Clovis Oncology, Inc.
Form 10-K
February 29, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the fiscal year ended December 31, 2015.

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

Commission file number: 001-35347

Clovis Oncology, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	90-0475355
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock par value $0.001 per share	The NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes x No ¨

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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

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

The aggregate market value of the registrant's common stock, par value $0.001 per share, held by non-affiliates of the registrant on June 30, 2015, the last business day of the registrant's most recently completed second quarter, was $2,122,270,803 based on the closing price of the registrant's common stock on the NASDAQ Global Market on that date of $87.88 per share.

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of February 19, 2016 was 38,359,454.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant's 2016 Annual Meeting of Stockholders, which is to be filed within 120 days after the end of the registrant's fiscal year ended December 31, 2015, are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated therein.

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PART I

This Annual Report filed on Form 10-K 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 Annual Report on Form 10-K 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 Annual Report on Form 10-K 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 Annual Report on Form 10-K or to reflect the occurrence of unanticipated events.

You should also read carefully the factors described in the "Risk Factors" section of this Annual Report on Form 10-K 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 Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and our website.

Clovis Oncology® and the Clovis logo are trademarks of Clovis Oncology, Inc. in the United States and in other selected countries. All other brand names or trademarks appearing in this report are the property of their respective holders. Unless the context requires otherwise, references in this report to "Clovis," the "Company," "we," "us" and "our" refe to Clovis Oncology, Inc., together with its consolidated subsidiaries.

ITEM 1. BUSINESS

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 three product candidates:

- Rociletinib, an oral epidermal growth factor receptor ("EGFR"), mutant-selective covalent inhibitor that is currently under review with the U.S. and E.U. regulatory authorities for the treatment of advanced non-small cell lung cancer ("NSCLC") in patients with activating EGFR mutations, as well as the dominant resistance mutation, T790M;

- Rucaparib, an oral inhibitor of poly (ADP-ribose) polymerase ("PARP") that is currently in advanced clinical development for the treatment of ovarian cancer and for which the first U.S. regulatory application is expected to be submitted for approval during the second quarter of 2016 and the first E.U. regulatory application is expected to be submitted in the second half of 2016; and
- Lucitanib, an oral inhibitor of the tyrosine kinase activity of vascular endothelial growth factor receptors 1-3 ("VEGFR1-3"), platelet-derived growth factor receptors alpha and beta ("PDGFR a/ß") and fibroblast growth factor receptors 1-3 ("FGFR1-3") that is currently in Phase II development for the treatment of breast cancer.

We hold global development and commercialization rights for rociletinib and rucaparib. 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 ("Servier").

We have built our organization to support innovative oncology drug development for the treatment of specific subsets of cancer populations. To implement our strategy, we have assembled an experienced team with core competencies in global clinical development and regulatory operations in oncology, as well as conducting collaborative relationships with companies specializing in companion diagnostic development. We have fully established our U.S. commercial and medical affairs organizations in preparation for potential approvals for our New Drug Applications ("NDAs") for rociletinib, which was filed in July 2015, and for rucaparib, which we expect to file in the second quarter of 2016.

Product Candidates

We are developing our product candidates for selected patient subsets and collaborating with partners for companion diagnostic development. The following table summarizes the ongoing studies for our product candidates:

Rociletinib - an Oral EGFR Mutant-Selective Inhibitor

Overview

Rociletinib is a novel, oral, targeted covalent (irreversible) mutant-selective inhibitor of EGFR in development for the treatment of NSCLC, and is the subject of a global clinical development program.

In May 2010, we in-licensed rociletinib from Avila Therapeutics, Inc. (now Celgene Avilomics Research Inc., part of Celgene Corporation). In May 2014, rociletinib received "Breakthrough Therapy" designation from the U.S. Food and Drug Administration ("FDA") for the treatment of patients with EGFR mutation-positive NSCLC, whose disease has progressed on prior EGFR-directed therapy due to T790M-mediated acquired drug resistance.

In July 2015, we submitted an NDA to the FDA and a Marketing Authorization Application ("MAA") to the European Medicines Agency ("EMA") for rociletinib as treatment for patients with mutant EGFR NSCLC who have been previously treated with an EGFR-targeted therapy and have the EGFR T790M mutation. During a regularly scheduled Mid-Cycle Communication meeting in early November 2015, the FDA requested additional clinical data for use in the efficacy analysis for both the 500mg and 625mg BID dose patient groups for rociletinib. We submitted these data in a Major Amendment on November 16, 2015 after which the FDA extended the Prescription Drug User Fee Act goal date for the rociletinib NDA by three months to June 28, 2016 to allow additional time for review of the new information requested by the agency. The FDA has scheduled the NDA for rociletinib for discussion by the Oncologic Drugs Advisory Committee ("ODAC") on April 12, 2016. 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.

Market Overview - Resistance to EGFR Tyrosine Kinase Inhibitors ("TKIs") Represents an Unmet Medical Need

Lung Cancer and EGFR TKIs. According to the American Cancer Society, in 2016, there will be an estimated 224,000 new cases of lung cancer in the United States, making it one of the most common types of cancer. In addition, according to GLOBOCAN, in 2012, there were an estimated 313,000 new cases of lung cancer in the European Union and an estimated 95,000 new cases in Japan. Lung cancer typically presents relatively late in its clinical course, when locally-directed therapy (surgery and radiation) is not curative.

Lung cancer is typically divided into two groups based upon the histologic appearance of the tumor cells (small cell and non-small cell lung cancer), each of which is treated with distinct chemotherapeutic approaches. According to the American Cancer Society, NSCLC accounts for approximately 85% of lung cancer cases. The standard of care for treatment of advanced or metastatic NSCLC has historically been a cytotoxic chemotherapy doublet of platinum plus paclitaxel. In the last few years, in a subset of NSCLC patients, Avastin® (bevacizumab) has been shown to prolong survival when added to the chemotherapy doublet, and Alimta® (pemetrexed) has replaced paclitaxel on the basis of improved tolerability and ease of administration. Despite these additions, patients with locally advanced or metastatic NSCLC have five-year survival rates of just 27% and 4%, respectively, according to the Survival Epidemiology and End Results program of the National Cancer Institute.

Small molecule inhibitors of the tyrosine kinase activity of EGFR were introduced into the treatment of lung cancer just over 10 years ago. The growth-promoting EGFR was known to be frequently expressed on lung cancer cells, often at high levels, and non-clinical work had suggested that EGFR TKIs, such as gefitinib and erlotinib, could provide effective cancer therapy in certain patient subsets. Iressa® (gefitinib) and Tarceva® (erlotinib) were approved by the FDA in 2003 and 2004, respectively, for patients who had failed to respond to conventional chemotherapy.

In 2004, it was discovered that the subset of NSCLC patients who experienced dramatic clinical responses to EGFR TKIs had activating mutations in the EGFR gene in their lung cancer tissue, typically either a point mutation in exon 21 (L858R) or a deletion mutation in exon 19 (del(19)). It became clear that the EGFR TKIs potently inhibited the mutant EGFR proteins, switching off their activity and causing dramatic tumor shrinkage in patients. This is an example of "oncogene addiction," whereby a single gene mutation (EGFR in this case) is absolutely necessary for the proliferation and/or survival of a tumor cell. A corollary of this situation is that inhibition of that single gene product (in this case with TKIs) is therapeutic and drives tumor shrinkage. It was subsequently shown in a study conducted by Jeffrey A. Engelman, et al. published in Clinical Cancer Research in 2008 that EGFR mutations generate tumors with adenocarcinoma histology and are found in approximately 10% to 15% of Caucasian NSCLC patients and 30% to 35% of East Asian NSCLC patients.

The original approvals of the TKIs made no reference to patient selection, but these more recent data suggest that the majority, if not all, of their therapeutic benefit can be attributed to the subset of patients with activating EGFR mutations. During 2013, the FDA approved Gilotrif® (afatinib) and expanded the label for Tarceva® (erlotinib) for the first-line treatment of patients with metastatic non-small cell lung cancer whose tumors have activating EGFR mutations, as detected by FDA-approved tests. During 2015, the FDA also approved Iressa® (gefitinib) for the same indication.

Resistance to EGFR TKIs. Despite the success of TKIs in patients with mutant EGFR-related NSCLC, most patients' disease will progress, typically after approximately one year of therapy. Molecular studies, including a study conducted by Helena A. Yu, et al., published in Clinical Cancer Research in 2013, have shown that approximately 60% of the resistant tumors carry a second, acquired resistance mutation in the EGFR gene. This resistance mutation is a specific change in the type of amino acid located at position 790 in the EGFR protein, called a "T790M" mutation. As a consequence of this switch, the three-dimensional structure of the TKI binding site changes and the EGFR becomes resistant to TKI therapy. This T790M mutation is also called the "gatekeeper" mutation because of its strategically important position in the EGFR protein. Until recently, there were no approved therapies for patients whose disease progressed due to the emergence of the T790M mutation. Patients who developed TKI resistance

received standard cytotoxic chemotherapy that carried toxicity and only modest palliative efficacy. In November 2015, the FDA approved Tagrisso™ (osimertinib) for the treatment of patients with metastatic EGFR T790M mutation-positive NSCLC as detected by an FDA-approved test, who have progressed on or after EGFR TKI therapy, representing 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.

Design of Rociletinib - a Targeted Covalent Drug

Most human diseases are rooted in the abnormal activity of certain proteins. Traditional small molecule drugs, while able to inhibit disease-causing proteins, are generally only able to form transient binding interactions with the disease targets and are thus considered reversible. A covalent drug, however, forms a strong and durable bond with its protein target, known as a covalent bond. A targeted covalent drug is designed to form its covalent bond in a highly directed and controlled manner with a specific site on the disease target. This directed bond formation is key to achieving a distinct selectivity profile that is difficult to achieve with traditional reversible small molecules. Rociletinib was developed using a proprietary platform to purposefully and systematically design and develop targeted covalent inhibitors.

Rociletinib was designed by identifying a site on the EGFR protein where a covalent bond could be formed and, using proprietary drug design techniques, modeling chemical structures that could selectively form a bond with this site. These molecules were then synthesized and tested in assays to verify their ability to form targeted covalent bonds and to potently inhibit the mutant forms of EGFR and also to demonstrate that covalent bonds were not formed indiscriminately with other targets.

Clinical Development

We are pursuing the development of rociletinib as both a second-line or later treatment for EGFR-mutated NSCLC patients who become resistant to TKIs due to the emergence of the T790M mutation, and potentially, as a first-line treatment for EGFR-mutated NSCLC when given in combination with other agents. We are also exploring rociletinib's utility for progressing EGFR-mutated NSCLC patients who do not express the T790M mutation (T790M-negative patients).

In the first quarter of 2012, we initiated our first Phase I/II study of rociletinib in patients with metastatic or unresectable recurrent NSCLC and a documented EGFR mutation. Patients were not required to be T790M positive for the Phase I portion of the study but had to have progressed on prior EGFR-directed TKI therapy (prior chemotherapy was also allowed). The Phase I portion of the study was conducted in the U.S., France and Australia. Data from this study were used to determine the tolerability and pharmacokinetics of rociletinib, as well as provide initial evidence of efficacy.

We recently completed enrollment of the Phase II expansion cohorts of that study, designated as TIGER-X under the TIGER (Third-generation Inhibitor of Mutant EGFR in Lung CancER) program, conducted in the U.S., Europe and Australia. These cohorts are testing the safety and efficacy of rociletinib in patients with T790M-positive NSCLC, either immediately after progression on their first and only TKI therapy or after progression on their second or later TKI therapy of subsequent chemotherapy.

