in Servier's licensed territory and elsewhere;

Servier is responsible for the first €80.0 million of development costs in support of the lucitanib program; however we have limited control over the costs Servier may incur with respect to its development activities for the compound, and therefore our obligation to share additional costs could be triggered sooner than planned;

If Servier does not agree to include within the global development plan new studies that we propose to conduct for lucitanib, we may be responsible for all costs associated with carrying out such activities;

We and Servier could disagree as to current or future development plans for lucitanib, and Servier may delay clinical trials or stop a clinical trial for which it is the sponsor;

There may be disputes between us and Servier, including disagreements regarding the collaboration and license agreement, that may result in (1) the delay of or failure to achieve regulatory and commercial objectives that would result in milestone or royalty payments, (2) the delay or termination of any future development or commercialization of lucitanib, and/or (3) costly litigation or arbitration that diverts our management's attention and resources;

Business combinations or significant changes in Servier's business strategy may adversely affect Servier's ability or willingness to perform its obligations under our collaboration and license agreement; and

The royalties we are eligible to receive from Servier may be reduced or eliminated based upon Servier's and our ability to maintain or defend our intellectual property rights and the presence of generic competitors in Servier's licensed territory.

The collaboration and license agreement is subject to early termination, including through Servier's right to terminate the agreement without cause upon advance notice to us. If the agreement is terminated early, we may not be able to find another collaborator for the further development and commercialization of lucitanib outside of the United States and Japan on acceptable terms, or at all, and we could incur significant additional costs by pursuing continued development and commercialization of lucitanib in those territories on our own.

We rely on third parties to conduct our non-clinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing non-clinical and clinical programs. We rely on these parties for execution of our non-clinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP, which are regulations and guidelines enforced by the FDA, the EEA and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under current GMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical and non-clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially influence our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition

and prospects.

We rely completely on third parties to manufacture our clinical drug supplies and we intend to rely on third parties to produce commercial supplies of any approved product candidate, and our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our clinical drug supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the GMP regulatory requirements for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly affect our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers of raw materials that we use to manufacture our drugs and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

We are dependent on our third party manufacturers to conduct process development and scale-up work necessary to support greater clinical development and commercialization requirements for our product candidates. Carrying out these activities in a timely manner, and on commercially reasonable terms, is critical to the successful development and commercialization of our product candidates. We expect that our third-party manufacturers are capable of providing sufficient quantities of our product candidates to meet anticipated clinical and full-scale commercial demands, however if third parties with whom we currently work are unable to meet our supply requirements, we will need to secure alternate suppliers. While we believe that there are other contract manufacturers having the technical capabilities to manufacture our product candidates, we cannot be certain that identifying and establishing relationships with such sources would not result in significant delay or material additional costs.

We expect to continue to depend on third-party contract manufacturers for the foreseeable future. We have not entered into long-term agreements with all of our current contract manufacturers or with any alternate fill/finish suppliers, and though we intend to do so prior to commercial launch in order to ensure that we maintain adequate supplies of finished drug product, we may be unable to enter into such an agreement or do so on commercially reasonable terms, which could have a material adverse effect upon our business. We currently obtain our supplies of finished drug product through individual purchase orders.

Although we have begun to build our marketing and sales organization, if we are unable to establish and maintain sufficient internal marketing, sales and distribution capabilities, or enter into agreements with third parties to market and sell our product candidates, we may not be able to successfully commercialize our products.

We have no history as a company in the sales and distribution of pharmaceutical products. In order to successfully commercialize any of our product candidates, if approved, we must establish and maintain our marketing, sales, distribution, managerial and other non-technical capabilities, or make arrangements with third parties to perform these services. Our commercial and medical affairs organizations in the U.S. are in place; however, we may not be able to retain the marketing and sales organization in place until the time of the potential launch of rucaparib, if and when approved for sale by the FDA. Establishing our sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates will continue to be expensive and time consuming.

With respect to our product candidates, we may elect to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems in certain territories. To the extent that we enter into licensing or co-promotion arrangements for any of our product candidates, our product revenue may be lower than if we directly marketed or sold our approved products. In addition, any revenue we receive as a result of such arrangements would depend in whole or in part upon the efforts of such third parties, which may not be successful and are generally not within our control. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates that receive regulatory approval. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payors and major operators of cancer clinics.

Even if we obtain regulatory approval for our product candidates, the product may not gain market acceptance among physicians, health care payors, patients and the medical community, which are critical to commercial success. Market acceptance of any product candidate for which we receive approval depends on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of such product candidate as well as competitive products;
- the clinical indications for which the drug is approved and the product label approved by regulatory authorities, including any warnings that may be required on the label;
- the approval, availability, market acceptance and reimbursement for the companion diagnostic;
- acceptance by physicians, major operators of cancer clinics and patients of the drug as a safe and effective treatment;
- the potential and perceived advantages of such product candidate over alternative treatments, especially with respect to patient subsets that we are targeting with such product candidate;
- the safety of such product candidate seen in a broader patient group, including its use outside the approved indications;
- the cost, safety and efficacy of the product in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third-party payors and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects; and
- the effectiveness of our sales and marketing efforts.

If our product candidates are approved but fail to achieve an adequate level of acceptance by physicians, healthcare payors and patients, we will not be able to generate significant revenues, and we may not become or remain profitable.

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

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. In addition, the competition in the oncology market is intense. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions.