In addition to TIGER-X, three global studies are currently ongoing as part of the TIGER program:

- TIGER-1, a randomized Phase II study of rociletinib vs. erlotinib in EGFR mutation-positive patients who have not had TKI therapy, but who may have received one type of chemotherapy. Enrollment for this study was recently discontinued, as we intend to focus our evaluation of rociletinib as a first-line therapy only in combination with other agents.
- TIGER-2, a single-arm study in second-line patients immediately after progression on their first and only TKI therapy, which includes both T790M-positive and T790M-negative cohorts. Enrollment in this study was recently completed.
- TIGER-3, a randomized study of rociletinib vs. chemotherapy in later-line patients progressing on second or later TKI or subsequent chemotherapy, which includes both T790M-positive and T790M-negative cohorts. TIGER-3 continues to enroll patients and is intended to serve as the confirmatory study following accelerated approval of rociletinib, which is currently under review by the FDA.

Data from the interim data cuts of the TIGER-X expansion cohorts, combined with an interim data cut of TIGER-2, serve as the basis of the NDA in the U.S. and the MAA in the E.U. filed in July 2015 for the initial approvals for rociletinib for the treatment of patients with mutant EGFR NSCLC who have been previously treated with an EGFR-targeted therapy and have the EGFR T790M mutation. The primary efficacy analysis for these submissions is based on pooled data from patients enrolled in the TIGER-X and TIGER-2 studies who were given rociletinib at doses of 500mg and 625mg BID, or twice daily. The data in the final MAA dataset will be based on a larger number of patients than in the NDA dataset.

In the intent to treat analysis of the 79 patients in the 500mg BID dose group, the confirmed response rate by investigator was 28% and by independent review was 23%, and the duration of response by both investigator and independent review was nine months. For the 170 patients in the 625mg BID dose group, the confirmed response rate by investigator was 34% and by independent review was 32%, and the duration of response by investigator was seven months and by independent review was nine months. The only grade 3 or higher treatment emergent adverse reaction observed in greater than 15% of patients is hyperglycemia (27% for the 500mg BID dose and 28% for the 625mg BID dose, both based on lab values), with QTc prolongation also notable, though with lower frequency of grade 3 or higher events. Based on this data set, we have requested that the FDA consider 625mg BID as the dose for rociletinib approval, although this matter is still under review by the FDA. The data in the final MAA dataset, including a pre-agreed update that includes a larger number of patients, is planned to be submitted to the EMA in the second quarter of 2016. Based on our planned second quarter submission, we anticipate the Committee for Medicinal Products for Human Use ("CHMP") to issue an opinion on the rociletinib MAA by the end of 2016.

We expect that should rociletinib be approved, the primary information on response rates and duration of response included in the prescribing information will be based on confirmed response rate by independent review.

As noted above, we are also exploring rociletinib's utility for progressing T790M-negative, EGFR-mutated NSCLC patients. In T790M-negative patients treated in the TIGER-X study at the 625mg BID dose, a confirmed response rate of 29% was achieved (N=24), with a median duration of response of approximately seven months. T790M-negative patient cohorts are being further evaluated in both the TIGER-2 and TIGER-3 studies.

These studies are ongoing, so data may change over time.

In January 2016, we announced our intention to explore rociletinib in Phase Ib/II combination studies with other agents in first- and later-line NSCLC patients who possess the EGFR mutation. These include combinations with immuno-oncology agents, anti-VEGF inhibitors (e.g. bevacizumab) and EGFR monoclonal antibodies (e.g. cetuximab). These studies will include both T790M-positive and T790M-negative patients. The first of these studies, a trial evaluating the combination of rociletinib with Genentech's investigational cancer immunotherapy atezolizumab (MPDL3280A; anti-PDL-1) for the treatment of advanced EGFR-mutant NSCLC, was initiated in January 2016.

Concurrent with our drug development program, we are collaborating with QIAGEN for the development of a companion diagnostic to enable identification of the T790M mutation in patients with mutant EGFR driven NSCLC. The PCR-based diagnostic test will build on QIAGEN's therascreen® EGFR RGQ PCR Kit, which was approved by the FDA in July 2013 as a companion diagnostic used in the treatment of metastatic NSCLC patients whose tumors have certain EGFR mutations. Analytical performance of the therascreen EGFR test has been established for 21 EGFR mutations, including T790M. The diagnostic is being developed in parallel with the clinical development of rociletinib, and QIAGEN submitted a Premarket Approval Application ("PMA") with the FDA during the third quarter of 2015, in a time frame intended to allow for regulatory approval of the companion diagnostic at substantially the same time that rociletinib may be approved.

Rucaparib - a PARP Inhibitor

Overview

Rucaparib is a novel, oral, small molecule inhibitor of PARP-1 and PARP-2, which is currently being explored in Phase II and III clinical trials as both treatment and maintenance therapy for advanced ovarian cancer patients with tumor-BRCA mutations (germline and somatic mutations in genes that are linked to breast and ovarian cancers) and with other DNA repair deficiencies, commonly referred to as "BRCA-like" mutations. We in-licensed rucaparib from Pfizer Inc. in June 2011. In April 2015, rucaparib received "Breakthrough Therapy" designation from the FDA as monotherapy treatment of advanced ovarian cancer in patients who have received at least two lines of prior platinum-containing therapy, with BRCA-mutated tumors, inclusive of both germline BRCA (gBRCA) and somatic

BRCA (sBRCA) mutations.

We intend to submit our initial NDA for rucaparib to the FDA as treatment for advanced ovarian cancer patients with a germline or somatic BRCA mutation in the second quarter of 2016. We completed enrollment of the mutant BRCA population that will serve as the basis of the submission during the fourth quarter of 2015. In addition, a planned MAA filing in the E.U. for the same indication is expected by the end of 2016. We also intend to study rucaparib as a treatment for BRCA mutant prostate cancer patients and plan to initiate a registration study in this patient population in the second half of 2016.

DNA Repair and PARP

Cells in the human body are under constant attack from agents that can cause damage to DNA, including sunlight and other forms of radiation, as well as DNA-binding chemicals that can cause changes in the composition of DNA. Since DNA is the vehicle by which fundamental information is passed on when a cell divides, it is critical to the integrity of cells and human health that DNA damage can be repaired. Cells have evolved multiple mechanisms to enable such DNA repair, and these mechanisms are complementary to each other, each driving repair of specific types of DNA damage. If a cell's DNA damage repair system is overwhelmed, then the cell will undergo a form of suicide called apoptosis that appears to operate as a fail-safe system to limit the ability of a mutated cell to proliferate and potentially form a cancer. A fundamental principle of cancer therapy is to damage cells profoundly with radiation or DNA-binding drugs, such as alkylating agents or platinums, and induce apoptosis in those cells, thus killing the cancer cells. DNA repair mechanisms may reduce the activity of these anti-cancer therapies but, conversely, inhibition of DNA repair processes may enhance the effects of DNA-damaging anti-cancer therapy.

Poly (ADP-ribose) is a part of the early warning system for DNA damage and is synthesized by PARP enzymes on regions of damaged DNA, where it signals to the cell that DNA repair needs to take place. In the absence of PARP, as is seen in gene-knockout mice, cells are unusually sensitive to DNA damage when exposed to radiation or DNA-alkylating agents. There are two major forms of PARP that signal DNA damage in this way, PARP-1 and PARP-2. Knockout of either PARP gene leads to enhanced DNA damage in both instances, although the mice may survive; however, the double knockout in which both the PARP-1 and PARP-2 genes are deleted is fatal to the mice at an embryonic stage. We believe that a drug that inhibits both PARP-1 and PARP-2, which rucaparib does, may have enhanced activity in preventing DNA repair.

Synthetic Lethality

An important advance in the field of cancer treatment occurred when it was recognized that germline mutations in the BRCA genes (BRCA1 and BRCA2, two tumor suppressor genes) were associated both with high rates of breast and ovarian cancer in female mutant gene carriers and also impaired the ability of cells to repair DNA damage. BRCA gene products were shown to be key mediators of DNA repair. The notion was that advanced treatment of BRCA-defective cells with PARP inhibitors could lead to a disabling blow against a tumor cell's ability to repair DNA and could induce apoptosis. This phenomenon was termed "synthetic lethality" and was demonstrated in humans in a study conducted by Peter C. Fong, M.D. et al., published in the New England Journal of Medicine in 2009, as evidenced by women with advanced breast and ovarian cancer and germline BRCA mutations experiencing objective tumor responses when treated with monotherapy PARP inhibitors. Germline and somatic BRCA mutations are a minority subset of all breast and ovarian cancers, representing approximately 20% to 25% of those cancers.

BRCA-like Tumors

The hypothesis that some tumors might have defective DNA repair function for reasons other than germline (hereditary) or somatic (acquired) gene mutation has also been explored. This notion has been called "BRCAness" or "BRCA-like." Subsequent work has shown that BRCA-like alterations exist, and that these cancer patients with normal BRCA genes, but BRCA-like mutations can respond to monotherapy with PARP inhibitors. Work is underway to identify a molecular signature for patients with tumors that are BRCA-like that could enable patient selection for therapy. If successful, this work has the potential to increase the percentage of high-grade serous ovarian cancer patients eligible for rucaparib therapy from the approximately 20% to 25% typically found to have germline or somatic BRCA mutations to an estimated 50%, which includes those patients whose tumors have certain DNA repair deficiencies, and thus may be considered a BRCA-like population.

Clinical Development

Rucaparib is currently the subject of several clinical studies, including the ARIEL (Assessment of Rucaparib In Ovarian CancEr TriaL) program, which includes the Phase II ARIEL2 treatment study and the Phase III ARIEL3 maintenance study, both in advanced ovarian cancer patients.

ARIEL2 is a single-arm, registration study of rucaparib treatment in relapsed patients, designed to identify tumor characteristics that predict sensitivity to rucaparib using DNA sequencing to evaluate each patient's tumor. Both archived tumor and recent biopsy samples are collected from patients and DNA sequenced. The patients' response to rucaparib is being assessed and those clinical responses are correlated to pre-defined molecularly defined patient sub-groups, including germline BRCA mutant, somatic BRCA mutant and the BRCA-like signature identified through the genetic diagnostic testing. The first part of the global ARIEL2 study completed enrollment of 206 ovarian cancer patients with relapsed, platinum-sensitive disease in 2014. In early 2015, ARIEL2 was expanded (ARIEL2 extension or ARIEL2 Part 2) to include an additional 300 patients with recurrent disease after at least three prior lines of chemotherapy. Enrollment in the ARIEL2 extension study is not limited to platinum-sensitive disease, but also includes patients with platinum-resistant or platinum-refractory disease.

ARIEL3 is a randomized, double-blind, registration study comparing the effects of rucaparib against placebo to evaluate whether rucaparib given as a maintenance therapy to platinum-sensitive patients can extend the period of time for which the disease is controlled after a positive outcome with platinum-based chemotherapy. Patients are randomized to receive either placebo or rucaparib and the primary endpoint of the study is progression-free survival ("PFS"). The primary efficacy analysis will evaluate mutant BRCA patients, all HRD patients (including mutant BRCA and BRCA-like) and all patients.

In addition to ARIEL2 and ARIEL3, the Phase II portion of rucaparib's initial dose finding study (Study 010) continues to assess efficacy of rucaparib in advanced ovarian cancer patients with tumors harboring a germline or somatic BRCA mutation.

Data from a blended population of patients from ARIEL2, the ARIEL2 extension and the Phase II portion of Study 010 are expected to form the basis of a planned NDA filing for the treatment of patients with tumor-BRCA-mutant advanced ovarian cancer, which includes both germline and somatic BRCA patients, expected to be submitted during the second quarter of 2016, as well as a planned MAA filing in the E.U. for the same indication, which is expected to be submitted by the end of 2016. During 2016, we currently plan to initiate the ARIEL4 study, a Phase III study of rucaparib versus chemotherapy as a treatment for patients with tumor-BRCA-mutant and, potentially, BRCA-like relapsed ovarian cancer. We expect that ARIEL4 will serve as the confirmatory study required by the FDA for the potential accelerated approval of rucaparib using data from ARIEL2 and Study 010.