In late 2014, Lynparza™ (olaparib) was approved in the U.S. as monotherapy in patients with germline BRCA mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy and in the EU for the maintenance treatment of BRCA mutated platinum-sensitive relapsed serous ovarian cancer. There are a number of other PARP inhibitors in clinical development including AbbVie’s ABT-888 (veliparib), currently in Phase III clinical

trials, Tesaro, Inc.'s niraparib, currently in Phase III trials, Eisai's E-7016, currently in Phase II trials and Medivation's talazoparib (BMN-673), currently in Phase III trials.

There are currently no approved drugs that specifically inhibit each of VEGFR, PDGFR and FGFR, as does lucitanib; however, there are currently a number of oral antiangiogenic drugs that target one or a subset of those markers and are approved or in development for various solid tumors, including: nintedanib (Boehringer Ingelheim), lenvatinib (Eisai), sunitinib (Pfizer), sorafenib (Bayer), pazopanib (Novartis), axitinib (Pfizer) and cabozantinib (Exelixis).

In November 2015, the FDA approved Tagrisso™ (osimertinib) for patients with metastatic EGFR T790M mutation-positive NSCLC who have progressed on or after EGFR TKI therapy. This represents the first approved therapy for the treatment of EGFR mutant NSCLC patients who test positive for the T790M mutation. In February 2016, the European Commission granted conditional marketing approval to Tagrisso™ for the treatment of advanced NSCLC patients who test positive for the T790M mutation. In addition, we are aware of a number of other products in development targeting cancer-causing mutant forms of EGFR for the treatment of NSCLC patients. These products include Pfizer's PF-06747775, currently in Phase I/II trials, Astellas Pharma's ASP8273, currently in Phase I/II trials, Novartis' EGF816, currently in Phase I/II trials, Hanmi Pharmaceutical's and Boehringer Ingelheim's BI-1482694 (HM61713), HM781-36B (Poziotinib), currently in Phase I/II trials and Acea Bio (Hangzhou)'s avitinib and AC0010MA, currently in Phase I/II trials. Bristol Myers Squibb's Opdivo® and Merck's Keytruda®, both approved for second-line NSCLC, may also represent competition to rociletinib.

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

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

Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our products profitably.

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. We intend to seek approval to market our product candidates in the United States, Europe and other selected foreign jurisdictions. Market acceptance and sales of our product candidates in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future healthcare reform measures. Government and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new drugs and, as a result, they may not cover or provide adequate payment for our product candidates. These payors may conclude that our product candidates are less safe, less effective or less cost-effective than existing or later introduced products, and third-party payors may not approve our product candidates for coverage and reimbursement or may cease providing coverage and reimbursement for these product candidates.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide to the payor supporting scientific, clinical and

cost-effectiveness data for the use of our products. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates. Even if we obtain coverage for our product candidates, third-party payors may not establish adequate reimbursement amounts, which may reduce the demand for, or the price of, our products. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

In both the United States and certain foreign jurisdictions, there have been and we expect there will continue to be a number of legislative and regulatory changes to the health care system that could affect our ability to sell our products profitably. The U.S. government and other governments have shown significant interest in pursuing healthcare reform. In particular, the Medicare Modernization Act of 2003 revised the payment methodology for many products under the Medicare program in the United States. This has resulted in lower rates of reimbursement. In 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the “Affordable Care Act”), was enacted. The Affordable Care Act substantially changed the way healthcare is financed by both governmental and private insurers. Such government-adopted reform measures may adversely affect the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect the demand for any drug products for which we may obtain regulatory approval, as well as our ability to set satisfactory prices for our products, to generate revenues, and to achieve and maintain profitability.

In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our product candidates is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability of our products in such country.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. Further, we will need to grow our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

Our industry has experienced a high rate of turnover of management personnel in recent years. Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, especially Patrick J. Mahaffy, our President and Chief Executive Officer, Lindsey Rolfe, our Executive Vice President of Clinical and Preclinical Development and Pharmacovigilance and Chief Medical Officer, Dale Hooks, our Senior Vice President and Chief Commercial Officer and Gillian C. Ivers-Read, our Executive Vice President, Technical Operations and Chief Regulatory Officer, whose services are critical to the successful implementation of our product candidate acquisition, development and regulatory strategies.

Despite our efforts to retain valuable employees, members of our management, scientific, development and commercial teams may terminate their employment with us on short notice. Pursuant to their employment arrangements, each of our executive officers may voluntarily terminate their employment at any time by providing as little as thirty days advance notice. Our employment arrangements with all of our employees provide for at-will employment, which means that any of our employees (other than our executive officers) could leave our employment at any time, with or without notice. For example, Andrew R. Allen, our former Executive Vice President of Clinical and Pre-Clinical Development and Chief Medical Officer, resigned in July 2015, Steven L. Hoerter, our former Executive Vice President and Chief Commercial Officer, resigned in January 2016 and Erle T. Mast, our former Executive Vice President and Chief Financial Officer, resigned in March 2016. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, financial condition and prospects. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

As of April 29, 2016, we employed 304 full-time employees. As our development plans and strategies develop, we expect to expand our employee base for managerial, operational, financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations which may result in

weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we have to offer. In order to induce valuable employees to continue their employment with us, we have provided stock options that vest over time. The value to employees of stock options that vest over time is significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize product candidates will be limited.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state health-care fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant effect on our business and results of operations, including the imposition of significant fines or other sanctions.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may affect, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- HIPAA which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by HITECH and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;