Data from ongoing rucaparib studies presented at medical conferences during 2015 demonstrated meaningful clinical activity and safety in ovarian cancer patients with tumors with BRCA mutations, as well as in those with the BRCA-like signature. Data from 204 evaluable patients in the first part of the ongoing ARIEL2 study presented in September 2015 and updated in January 2016 demonstrated encouraging clinical activity and safety in two pre-specified subgroups of these patients. The most robust clinical activity was observed in platinum-sensitive patients with tumor BRCA mutations. Seventy-five percent (30/40) of BRCA-mutant patients achieved a confirmed response. The response rate was similar in both germline and somatic BRCA-mutant tumors. Six of these patients achieved a complete response by RECIST. The median duration of response was 9.5 months in this patient population, in which patients had received a median of two prior therapies. In addition, in platinum-sensitive patients with normal BRCA genes, rucaparib activity was different between those with the prospectively-defined BRCA-like signature versus biomarker negative (normal BRCA and no BRCA-like mutations) patients. Thirty percent (23/77) of patients with normal BRCA, but with the BRCA-like signature, achieved a confirmed response. In biomarker negative patients, few responses were observed. Ten percent (7/68) achieved a confirmed response. Median duration of response in both the tumor BRCA mutant and the BRCA-like populations was 9.5 months compared to 5.5 months in the biomarker negative patients.

In early 2016, we also presented interim data from a blended population of tumor BRCA-mutant ovarian cancer patients who had received at least three prior lines of therapy from Study 010 and ARIEL2. Sixty-one percent (14/23) of the platinum-sensitive patients achieved a confirmed response, including 13% who achieved a complete response. The median duration of response for these patients was 12.9 months. As we expand enrollment to a larger number of patients, the response rate and duration of response may be different than that reported to date for the smaller set of patients. Data presented to date include only platinum-sensitive patients, while the NDA submission will include a blended population of platinum-sensitive, -resistant and –refractory patients from the ARIEL2 extension study, in addition to the platinum-sensitive patients in ARIEL2 and Study 010.

Data from ARIEL2 and Study 010 have also demonstrated that rucaparib is generally well-tolerated with a manageable safety profile. The only grade 3/4 treatment-related adverse reactions observed in greater than 15% of patients are anemia/decreased hemoglobin (19%) in the first part of ARIEL2 and fatigue/asthenia (21%) and anemia (26%) in the Phase II portion of Study 010. The safety profile of rucaparib is an important attribute for a drug that is also intended to be used in a maintenance setting. These studies are ongoing, so data may change over time.

We intend to explore rucaparib as a treatment for BRCA-mutant and BRCA-like patients with other solid tumors through a combination of Company-sponsored and investigator initiated studies. In particular, we plan to initiate a registration study of rucaparib in castrate-resistant BRCA mutant prostate cancer patients in the second half of 2016.

We are collaborating with Foundation Medicine, Inc. for the development of a companion diagnostic to identify our BRCA-like signature, as well as both germline and somatic BRCA mutations. The diagnostic is being developed in parallel with the clinical development of rucaparib, with a goal of filing a PMA with the FDA in a time frame that would allow for regulatory approval of the companion diagnostic at substantially the same time that rucaparib would be approved.

Lucitanib – a VEGFR, PDGFR and FGFR Inhibitor

Overview

Lucitanib is a potent, oral angiogenesis inhibitor that selectively inhibits vascular endothelial growth factor receptors 1-3 (VEGFR1-3), platelet-derived growth factor receptors alpha and beta (PDGFR a/ß) and fibroblast growth factor receptors 1-3 (FGFR1-3). In a Phase I/IIa clinical study, lucitanib demonstrated multiple tumor responses in FGFR1 gene-amplified breast cancer patients, as well as in patients with tumors often sensitive to VEGFR inhibitors, such as renal cell and thyroid cancer. In collaboration with Servier, we initiated a broad Phase II development program in advanced breast and lung cancer, where FGFR amplification is common.

We obtained rights to lucitanib through our acquisition of Ethical Oncology Science S.p.A. (“EOS”) (now known as Clovis Oncology Italy S.r.l.) in November 2013, which had in-licensed exclusive development and commercial rights to lucitanib on a global basis, excluding China, from Advenchen Laboratories LLC in 2008. EOS, in turn, sublicensed lucitanib rights to markets outside of the U.S. and Japan to Servier in 2012. We hold exclusive rights for lucitanib in the U.S. and Japan, and we are collaborating with Servier on the global clinical development of lucitanib outside of China.

VEGF, PDGF and FGF

The VEGFs are a family of related extracellular proteins that normally regulate blood and lymphatic vessel development in humans. They act by binding to and activating VEGF receptors, which are cell surface proteins that transmit growth signals to specific cells that are involved in the development of new blood vessels. Certain VEGFs promote growth of multiple solid tumors by stimulating the formation of new blood vessels to feed the tumor and allow it to grow and metastasize. Tumors produce an excessive amount of VEGF. This results in excess VEGFR signaling and the formation of new blood vessels within the tumor. The VEGF ligands that induce angiogenesis are often present in a wide range of cancer indications, including a type of kidney cancer called renal cell carcinoma, a type of liver cancer called hepatocellular carcinoma, gastric cancer, head and neck cancers and other solid tumors.

The PDGF family consists of five different isoforms of PDGF ligand that bind to and activate cellular responses through two different receptors (PDGFR a/ß). In tumors, PDGF signaling plays a diverse role in many aspects of tumor development promoting cell proliferation, invasion, migration and angiogenesis. Amplification and/or mutation of the gene encoding the PDGFR a receptor is observed in a wide range of cancers, including lung cancer, an aggressive form of brain cancer called glioblastoma and a cancer of the gastrointestinal tract known as gastrointestinal stromal tumors. Amplification of the PDGFR a gene results in excess production, or the over-expression, of PDGFR a protein on the surface of the tumor cell. The over-expression of PDGFR a on the tumor cell surface leads to an increased receptor signaling, which stimulates uncontrolled proliferation of some types of tumor cells.

The FGFs are a family of related extracellular proteins that normally regulate cell proliferation and survival in humans. The FGF family consists of 22 ligands that exert their physiological effect on cells by binding to four FGFRs (FGFR1- 4). As with the PDGF family, some cancers display FGF/FGFR gene amplification/mutation resulting in continual activation of the FGFR signaling pathway leading to uncontrolled cell division. Tumors with a relatively high incidence of FGF aberrations, which include amplification of the FGFR1 gene and amplification of a region of chromosome 11q that contains several FGF ligands, include breast cancer (25%) and lung cancer (15%). In addition, FGFR gene amplification/mutation is also observed at a frequency of 3% to 19% in a wide range of cancer indications including sarcoma, ovarian cancer, adenocarcinoma of the lung, bladder cancer, colorectal cancer and endometrial cancer.

As an inhibitor of VEGFR1-3, PDGFR a/ß and FGFR1-3 and given the role that each of these receptor kinases plays in tumor progression and metastasis formation, lucitanib has the potential benefit of targeting three relevant pro-angiogenic growth factors in targeted patient populations identified by molecular markers.

Clinical Development

The first-in-man clinical trial of lucitanib was initiated in Europe in July 2010. This initial trial was an open-label, dose-escalation, Phase I/IIa study to determine efficacy, pharmacokinetics and pharmacodynamics of oral lucitanib in adult patients with advanced solid tumors. A maximum tolerated dose ("MTD") dose of 20mg QD was identified using a standard dose limiting toxicity window definition, but in the heavily pre-treated study population, toxicity-related dose reductions were frequent and, therefore, 15mg QD was adopted as a starting dose for the Phase II portion of the study. Overall, the toxicity profile observed to date is consistent with what was expected from non-clinical studies, with hypertension, proteinuria and subclinical hypothyroidism requiring supplementation being commonly observed. Other common treatment-related events include asthenia and gastrointestinal symptoms (diarrhea, abdominal pain, nausea and vomiting). Subsequent to MTD identification, a dose expansion phase was initiated in patients who were either FGFR or 11q amplified or angiogenesis inhibitor-sensitive. Six of 12 FGF-aberrant breast cancer patients achieved partial responses, some of which were confirmed, with additional responses seen across other tumor types. Median PFS for these heavily pre-treated breast cancer patients (median of six prior lines of therapy) was 9.4 months.

Development Strategy

Based on the initial signals of activity and safety described above, a Phase II program is underway exploring lucitanib in advanced breast cancer. A Clovis-sponsored study of lucitanib monotherapy in metastatic breast cancer initiated in 2014 and is expected to complete enrollment in early 2016. The goal of this study is to compare two doses of lucitanib, 10mg and 15mg, with PFS as the primary endpoint. In 2015, an interim analysis was completed, which indicated a difference in tolerability of the two doses. Based on this result, the go-forward dose for all lucitanib studies is 10mg. An ongoing Phase II study in advanced metastatic lung cancer is being discontinued due to low enrollment.

In parallel with our breast study underway in the U.S., Servier is conducting a Phase II study of lucitanib monotherapy in patients with advanced breast cancer. This ex-U.S. study, known as FINESSE, is expected to enroll approximately 100 patients into three cohorts: (1) FGFR-1 amplified, (2) 11q amplified and (3) neither FGFR-1 nor 11q amplified. This study seeks to determine whether the activity of lucitanib is limited to a biomarker-defined population of breast cancer tumors with FGF-aberrations or if a more broadly defined population may benefit.

As data emerge from ongoing studies, it appears that lucitanib's VEGF inhibition may be the primary driver of its activity. Accordingly, we believe its future development will likely be focused in combination with other cancer therapies. In addition to evaluating lucitanib in breast cancer, we intend to explore it in combination with other agents and in other solid tumors, including ovarian and hepatocellular cancers.

Development costs for lucitanib incurred to date have been fully funded by Servier as part of its commitment to fund the first €80 million of development costs in accordance with the sub-license agreement (see License Agreements – Les Laboratoires Servier below). 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.

Competition

The development and commercialization of new drugs is competitive, and we face competition from major pharmaceutical and biotechnology companies worldwide. Our competitors may develop or market products or other novel technologies that are more effective, safer or less costly than any that have been or will be commercialized by us, or may obtain regulatory approval for their products more rapidly than we may obtain approval for ours.

The acquisition or licensing of pharmaceutical products is also very competitive, and a number of more established companies, which have acknowledged strategies to license or acquire products, may have competitive advantages over us, as may other emerging companies taking similar or different approaches to product acquisitions. Many of our competitors will have substantially greater financial, technical and human resources than we have. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields. Our success will be based in part on our ability to build and actively manage a portfolio of drugs that addresses unmet medical needs and creates value in patient therapy.

Rociletinib Competition

Tarceva®, Iressa® and Gilotrif® are currently approved drugs for the treatment of first-line EGFR-mutant NSCLC, and Tagrisso™ was approved in November 2015 for patients with metastatic EGFR T790M mutation-positive NSCLC who have progressed on or after EGFR TKI therapy. Tagrisso™ is the first approved therapy for the treatment of EGFR mutant NSCLC 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.

Rucaparib Competition

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.

Lucitanib Competition

There are currently no approved drugs that specifically inhibit each of VEGFR, PDGFR and FGFR; 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).

License Agreements

Celgene Corporation

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. 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. Under the agreement, we are required to use commercially reasonable efforts to develop and commercialize rociletinib, and 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 the acceptance by the FDA of our Investigational New Drug ("IND") 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.

When and if commercial sales of rociletinib commence, we will pay Celgene tiered royalties at percentage rates ranging from mid-single digits to low teens based on 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, the majority of which relate to annual sales targets of $500.0 million and above.

We have full sublicensing rights under the license agreement, subject to our sharing equally with Celgene any upfront payments from any sub-licensing arrangements relating to Japan, or Japan and any one or more of China, South Korea and Taiwan, which we refer to herein as an Asian Partnership, and subject to our paying royalties on sales in Asia equal to the greater of the royalty rates contained in our license agreement or 50% of the royalties we receive from our Asian Partnership.

The license agreement will remain in effect until the expiration of all of our royalty and sublicense revenue obligations to Celgene, determined on a product-by-product and country-by-country basis, unless we elect to

terminate the license agreement earlier. If we fail to meet our obligations under the agreement and are unable to cure such failure within specified time periods, Celgene can terminate the agreement, resulting in a loss of our rights to rociletinib and an obligation to assign or license to Celgene any intellectual property rights or other rights we may have in rociletinib, including our regulatory filings, regulatory approvals, patents and trademarks for rociletinib.

Pfizer Inc.

In June 2011, we entered into a license agreement with Pfizer Inc. to obtain the exclusive global rights to develop and commercialize rucaparib. The exclusive rights are exclusive even as to Pfizer and include the right to grant sublicenses. Under the terms of the license agreement, we made a $7.0 million upfront payment to Pfizer. In April 2014, the Company initiated the ARIEL3 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 obligated under the license agreement to use commercially reasonable efforts to develop and commercialize rucaparib, and we are responsible for all remaining development and commercialization costs for rucaparib. When and if commercial sales of rucaparib begin, we will pay Pfizer tiered royalties at a mid-teen percentage rate on our net sales, with standard provisions for royalty offsets to the extent we need to obtain any rights from third parties to commercialize rucaparib.

We are required to make regulatory milestone payments to Pfizer of up to an additional $88.5 million if specified clinical study objectives and regulatory filings, acceptances and approvals are achieved, including $20.75 million associated with the first approval of an NDA by the FDA. In addition, we are obligated to make sales milestone payments to Pfizer if specified annual sales targets for rucaparib are met, the majority of which relate to annual sales targets of $500.0 million and above, which, in the aggregate, could amount to total milestone payments of $170.0 million.

The license agreement with Pfizer will remain in effect until the expiration of all of our royalty and sublicense revenue obligations to Pfizer, determined on a product-by-product and country-by-country basis, unless we elect to terminate the license agreement earlier. If we fail to meet our obligations under the agreement and are unable to cure such failure within specified time periods, Pfizer can terminate the agreement, resulting in a loss of our rights to rucaparib and an obligation to assign or license to Pfizer any intellectual property rights or other rights we may have in rucaparib, including our regulatory filings, regulatory approvals, patents and trademarks for rucaparib.

Advenchen Laboratories LLC

In October 2008, EOS entered into an exclusive license agreement with Advenchen Laboratories LLC (“Advenchen”) to develop and commercialize lucitanib on a global basis, excluding China. If and when commercial sales commence, we are obligated to pay Advenchen tiered royalties at percentage rates in the mid-single digits on net sales of lucitanib, based on the volume of annual net sales achieved. In addition, after giving effect to the first and second amendments to the license agreement, we are required to pay to Advenchen 25% of any consideration, excluding royalties, we receive from sublicensees, in lieu of the milestone obligations set forth in the agreement. We are obligated under the agreement to use commercially reasonable efforts to develop and commercialize at least one product containing lucitanib, and we are also responsible for all remaining development and commercialization costs for lucitanib.

The license agreement with Advenchen will remain in effect until the expiration of all of our royalty obligations to Advenchen, determined on a product-by-product and country-by-country basis, unless we elect to terminate the agreement earlier. If we fail to meet our obligations under the agreement and are unable to cure such failure within specified time periods, Advenchen can terminate the agreement, resulting in a loss of our rights to lucitanib.

Les Laboratoires Servier

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 on the achievement of specified development, regulatory and commercial milestones up to €100.0 million in the aggregate, €10.0 million of which was received in the first quarter of 2014. In addition, we are entitled to receive sales milestone payments if specified annual sales targets for lucitanib are met, each of which relates to annual sales targets of €250.0 million and above, which, in the aggregate, could amount to a total of €250.0 million. We are also entitled to receive royalties at percentage rates ranging from low to mid-teens on sales of lucitanib by Servier.

We, along with Servier, are obligated to use diligent efforts to develop a product containing lucitanib and to carry out the activities delegated to each party under a mutually-agreed global development plan. Servier is responsible for all of the development costs for lucitanib up to €80.0 million, as incurred by each party in connection with global

development plan activities. Cumulative global development plan 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 late 2016 or early 2017, and thereafter, we and Servier will share in future development costs pursuant to a mutually agreed upon global development plan.

The collaboration and license agreement will remain in effect until the expiration of all of Servier's royalty obligations to us, determined on a product-by-product and country-by-country basis, unless Servier elects to terminate the agreement earlier. If we fail to meet our obligations under the agreement and are unable to cure such failure within specified time periods, Servier can terminate the agreement, resulting in the granting of a perpetual license to Servier of rights to lucitanib.

Government Regulation

Government authorities in the United States (including federal, state and local authorities) and in other countries, extensively regulate, among other things, the manufacturing, research and clinical development, marketing, labeling and packaging, storage, distribution, post-approval monitoring and reporting, advertising and promotion, pricing and export and import of pharmaceutical products, such as those we are developing. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Moreover, failure to comply with applicable regulatory requirements may result in, among other things, warning letters, clinical holds, civil or criminal penalties, recall or seizure of products, injunction, disbarment, partial or total suspension of production or withdrawal of the product from the market. Any agency or judicial enforcement action could have a material adverse effect on us.

U.S. Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- submission to the FDA of an IND which must become effective before human clinical trials may begin and must be updated annually;
- completion of extensive non-clinical laboratory tests and non-clinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice regulations;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the active pharmaceutical ingredient ("API") and finished drug product are produced and tested to assess compliance with Current Good Manufacturing Practices ("cGMP"); and
- FDA review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. The IND also includes results of animal studies or other human studies, as appropriate, as well as manufacturing information, analytical data and any available clinical data or literature to support the use of the investigational new drug. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical trials. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical trials can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators in accordance with Good Clinical Practices ("GCPs"), which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site's Institutional Review Board ("IRB") before the trials may be initiated, and the IRB must monitor the study until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

The clinical investigation of a drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The three phases of an investigation are as follows:

Phase I. Phase I includes the initial introduction of an investigational new drug into humans. Phase I clinical trials are typically closely monitored and may be conducted in patients with the target disease or condition or in healthy volunteers. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase I clinical trials, sufficient information about the investigational drug's pharmacokinetics and pharmacological effects may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials. The total number of participants included in Phase I clinical trials varies, but is generally in the range of 20 to 80.

Phase II. Phase II includes controlled clinical trials conducted to preliminarily or further evaluate the effectiveness of the investigational drug for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the drug. Phase II clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population, usually involving no more than several hundred participants.

Phase III. Phase III clinical trials are generally controlled clinical trials conducted in an expanded patient population generally at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug product and to provide an adequate basis for product approval. Phase III clinical trials usually involve several hundred to several thousand participants.

A pivotal study is a clinical study which adequately meets regulatory agency requirements for the evaluation of a drug candidate's efficacy and safety such that it can be used to justify the approval of the product. Generally, pivotal studies are also Phase III studies but may be Phase II studies if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need.

The FDA, the IRB or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the study. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational drug product information is submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications.

The application includes all relevant data available from pertinent non-clinical and clinical trials, including negative or ambiguous results, as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA.

Once the NDA submission has been accepted for filing, the FDA's goal is to review applications within 10 months of submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months from submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations.

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities where the drug product and/or its API will be produced, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase III clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, non-clinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategies plan to mitigate risks, which could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and

other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase IV clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to determine the overall survival benefit of the drug.

After regulatory approval of a drug product is obtained, we are required to comply with a number of post-approval requirements. As a holder of an approved NDA, we would be required to report, among other things, certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling for any of our products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to ensure and preserve the long term stability of the drug product. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive and record keeping requirements. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Europe/Rest of World Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application, ("CTA") must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the NDA in the United States is similar to that required in Europe, with the exception of, among other things, country-specific document requirements.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Available Special Regulatory Procedures

Formal Meetings

We are encouraged to engage and seek guidance from health authorities relating to the development and review of investigational drugs, as well as marketing applications. In the United States, there are different types of official meetings that may occur between us and the FDA. Each meeting type is subject to different procedures. Conclusions and agreements from each of these meetings are captured in the official final meeting minutes issued by the FDA.

The EMA also provides the opportunity for dialogue with us. This is usually done in the form of Scientific Advice, which is given by the Scientific Advice Working Party of the CHMP. A fee is incurred with each Scientific Advice meeting.

Advice from either the FDA or EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies and pharmacovigilance plans and risk-management programs. Such advice is not legally binding on the sponsor. To obtain binding commitments from health authorities in the United States and the European Union, SPA or Protocol Assistance procedures are available. A SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement with the sponsor that the protocol design, clinical endpoints and statistical analyses are acceptable to support regulatory approval of the product candidate with respect to effectiveness in the indication studied. The FDA's agreement to a SPA is binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining the safety or effectiveness of the product after clinical studies begin, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. There is no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to a SPA.

Orphan Drug Designation

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the United States. In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Union Community. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity.

In the European Union, orphan drug designation also entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Pediatric Development

In the United States, the FDCA provides for an additional six months of marketing exclusivity for a drug if reports are filed of investigations studying the use of the drug product in a pediatric population in response to a written request from the FDA. Separate from this potential exclusivity benefit, NDAs must contain data (or a proposal for post-marketing activity) to assess the safety and effectiveness of an investigational drug product for the claimed indications in all relevant pediatric populations in order to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers if certain criteria are met. Discussions about pediatric development plans can be discussed with the FDA at any time, but usually occur any time between the end-of-Phase II meeting and submission

of the NDA.

For the EMA, a Pediatric Investigation Plan, and/or a request for waiver or deferral, is required for submission prior to submitting a marketing authorization application.

Authorization Procedures in the European Union

Medicines can be authorized in the European Union by using either the centralized authorization procedure or national authorization procedures.

Centralized procedure. The EMA implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the European Union. This procedure results in a single marketing authorization issued by the EMA that is valid across the European Union, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human medicines that are: derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines.

For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

National authorization procedures. There are also two other possible routes to authorize medicinal products in several countries, which are available for investigational drug products that fall outside the scope of the centralized procedure:

- Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one European Union country of medicinal products that have not yet been authorized in any European Union country and that do not fall within the mandatory scope of the centralized procedure.
- Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one European Union Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

Breakthrough Therapy Designation in the United States

The U.S. Congress created the Breakthrough Therapy designation program as a result of the passage of the Food and Drug Administration Safety Act of 2012. FDA may grant Breakthrough Therapy status to a drug intended for the treatment of a serious condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. The Breakthrough Therapy designation, which may be requested by a sponsor when filing or amending an IND, is intended to facilitate and expedite the development and FDA review of a product candidate. Specifically, the Breakthrough Therapy designation may entitle the sponsor to more frequent meetings with FDA during drug development, intensive guidance on clinical trial design and expedited FDA review by a cross-disciplinary team comprised of senior managers. The designation does not guarantee a faster development or review time as compared to other drugs, however, nor does it assure that the drug will obtain ultimate marketing approval by the FDA. Once granted, the FDA may withdraw this designation at any time.

We have received Breakthrough Therapy designation for rociletinib for the treatment of second-line EGFR mutant NSCLC in patients with the T790M mutation and for rucaparib as monotherapy treatment of advanced ovarian cancer in patients who have received at least two lines of prior platinum-containing therapy, with BRCA-mutated tumors, inclusive of both germline BRCA and somatic BRCA. Because the Breakthrough Therapy designation program is relatively new, it is difficult for us to predict the effect that this designation will have on the development and FDA review of rociletinib or rucaparib.

Expedited Review and Approval in the United States

The FDA has various programs, including Fast Track, priority review and accelerated approval, which are intended to expedite or simplify the process for reviewing drugs and biologics, and/or provide for the approval of a drug or biologic on the basis of a surrogate endpoint. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will be shortened. Generally, drugs that are eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing treatments. For example, based on results of the Phase III clinical trial(s) submitted in an NDA, upon the request of an applicant, the FDA may grant the NDA a priority review designation, which sets the target date for FDA action on the application at six months, rather than to the standard FDA review period of 10 months. Priority review is granted where preliminary estimates indicate that a product, if approved, has the potential to provide a safe and effective therapy where no satisfactory alternative therapy exists, or a significant improvement compared to marketed products is possible. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Accelerated approval provides for an earlier approval for a new drug that is intended to treat a serious or life-threatening disease or condition upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit and is better than available therapy. A surrogate endpoint is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. The FDA will also take into account the severity, rarity or prevalence of the condition. As a condition of approval for drugs granted accelerated approval, one or more post-marketing confirmatory studies are required to confirm as predicted by the surrogate marker trial an effect on clinical benefit, which is defined as having a positive effect on how a patient feels, functions or survives.

Accelerated Review in the European Union

Under the Centralized Procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, defined by three cumulative criteria: the seriousness of the disease (e.g. heavy disabling or life-threatening diseases) to be treated; the absence or insufficiency of an appropriate alternative therapeutic approach; and anticipation of high therapeutic benefit. In this circumstance, EMA ensures that the opinion of the CHMP is given within 150 days of submission of the MAA, excluding clock stops.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be established. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

There have been a number of federal and state proposals in recent years regarding the pricing of pharmaceutical products, government control and other changes to the healthcare system of the United States. The U.S. government enacted legislation providing a partial prescription drug benefit for Medicare beneficiaries. Government payment for some of the costs of prescription drugs may increase demand for any products for which we receive marketing approval; however, to obtain payments under this program, we would be required to sell products to Medicare recipients through prescription drug plans operating pursuant to this legislation. These plans will likely negotiate discounted prices for our products. Additionally, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "Affordable Care Act") was enacted in 2010 with a goal of reducing the cost of healthcare and substantially changing the way healthcare is financed by both government and private insurers. Among other cost containment measures, the Affordable Care Act established:

- An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;
- A Medicare Part D coverage gap discount program, in which pharmaceutical manufacturers who wish to have their drugs covered under Part D must offer discounts to eligible beneficiaries during their coverage gap period (the "donut hole"); and
- A formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program.

We expect that federal, state and local governments in the United States will continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs. Future legislation could limit payments for pharmaceuticals such as the drug candidates that we are developing.

Different pricing and reimbursement schemes exist in other countries. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on reducing the rate of healthcare spending in the United States has increased, and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Advertising and Promotion

The FDA and other U.S. federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, the FDCA and the FDA's implementing regulations and standards. The FDA's review of marketing and promotional activities encompasses, but is not limited to, direct-to-consumer advertising, healthcare provider-directed advertising and promotion, sales representative communications to healthcare professionals, communications regarding unapproved or "off-label" uses, industry-sponsored scientific and educational activities and promotional activities involving the internet. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. FDA regulations impose stringent restrictions on manufacturers' communications regarding off-label uses. Failure to comply with applicable FDA requirements and restrictions regarding unapproved uses of a drug or for other violations of its advertising and labeling laws and regulations, may result in adverse publicity and enforcement action by the FDA, the Department of Justice or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. A range of penalties are possible that could have a significant commercial consequences, including product seizures, injunctions, civil and/or criminal fines and agreements that materially restrict the manner in which a company promotes or distributes its products or regulatory letters, which may require corrective advertising or other corrective communications to healthcare professionals.

Other Healthcare Laws and Compliance Requirements

If we obtain regulatory approval for any of our product candidates, we may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. For example, in the United States, there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services or reward past purchases or recommendations. Violations of these laws can lead to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The reach of the Anti-Kickback Statute was broadened by the Affordable Care Act, which, among other things, amended the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute. Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal program, including federal healthcare programs. The "qui tam" provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In addition, various states have enacted false claims laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal healthcare program. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties.

In addition to the laws described above, the Affordable Care Act also imposed new reporting requirements on drug manufacturers for payments made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1.0 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Applicable drug manufacturers are required to collect data for each calendar year and submit reports to CMS by March 31st of each subsequent calendar year.

Also, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created several new federal crimes, including health care fraud and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. In addition, we may be subject to, or our marketing activities may be limited by, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and its implementing regulations, which established uniform standards for certain "covered entities" (healthcare providers, health plans and healthcare clearinghouses) and their business associates governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information.

Regulation of Diagnostic Tests

In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, non-clinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Diagnostic tests are classified as medical devices under the FDCA. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA approval. Because the diagnostic tests being developed by our third-party collaborators are of substantial importance in preventing impairment of human health, they are subject to the PMA approval process.

PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, non-clinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA application typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. FDA review of an initial PMA application is required by statute to take between six to ten months, although the process typically takes longer, and may require several years to complete. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

We and our third-party collaborators who are developing the companion diagnostics will work cooperatively to generate the data required for submission with the PMA application, and will remain in close contact with the Center for Devices and Radiological Health ("CDRH") at the FDA to ensure that any changes in requirements are incorporated into the development plans. We anticipate that meetings with the FDA with regard to our drug product candidates, as well as companion diagnostic product candidates, will include representatives from the Center for Drug Evaluation and Research and CDRH to ensure that the NDA and PMA submissions are coordinated to enable FDA to conduct a parallel review of both submissions. On July 14, 2011, the FDA issued its final guidance document addressing the development and approval process for "In Vitro Companion Diagnostic Devices." According to the guidance, for novel therapeutic products such as our product candidates, the PMA for a companion diagnostic device should be developed and approved or cleared contemporaneously with the therapeutic. We believe our programs for the development of our

companion diagnostics are consistent with this guidance.

In the European Economic Area ("EEA"), in vitro medical devices are required to conform with the essential requirements of the E.U. Directive on in vitro diagnostic medical devices (Directive No 98/79/EC, as amended). To demonstrate compliance with the essential requirements, the manufacturer must undergo a conformity assessment procedure. The conformity assessment varies according to the type of medical device and its classification. For low-risk devices, the conformity assessment can be carried out internally, but for higher risk devices it requires the intervention of an accredited EEA Notified Body. If successful, the conformity assessment concludes with the drawing up by the manufacturer of an EC Declaration of Conformity entitling the manufacturer to affix the CE mark to its products and to sell them throughout the EEA. The data generated for the U.S. registration will be sufficient to satisfy the regulatory requirements for the European Union and other countries.

Patents and Proprietary Rights

The proprietary nature of, and protection for, our product candidates, processes and know-how are important to our business. Our success depends in part on our ability to protect the proprietary nature of our product candidates, technology, and know-how, to operate without infringing on the proprietary rights of others, and to prevent others from infringing our proprietary rights. We seek patent protection in the United States and internationally for our product candidates and other technology. Our policy is to patent or in-license the technology, inventions and improvements that we consider important to the development of our business. We also rely on trade secrets, know-how and continuing innovation to develop and maintain our competitive position. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents granted to us in the future will be commercially useful in protecting our technology.

In May 2010, we acquired an exclusive, worldwide license to rociletinib from Avila Therapeutics, Inc. (now Celgene Avilomics Research Inc., part of Celgene Corporation). U.S. Patent 8,975,927, directed to rociletinib composition of matter, expires in 2032 and U.S. Patent 9,108,927, directed to rociletinib HBr salts and polymorphs, expires in 2033. Other patent applications are pending that claim rociletinib generically that, if issued, would have expiration dates in 2029. In January 2013, we acquired from Gatekeeper Pharmaceuticals, Inc. an exclusive worldwide sub-license to a Dana Farber patent family having claims directed to wild-type sparing irreversible EGFR inhibitors, such as rociletinib. We or our licensors have filed additional patent applications related to rociletinib methods of use, metabolites, combinations, diagnostic methods and dosing regimens.

In June 2011, we obtained an exclusive, worldwide license from Pfizer to develop and commercialize rucaparib. U.S. Patent 6,495,541, and its equivalent counterparts issued or pending in dozens of countries, directed to the rucaparib composition of matter, expire in 2020 and are potentially eligible for up to five years patent term extension in various jurisdictions. We believe that patent term extension under the Hatch-Waxman Act could be available to extend our patent exclusivity for rucaparib to at least 2024 in the United States depending on timing of our first approval. In Europe, we believe that patent term extension under a supplementary protection certificate could be available for an additional five years to at least 2025. In April 2012, we obtained an exclusive license from AstraZeneca under a family of patents and patent applications which will permit the development and commercialization of rucaparib for certain methods of treating patients with PARP inhibitors. Additionally, other patents and patent applications are directed to methods of making, methods of using, dosing regimens, various salt and polymorphic forms and formulations and have expiration dates ranging from 2020 through 2035.

We obtained rights to lucitanib by acquiring EOS in November 2013, along with its license agreements with Advenchen and Servier. In October 2008, EOS entered into an exclusive license agreement with Advenchen to develop and commercialize lucitanib on a global basis, excluding China. 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. Composition of matter and method of use patent protection for lucitanib and a group of structurally-related compounds is issued in the U.S., Europe and Japan and is issued or pending in other jurisdictions. In the U.S., the composition of matter patent will expire in 2030, and in other jurisdictions, it expires in 2028. We believe that patent term extension could be available to extend our composition of matter patent up to five years beyond the scheduled expiration under the Hatch-Waxman Act. Additionally, patents or patent applications directed to methods of manufacturing lucitanib are issued or pending in the United States, Europe, Japan, and China.

In addition, we intend to seek patent protection whenever available for any products or product candidates and related technology we acquire in the future.

The patent positions of pharmaceutical firms like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the

patent is issued. Consequently, we do not know whether any of the product candidates we acquire or license will gain patent protection or, if any patents are issued, whether they will provide significant proprietary protection or will be challenged, circumvented or invalidated. Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, until that time we cannot be certain that we were the first to file any patent application related to our product candidates. Moreover, we may have to participate in interference proceedings declared by the U.S. PTO to determine priority of invention or in opposition or other third-party proceedings in the U.S. or a foreign patent office, either of which could result in substantial cost to us, even if the eventual outcome is favorable to us. There can be no assurance that the patents, if issued, would be held valid by a court of competent jurisdiction. An adverse outcome in a third-party patent dispute could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using specific compounds or technology.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. PTO in granting a patent, or may be shortened if a patent is terminally disclaimed over another patent.

The patent term of a patent that covers a FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act") permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other non-U.S. jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our pharmaceutical products receive FDA approval, we expect to apply for patent term extensions on patents covering those products.

To protect our rights to any of our issued patents and proprietary information, we may need to litigate against infringing third parties, or avail ourselves of the courts or participate in hearings to determine the scope and validity of those patents or other proprietary rights. These types of proceedings are often costly and could be very time-consuming to us, and we cannot assure you that the deciding authorities will rule in our favor. An unfavorable decision could allow third parties to use our technology without being required to pay us licensing fees or may compel us to license needed technologies to a third-party. Such a decision could even result in the invalidation or a limitation in the scope of our patents or forfeiture of the rights associated with our patents or pending patent applications. To the extent prudent, we intend to bring litigation against third parties that we believe are infringing one or more of our patents.

In addition we have sought and intend to continue seeking orphan drug status whenever it is available. If a product which has an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the applicable regulatory authority may not approve any other applications to market the same drug for the same indication, except in certain very limited circumstances, for a period of seven years in the United States and ten years in the European Union. Orphan drug designation does not prevent competitors from developing or marketing different drugs for an indication.

We also rely on trade secret protection for our confidential and proprietary information. No assurance can be given that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology, or that we can meaningfully protect our trade secrets. However, we believe that the substantial costs and resources required to develop technological innovations will help us to protect the competitive advantage of our products.

It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual shall be our exclusive property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

Manufacturing

We currently contract with third parties for the manufacture of our product candidates for non-clinical studies and clinical trials and intend to do so in the future. We currently have a long-term agreement with a third-party contract manufacturing organization ("CMO") for the production of the active ingredient for rucaparib. For contract manufacturers not under long-term agreements, we currently obtain our supplies of active ingredients and finished drug product through individual purchase orders. We do not own or operate manufacturing facilities for the production of clinical quantities of our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. To meet our projected needs for commercial manufacturing, third parties with whom we currently work will need to increase their scale of production or we will need to secure alternate suppliers. Although we rely on contract manufacturers, we have personnel with extensive manufacturing experience to oversee the relationships with our contract manufacturers.

The active pharmaceutical ingredient for rociletinib is currently being manufactured by two CMOs, each at a single site. The current drug substance production process has already been sufficiently developed to satisfy immediate clinical demands. Additional scale-up work and/or additional production capacity is in process to support larger clinical development or commercialization requirements. We have engaged a single CMO capable of both formulation development and drug product manufacturing. The current drug product production process has already been sufficiently developed to satisfy immediate clinical demands. Additional scale-up work and/or additional production capacity may be necessary to support larger clinical development or commercialization requirements.

We have developed the process for manufacturing rucaparib's active pharmaceutical ingredient to a degree sufficient to meet clinical demands and projected commercial requirements. Manufacturing of rucaparib drug substance is being performed at a single CMO. The rucaparib drug product formulation and manufacturing process to produce that formulation have been developed to a degree sufficient to meet clinical demands. Additional development work is being performed to optimize the drug product formulation and manufacturing process to meet projected commercial requirements. A single third-party contract manufacturer capable of both formulation development and drug product manufacturing is currently producing rucaparib drug product. To date, our third-party manufacturers have met our manufacturing requirements. We expect third-party manufacturers to be capable of providing sufficient quantities of our product candidates to meet anticipated full scale commercial demands.

The active pharmaceutical ingredient for lucitanib is currently being produced by a third-party supplier. To date, the current production process has been sufficient to satisfy immediate clinical demands. We may undertake additional development work to further optimize the active pharmaceutical ingredient manufacturing process. The finished drug product for lucitanib is currently being manufactured at a CMO. The current product and process are sufficiently developed to meet immediate clinical demands. Additional development work is being performed to optimize the drug product formulation and manufacturing process to meet projected clinical and commercial requirements. Additional scale-up work and/or additional production capacity will be necessary to support larger clinical development or commercialization requirements.

Sales and Marketing

We have built the commercial infrastructure in the U.S. necessary to effectively support the commercialization of our product candidates, if and when they receive regulatory approval. The commercial infrastructure for oncology products typically consists of a targeted, specialty sales force that calls on a limited and focused group of physicians supported by sales management, internal sales support, an internal marketing group and distribution support. Additional capabilities important to the oncology marketplace include the management of key accounts such as managed care organizations, group-purchasing organizations, specialty pharmacies, oncology group networks and government accounts. To develop the appropriate commercial infrastructure, we have invested significant amounts of financial and management resources, some of which have been committed prior to any confirmation that rociletinib, rucaparib or lucitanib will be approved. We have also begun to establish a commercial presence in the major European markets with the hiring of certain country managers and market access professionals.

We may also elect in the future to utilize strategic partners, distributors or contract sales forces to assist in the commercialization of our products.

Employees

As of February 22, 2016, we had 309 full-time employees. None of our employees is represented by labor unions, and a small number of international employees are covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Research and Development

We invested $269.3 million, $137.7 million and $66.5 million in research and development during the years ended December 31, 2015, 2014 and 2013, respectively.

About Clovis

We were incorporated under the laws of the State of Delaware in April 2009 and completed our initial public offering of our common stock in November 2011. Our common stock is listed on the NASDAQ Global Select Market under the symbol “CLVS.” Our principal executive offices are located at 5500 Flatiron Parkway, Suite 100, Boulder, Colorado 80301, and our telephone number is (303) 625-5000. We maintain additional offices in San Francisco, California, Cambridge, UK, and Milan, Italy. Our website address is www.clovisoncology.com. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this report.

Available Information

As a public company, we file reports and proxy statements with the Securities and Exchange Commission ("SEC"). These filings include our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and proxy statements on Schedule 14A, as well as any amendments to those reports and proxy statements, and are available free of charge through our website as soon as reasonably practicable after we file them with, or furnish them to, the SEC. Once at www.clovisoncology.com, go to Investors & News/SEC Filings to locate copies of such reports. You may also read and copy materials that we file with SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website at www.sec.gov that contains reports, proxy statements and other information regarding us and other issuers that file electronically with the SEC.

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 Annual Report on Form 10-K 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.

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. 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 December 31, 2015, we had an accumulated deficit of $781.9 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, 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 the next 12 months. As of December 31, 2015, we had cash, cash equivalents and available-for-sale securities totaling $528.6 million. We expect that we will need to raise additional capital during 2016 in order to fully implement our business plan to further the development and commercialization of our product candidates, as well as to fund our other operating expenses and capital expenditures, including milestone payments to our licensors. 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 I, Item 3-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 December 31, 2015, 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 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. The complaints seek unspecified damages. Additionally, in December 2015, a plaintiff filed a derivative complaint allegedly on our behalf, naming certain of our officers and directors as defendants and alleging breach of fiduciary duty, abuse of control, gross mismanagement and unjust enrichment. The derivative complaint seeks, among other relief, an award of money damages and declaratory and injunctive relief concerning the alleged fiduciary breaches. 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. A second derivative complaint was filed in February 2016. This derivative complaint also alleges breach of fiduciary duty, abuse of control and gross mismanagement and seeks, among other relief, an award of money damages.

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. Rociletinib is currently under review with the U.S. and E.U regulatory authorities and rucaparib and lucitanib are currently in clinical trials. Our business depends entirely on the successful development and commercialization of our product candidates, which may never occur. 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. 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. 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. 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.

For example, in early November 2015, during the regularly scheduled Mid-Cycle Communication meeting with the FDA held in connection with its review of the rociletinib NDA, the agency requested additional clinical efficacy data. We submitted these data in a Major Amendment on November 16, 2015 after which the FDA extended the Prescription Drug User Fee Act goal date for the rociletinib NDA to June 28, 2016 to allow additional time for review of the new information. The FDA has scheduled the rociletinib NDA for discussion by the Oncologic Drugs Advisory Committee ("ODAC") on April 12, 2016. 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.

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.

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. The most notable AEs experienced by patients treated with rociletinib include hyperglycemia and QTc prolongation, while 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. 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.

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.

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.

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 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, but we are only beginning to build those capabilities in Europe to support the marketing, sales and distribution of our pharmaceutical products. 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. For example, 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.

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).

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, Erle T. Mast, our Executive Vice President and Chief Financial 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. As previously announced, Erle T. Mast intends to resign as Executive Vice President and Chief Financial Officer effective as of March 31, 2016. We are currently searching for a successor CFO; however, we have not yet identified his replacement.

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, and Steven L. Hoerter, our former Executive Vice President and Chief Commercial Officer, resigned in January 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 February 22, 2016, we employed 309 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.

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;
withdrawal of clinical trial participants;
initiation of investigations by regulators;
costs to defend the related litigation;
a diversion of management's time and our resources;
substantial monetary awards to trial participants or patients;
increase in insurance premiums;
product recalls, withdrawals or labeling, marketing or promotional restrictions;
loss of revenues from product sales;
the inability to commercialize our product candidates; and
a decline in our stock price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We have a program of product liability insurance covering our ongoing clinical trials; however, the amount of insurance we maintain may not be adequate to cover all liabilities that we may incur. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

We and our business partners maintain sensitive company data on our computer networks, including our intellectual property and proprietary business information, as well as certain clinical trial information. Cybersecurity attacks are becoming more commonplace and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of information and corruption of data. Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and business operations. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

Risks Related to Our Intellectual Property

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or license may fail to result in issued patents in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we hold or pursue with respect to our product candidates is threatened, it could threaten our ability to commercialize our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, an interference proceeding can be provoked by a third-party or instituted by the United States Patent and Trademark Office ("U.S. PTO") to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our drug discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including interference, inter parties review and reexamination proceedings before the U.S. PTO or oppositions and other comparable proceedings in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are employing their proprietary technology without authorization. There are or may be third-party patents with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications, which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, or until such patents expire or they are finally

determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license, limit our uses, or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, limit our uses, pay royalties or redesign our infringing product candidates, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

The patent protection and patent prosecution for some of our product candidates is dependent on third parties.

While we normally seek and gain the right to fully prosecute the patents relating to our product candidates, there may be times when platform technology patents that relate to our product candidates are controlled by our licensors. This is the case with our license to rociletinib, under which Celgene holds the right to prosecute and maintain the patents and patent applications covering its core discovery technology, including molecular backbones, building blocks and classes of compounds generated by that technology, aspects of which relate to rociletinib. While we have the right to jointly prosecute and maintain the patent rights for the composition of matter for rociletinib, if Celgene or any of our future licensing partners fail to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by the U.S. PTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees.

We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in

violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

If we breach any of the agreements under which we license commercialization rights to our product candidates from third parties, we could lose license rights that are important to our business.

We license the use, development and commercialization rights for all of our product candidates, and may enter into similar licenses in the future. Under each of our existing license agreements we are subject to commercialization and development, diligence obligations, milestone payment obligations, royalty payments and other obligations. If we fail to comply with any of these obligations or otherwise breach our license agreements, our licensing partners may have the right to terminate the license in whole or in part. Generally, the loss of any one of our three current licenses or other licenses in the future could materially harm our business, prospects, financial condition and results of operations.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- We or our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- It is possible that our pending patent applications will not lead to issued patents.
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.
- We may not develop additional proprietary technologies that are patentable.
- The patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to Ownership of our Common Stock and Convertible Senior Notes

There may not be a viable public market for our common stock and as a result it may be difficult for you to sell your shares of our common stock.

Our common stock had not been publicly traded prior to our initial public offering in November 2011. The trading market for our common stock on The NASDAQ Global Select Market has been limited and an active trading market for our shares may not be sustained. As a result of these and other factors, you may be unable to resell your shares at a price that is attractive to you or at all. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

The price of our stock has been, and may continue to be, volatile, and you could lose all or part of your investment.

The trading price of our common stock has been, and may continue to be, volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. During calendar year 2015, the price of our common stock on the NASDAQ Global Select Market ranged from $24.50 per share to $116.75 per share. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this report, these factors include:

- adverse results of regulatory actions or decisions;
- our failure to successfully commercialize our product candidates, if approved;
- actual or anticipated adverse results or delays in our clinical trials;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approvals;

disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates;
our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
inability to obtain adequate product supply for any approved drug product or inability to do so at acceptable prices;
our dependence on third parties, including CMOS and CROs, as well as our partners that provide us with companion diagnostic products;

- additions or departures of key scientific or management personnel;
- failure to meet or exceed any financial guidance or expectations regarding development milestones that we may provide to the public;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of the investment community;
- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- introduction of new products offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- issuances of debt or equity securities;
- significant lawsuits, including patent or stockholder litigation;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- ineffectiveness of our internal controls;
- general political and economic conditions;
- effects of natural or man-made catastrophic events; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the NASDAQ Global Select Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in these “Risk Factors,” could have a dramatic and material adverse effect on the market price of our common stock.

Because our outstanding Notes are convertible into shares of our common stock, volatility or depressed prices of our common stock could have a similar effect on the trading price of our Notes. In addition, the existence of the Notes may encourage short selling in our common stock by market participants because the conversion of the Notes could depress the price of our common stock.

The conversion of some or all of the Notes may dilute the ownership interest of existing stockholders. Holders of the outstanding Notes will be able to convert them at any time prior to the close of business on the business day immediately preceding September 15, 2021. Upon conversion, holders of the Notes will receive shares of common stock. Any sales in the public market of shares of common stock issued upon conversion of such Notes could adversely affect the trading price of our common stock. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price of our common stock. The issuance and sale of substantial amounts of common stock, or the perception that such issuances and sales may occur, could adversely affect the market price of our common stock and impair our ability to raise capital through the sale of additional equity or convertible debt securities.

Following periods of volatility in a company’s stock price, litigation has often been initiated against companies. Following the decline in our stock price related to the rociletinib regulatory update in November 2015, a number of lawsuits have been filed against us (see “Part I, Item 3-Legal Proceedings”). These proceedings and other similar litigation, if instituted against us, could result in substantial costs and diversion of management’s attention and resources, which could materially and adversely affect our business and financial condition.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates known to us beneficially owned approximately 36.9% of our voting stock as of December 31, 2015. These stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Persons who were our stockholders prior to our initial public offering continue to hold a substantial number of shares of our common stock. If such persons sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act, and, in any event, we have filed a registration statement permitting shares of common stock issued on exercise of options to be freely sold in the public market. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

Pursuant to our equity incentive plan(s), our compensation committee (or its designee) is authorized to grant equity-based incentive awards to our employees, directors and consultants. As of December 31, 2015, the number of shares of our common stock available for future grant under our 2011 Stock Incentive Plan (“2011 Plan”) is 1,181,722. The number of shares of our common stock reserved for issuance under our 2011 Plan will be increased (i) from time to time by the number of shares of our common stock forfeited upon the expiration, cancellation, forfeiture, cash settlement or other termination of awards under our 2009 Equity Incentive Plan, and (ii) at the discretion of our board of directors, on the date of each annual meeting of our stockholders, by up to the lesser of (x) a number of additional shares of our common stock representing 4% of our then-outstanding shares of common stock on such date and (y) 2,758,621 shares of our common stock. Future option grants and issuances of common stock under our 2011 Plan may have an adverse effect on the market price of our common stock. In addition, a substantial number of shares of our common stock are reserved for issuance upon conversion of the Notes.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third-party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders;

- permitting our board of directors to accelerate the vesting of outstanding option grants upon certain transactions that result in a change of control; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our certificate of incorporation or bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock. Additionally, certain provisions of our outstanding Notes could make it more difficult or more expensive for a third party to acquire us. The repurchase price of the Notes must be paid in cash, and this obligation may have the effect of discouraging, delaying or preventing an acquisition of the Company that would otherwise be beneficial to our security holders.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

We may not be able to raise the funds necessary to repurchase the Notes upon a fundamental change, and our future debt may contain limitations on our ability to repurchase 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. We may not have or be able to borrow the funds required to repurchase the Notes on the fundamental change repurchase date. In addition, our ability to repurchase the Notes may otherwise be limited by law, regulatory authority or agreements governing our future indebtedness. Our failure to repurchase the Notes at a time when the repurchase is required by the indenture would constitute a default under the indenture. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes when required.

We may incur substantially more debt or take other actions which would intensify the risks discussed above; and we may not generate cash flow from operations in the future sufficient to satisfy our obligations under the Notes and any future indebtedness we may incur.

We may incur substantial additional debt in the future, subject to the restrictions contained in any debt instruments that we enter into in the future, some of which may be secured debt. We are not restricted under the terms of the indenture governing the Notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture governing the Notes that could have the effect of diminishing our ability to make payments on the Notes when due. Our ability to refinance the Notes

or future indebtedness will depend on the capital markets and our financial condition at such time. In addition, agreements that govern any future indebtedness that we may incur may contain financial and other restrictive covenants that will limit our ability to engage in activities that may be in our long-term best interests. Our failure to comply with those covenants could result in an event of default that, if not cured or waived, could result in the acceleration of some or all of our debt.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Our principal offices are located at four leased facilities, a 29,177 square foot facility in Boulder, Colorado used primarily for corporate functions, a 24,877 square foot facility in San Francisco, California used for clinical development operations and research laboratory space, a 4,411 square foot facility in Cambridge, United Kingdom used for our European regulatory and clinical operations and a 416 square foot facility in Milan, Italy used for clinical operations. These leases expire in January 2023, December 2021, May 2016 and March 2017, respectively. We believe that our existing facilities are sufficient for our needs for the foreseeable future.

ITEM 3. 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. 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. If the lawsuits were to result in a loss, the amount of any such loss cannot reasonably be estimated.

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. If the lawsuit were to result in a loss, the amount of any such loss cannot reasonably be estimated.

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. 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. If the lawsuit were to result in a loss, the amount of any such loss cannot reasonably be estimated.

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 alleges 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 alleges claims for abuse of control and gross mismanagement. The Sanchez Complaint seeks, among other things, an award of money damages. The Company intends to vigorously defend against the allegations contained in the Sanchez Complaint, but there can be no assurance that the defense will be successful. If the lawsuit were to result in a loss, the amount of any such loss cannot reasonably be estimated.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information and Holders

Our common stock trades on the NASDAQ Global Select Market under the symbol "CLVS." The following table sets forth, for the periods indicated, the high and low sales prices for our common stock as reported on the NASDAQ Global Select Market:

	HIGH	LOW
Year Ended December 31, 2015		
First Quarter	$83.46	$54.88
Second Quarter	$102.28	$68.40
Third Quarter	$116.75	$65.00
Fourth Quarter	$109.18	$24.50
Year Ended December 31, 2014		
First Quarter	$93.33	$58.18

Second Quarter	$72.48	$36.11
Third Quarter	$50.87	$35.33
Fourth Quarter	$62.20	$40.66

On February 19, 2016, there were approximately 27 holders of record of our common stock.

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

Equity Compensation Plan Information

As of December 31, 2015

Plan Category	Number of securities to be issued upon exercise of outstanding options and rights (a)	Weighted-average exercise price of outstanding options and rights (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders (1) (2)	5,360,257	$ 51.53	1,557,953
Equity compensation plans not approved by security holders	—	—	—
Total	5,360,257	$ 51.53	1,557,953

(1) As of December 31, 2015, 6,262,641 shares were authorized for issuance under our 2011 Stock Incentive Plan ("2011 Plan"), which became effective upon closing of the Company's initial public offering in November 2011, including 191,496 remaining shares available for future issuance under the 2009 Equity Incentive Plan ("2009 Plan"), which were transferred to the 2011 Plan. The number of shares of our common stock reserved for issuance under the 2011 Plan will be increased (i) from time to time by the number of shares of our common stock forfeited upon the expiration, cancellation, forfeiture, cash settlement or other termination of awards under the 2009 Plan and (ii) at the discretion of our board of directors, on the date of each annual meeting of our stockholders, by up to the lesser of (x) a number of additional shares of our common stock representing 4% of our then-outstanding shares of common stock on such date and (y) 2,758,621 shares of our common stock.

(2) As of December 31, 2015, 376,231 shares were reserved for issuance under our 2011 Employee Stock Purchase Plan ("ESPP"), which became effective upon closing of the Company's initial public offering in November 2011. The number of shares of our common stock reserved for issuance under the ESPP will be increased at the discretion of our board of directors, on the date of each annual meeting of our stockholders, by up to the lesser of (x) a number of additional shares of our common stock representing 1% of our then-outstanding shares of common stock on such date and (y) 344,828 shares of our common stock.

Performance Graph [1]

The following graph shows a comparison from November 16, 2011 through December 31, 2015 of the cumulative total return on an assumed investment of $100 in cash in our common stock, the NASDAQ Composite Index and the NASDAQ Biotechnology Index. Such returns are based on historical results and are not intended to suggest future performance. Data for the NASDAQ Composite Index and the NASDAQ Biotechnology Index assume reinvestment of dividends.

[1] This performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities under that Section, and shall not be deemed incorporated by reference into any filing of Clovis Oncology, Inc. under the Securities Act of 1933, as amended.

ITEM 6. SELECTED FINANCIAL DATA

The following table sets forth certain of our selected historical financial data at the dates and for the periods indicated. The selected historical statement of operations data presented below for the years ended December 31, 2015, 2014 and 2013 and the historical balance sheet data as of December 31, 2015 and 2014 have been derived from our audited financial statements, which are included elsewhere in this Annual Report on Form 10-K. The historical statement of operations data presented below for the years ended December 31, 2012 and 2011 and the historical balance sheet data as of December 31, 2013, 2012 and 2011 have been derived from our audited financial statements that do not appear in this report.

Our historical results are not necessarily indicative of results expected in any future period.

The selected historical financial data presented below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes thereto, which are included elsewhere in this Annual Report on Form 10-K. The selected historical financial information in this section is not intended to replace our financial statements and the related notes thereto.

Statement of Operations Data:

	Year Ended December 31,				
	2015	2014	2013	2012	2011
	(in thousands, except per share amounts)				
Revenues:					
License and milestone revenue	$—	$13,625	$—	$—	$—
Operating expenses:					
Research and development	269,251	137,705	66,545	58,894	40,726
General and administrative	30,524	21,457	16,567	10,638	6,860
Acquired in-process research and development	12,000	8,806	250	4,250	7,000
Impairment of intangible asset	89,557	3,409	—	—	—
Change in fair value of contingent purchase consideration	(24,611)	707	405	—	—
Total expenses	376,721	172,084	83,767	73,782	54,586
Operating loss	(376,721)	(158,459)	(83,767)	(73,782)	(54,586)
Other income (expense):					
Interest expense	(8,372)	(2,604)	—	—	(949)
Foreign currency gains (losses)	2,740	3,580	(535)	(65)	49
Other income (expense)	416	(240)	(178)	(163)	(57)
Other income (expense), net	(5,216)	736	(713)	(228)	(957)
Loss before income taxes	(381,937)	(157,723)	(84,480)	(74,010)	(55,543)
Income tax benefit (expense)	29,076	(2,308)	(52)	27	(27)
Net loss	$(352,861)	$(160,031)	$(84,532)	$(73,983)	$(55,570)
Basic and diluted net loss per common share	$(9.79)	$(4.72)	$(2.95)	$(2.97)	$(14.42)
Basic and diluted weighted average common shares outstanding	36,026	33,889	28,672	24,915	3,854

Balance Sheet Data:

	As of December 31,				
	2015	2014	2013	2012	2011
	(in thousands)				
Cash, cash equivalents and available-for-sale securities	$528,588	$482,677	$323,228	$144,097	$140,248
Working capital	464,125	443,400	307,644	132,712	130,519
Total assets	713,386	786,206	649,635	145,994	143,445
Convertible senior notes	279,885	278,680	—	—	—
Common stock and additional paid-in capital	1,130,016	785,123	762,204	317,925	242,243
Total stockholders' equity	300,650	331,630	497,886	133,496	131,793

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing at the end of this Annual Report on Form 10-K. Some of the

information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the “Risk Factors” section of this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

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 three product candidates:

- Rociletinib, an oral epidermal growth factor receptor ("EGFR"), mutant-selective covalent inhibitor that is currently under review with the U.S. and E.U. regulatory authorities for the treatment of advanced non-small cell lung cancer ("NSCLC") in patients with activating EGFR mutations, as well as the dominant resistance mutation, T790M;
- Rucaparib, an oral inhibitor of poly (ADP-ribose) polymerase ("PARP") that is currently in advanced clinical development for the treatment of ovarian cancer and for which the first U.S. regulatory application is expected to be submitted for approval during the second quarter of 2016 and the first E.U. regulatory application is expected to be submitted in the second half of 2016; and
- Lucitanib, an oral inhibitor of the tyrosine kinase activity of vascular endothelial growth factor receptors 1-3 ("VEGFR1-3"), platelet-derived growth factor receptors alpha and beta ("PDGFR a/ß") and fibroblast growth factor receptors 1-3 ("FGFR1-3") that is currently in Phase II development for the treatment of breast cancer.

We hold global development and commercialization rights for rociletinib and rucaparib. 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").

We commenced operations in April 2009. 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. Through December 31, 2015, we have generated $13.6 million in license and milestone revenue related to our collaboration and license agreement with Servier, 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 December 31, 2015, we had an accumulated deficit of $781.9 million. We incurred net losses of $352.9 million, $160.0 million and $84.5 million for the years ended December 31, 2015, 2014 and 2013, respectively, and had cash, cash equivalents and available-for-sale securities totaling $528.6 million at December 31, 2015.

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 will allow us to fund activities through the next 12 months; however, we expect that we will need to raise capital during 2016 in order to fully implement our business plan to further the development and commercialization of our product candidates, as well as to fund our other operating expenses, milestone payments to licensors and capital expenditures. 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.

In July 2015, the Company sold 4,054,487 shares of its common stock in a public offering at $78.00 per share. The net proceeds to the Company from the offering were $298.5 million, after deducting underwriting discounts and commissions and offering expenses.

In July 2015, the Company submitted a New Drug Application (“NDA”) regulatory filing and a Marketing Authorization Application (“MAA”) for rociletinib to the U.S. Food and Drug Administration (“FDA”) and the European Medicines Agency (“EMA”), respectively. Both the FDA and EMA subsequently accepted the respective filings, and they are currently under active review. In December 2015, the FDA extended the Prescription Drug User Fee Act goal date for the rociletinib NDA by three months to June 28, 2016 to allow additional time for review of additional clinical data submitted by the Company in a Major Amendment in November 2015. The FDA has scheduled the NDA for rociletinib for discussion by the Oncologic Drugs Advisory Committee (“ODAC”) on April 12, 2016. 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.

Product License Agreements

Rociletinib

In May 2010, we entered into an exclusive worldwide license agreement with Avila Therapeutics, Inc. (now Celgene Avilomics Research Inc., part of Celgene Corporation ("Celgene")) to discover, develop and commercialize a covalent inhibitor of mutant forms of the EGFR gene product. 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. Under the agreement, we are required to use commercially reasonable efforts to develop and commercialize rociletinib, and 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 the acceptance by the FDA of our Investigational New Drug ("IND") 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.

When and if commercial sales of rociletinib commence, we will pay Celgene tiered royalties at percentage rates ranging from mid-single digits to low teens based on 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, the majority of which relate to annual sales targets of $500.0 million and above.

In January 2013, the Company entered into an exclusive license agreement with Gatekeeper Pharmaceuticals, Inc. ("Gatekeeper") to acquire exclusive rights under patent applications associated with mutant EGFR inhibitors and methods of treatment. Pursuant to the terms of the license agreement, the Company made an upfront payment of $0.25 million upon execution of the agreement, which was recognized as acquired in-process research and development expense. If rociletinib is approved for commercial sale, the Company will pay royalties to Gatekeeper on future net sales.

Rucaparib

In June 2011, we entered into a license agreement with Pfizer Inc. to obtain the exclusive global rights to develop and commercialize rucaparib. The exclusive rights are exclusive even as to Pfizer and include the right to grant sublicenses. Under 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 obligated under the license agreement to use commercially reasonable efforts to develop and commercialize rucaparib, and we are responsible for all remaining development and commercialization costs for rucaparib. When and if commercial sales of rucaparib begin, we will pay Pfizer tiered royalties at a mid-teen percentage rate on our net sales, with standard provisions for royalty offsets to the extent we need to obtain any rights from third parties to commercialize rucaparib.

We are required to make regulatory milestone payments to Pfizer of up to an additional $88.5 million if specified clinical study objectives and regulatory filings, acceptances and approvals are achieved, including $20.75 million

associated with the first approval of an NDA by the FDA. In addition, we are obligated to make sales milestone payments to Pfizer if specified annual sales targets for rucaparib are met, the majority of which relate to annual sales targets of $500.0 million and above, which, in the aggregate, could amount to total milestone payments of $170.0 million.

In April 2012, the Company entered into a license agreement with AstraZeneca UK Limited to acquire exclusive rights associated with rucaparib under a family of patents and patent applications that claim methods of treating patients with PARP inhibitors in certain indications. The license enables the development and commercialization of rucaparib for the uses claimed by these patents. Pursuant to the terms of the license agreement, the Company made an upfront payment of $0.25 million upon execution of the agreement, which was recognized as acquired in-process research and development expense. The Company may be required to pay up to an aggregate of $0.7 million in milestone payments if certain regulatory filings, acceptances and approvals are achieved. If approved, AstraZeneca will also receive royalties on any net sales of rucaparib.

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 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. If and when commercial sales commence, we are obligated to pay Advenchen tiered royalties at percentage rates in the mid-single digits on net sales of lucitanib, based on the volume of annual net sales achieved. In addition, after giving effect to the first and second amendments to the license agreement, we are required to pay to Advenchen 25% of any consideration, excluding royalties, received by the Company from sublicensees, in lieu of the milestone obligations set forth in the agreement.

We are obligated under the agreement to use commercially reasonable efforts to develop and commercialize at least one product containing lucitanib, and we are also responsible for all remaining development and commercialization costs for lucitanib. 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, we are entitled to receive sales milestone payments if specified annual sales targets for lucitanib are met, which, in the aggregate, could total €250.0 million. We are also entitled to receive royalties at percentage rates ranging from low to mid-teens on sales of lucitanib by Servier.

We, along with Servier, are obligated to use diligent efforts to develop a product containing lucitanib and to carry out the activities delegated to each party under a mutually-agreed global development plan. Servier is responsible for all of the development costs for lucitanib up to €80.0 million, as incurred by each party in connection with global development plan activities. Cumulative global development plan 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 late 2016 or 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 currently under review with the U.S. and E.U. regulatory authorities and 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 ("CROs") 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 plan to increase our research and development expenses for the foreseeable future as we seek to expand our clinical and companion diagnostic development activities for our product candidates.

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.

	Year Ended December 31,		
	2015	2014	2013
	(in thousands)		
Rociletinib Expenses			
Research and development	$122,912	$69,920	$17,020
Acquired in-process R&D	12,000	5,000	250
Rociletinib Total	134,912	74,920	17,270
Rucaparib Expenses			
Research and development	58,922	35,010	24,625
Acquired in-process R&D	—	400	—
Rucaparib Total	58,922	35,410	24,625
Lucitanib Expenses			
Research and development (a)	1,923	(491)	110
Acquired in-process R&D	—	3,406	—
Lucitanib Total	1,923	2,915	110
CO-101 Expenses			
Research and development (b)	—	—	795
CO-101 Total	—	—	795
cKIT Inhibitor Expenses			
Research and development (c)	—	—	4,373
cKIT Inhibitor Total	—	—	4,373
Personnel and other expenses	85,494	33,266	19,622
Total	$281,251	$146,511	$66,795

(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 audited consolidated financial statements included in this Annual Report on Form 10-K.

(b) In November 2009, the Company entered into a license agreement with Clavis Pharma ASA to develop and commercialize CO-101. In November 2012, the Company ceased development of CO-101 due to negative results

from a pivotal study and terminated the license agreement.

(c) In July 2012, the Company entered into a drug discovery collaboration agreement with Array BioPharma Inc. for the discovery of a novel cKIT inhibitor targeting resistance mutations for the treatment of GIST, a gastrointestinal cancer. Under the terms of the agreement, the Company was responsible for funding all costs of the discovery program, as well as costs to develop and commercialize any clinical candidates discovered. This drug discovery program did not identify a compound to be used in further development activities, and the program was terminated in the fourth quarter of 2013.

Research and development expenses increased significantly from 2013 through 2015 due to the expansion of our clinical development activities for rociletinib and rucaparib. In addition, during 2015, we increased commercial product planning activities in anticipation of the potential regulatory approval and commercial launch in the U.S. of rociletinib. These activities included the hiring of our U.S. sales and marketing and medical affairs organizations. For 2016, we do not expect research and development expenses to increase over 2015 as they have for the previous two years, but we expect such costs to remain consistent with 2015 expenses.

General and Administrative Expenses

General and administrative expenses consist principally of salaries, share-based compensation expense and other personnel-related costs for employees 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.

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. During the fourth quarter of 2015, the Company recorded an $89.6 million impairment charge to the IPR&D intangible asset as the result of the Company's and our 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.

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. During the fourth quarter of 2015, the Company recorded a $26.9 million reduction in the fair value of the contingent purchase consideration liability due to a change in the estimated probability-weighted future milestone payments, as well as the timing of such payments, for the lucitanib program.

Other Income and Expense

Other income and expense is primarily comprised of foreign currency gains and losses resulting from transactions with CROs, 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.

Our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. We believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include:

- fees paid to CROs in connection with clinical studies;
- fees paid to investigative sites in connection with clinical studies;
- fees paid to vendors in connection with non-clinical development activities;
- fees paid to vendors associated with the development of companion diagnostics; and
- fees paid to vendors related to product manufacturing, development and distribution of clinical supplies.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. Based on the amount of accrued research and development expenses as of December 31, 2015, if our estimates of our net accrued liabilities are too high or too low by 5%, this could increase or decrease our research and development expenses by approximately $2.7 million.

Share-Based Compensation

Determining the amount of share-based compensation to be recorded requires us to develop estimates of the fair value of stock options as of their grant date. Compensation expense is recognized over the vesting period of the award. Calculating the fair value of share-based awards requires that we make highly subjective assumptions. We use the Black-Scholes option pricing model to value our stock option awards. Use of this valuation methodology requires that we make assumptions as to the expected dividend yield, price volatility of our common stock, the risk-free interest rate for a period that approximates the expected term of our stock options and the expected term of our stock options. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention to pay cash dividends.

The fair value of stock options for the years ended December 31, 2015, 2014 and 2013 was estimated at the grant date using the following weighted average assumptions for the respective periods:

	Year Ended December 31,		
	2015	2014	2013
Dividend yield	—	—	—
Volatility (a)	72%	70%	69%
Risk-free interest rate (b)	1.77%	1.92%	1.16%
Expected term (years) (c)	6.1	6.2	6.2

(a) Volatility: The expected volatility was estimated using peer data of companies in the biopharmaceutical industry with similar equity plans.
(b) Risk-free interest rate: The rate is based on the yield on the grant date of a zero-coupon U.S. Treasury bond whose maturity period approximates the option's expected term.
(c) Expected term: The expected term of the award was estimated using peer data of companies in the biopharmaceutical industry with similar equity plans.

We recognized share-based compensation expense of approximately $40.4 million, $21.5 million and $9.5 million for the years ended December 31, 2015, 2014 and 2013, respectively. As of December 31, 2015, we had $88.6 million in total unrecognized share-based compensation expense, net of related forfeiture estimates, which is expected to be recognized over a weighted-average remaining vesting period of 2.7 years. We expect our share-based compensation to continue to grow in future periods due to the potential increases in the value of our common stock and headcount.

We are required to estimate the level of forfeitures expected to occur and record compensation expense only for those awards that we ultimately expect will vest. Due to the lack of historical forfeiture activity of our plan, we estimated our forfeiture rate based on peer company data with characteristics similar to our company.

Valuation of Contingent Consideration Resulting from a Business Combination

Contingent consideration resulting from a business combination is reported at its fair value on the acquisition date. Each subsequent reporting period, the contingent consideration obligations are revalued and changes in fair value are recorded 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 to contingent consideration obligations can result from adjustments to discount rates and time periods, updates in the assumed achievement or timing of any development milestone or changes in the probability of certain clinical events and regulatory approvals. The assumptions related to determining the value of contingent consideration require significant judgment and changes to the assumptions may have a material impact on the amount of expense recorded in any given period. The acquisition of EOS resulted in the recognition of a contingent consideration liability, based on assumptions related to potential future payout amounts, estimated discount rate, probability of success for each milestone achievement and the estimated timing of the milestone payments to the former EOS shareholders.

Intangible Assets

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 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.

Revenue Recognition

Revenue is recognized from milestone payments when the following criteria have been met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the price is fixed or determinable; and (4) collectability is reasonably assured. We exercise judgment in determining that collectability is reasonably assured or that services have been delivered in accordance with the arrangement. We assess whether the fee is fixed or determinable based on the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. We assess collectability based primarily on the customer’s payment history and creditworthiness of the customer. Payments that are contingent upon the achievement of a milestone will be recognized in the period in which the milestone is achieved.

Results of Operations

Comparison of Years Ended December 31, 2015, 2014 and 2013:

License and Milestone Revenue. License and milestone revenue for the year ended December 31, 2014 was due to the recognition of $13.6 million of milestone revenue from Servier upon the end of opposition and appeal of the lucitanib patent by the European Patent Office in the first quarter of 2014. We did not recognize any revenue in 2015 and 2013.

Research and Development Expenses. Research and development expenses for the years ended December 31, 2015, 2014 and 2013 were as follows:

	Year Ended December 31,		
	2015	2014	2013
	(in thousands)		
Research and development expenses	$269,251	$137,705	$66,545
Increase from prior year	$131,546	$71,160	$7,651
% Change from prior year	95.5 %	106.9 %	13.0 %

The increase in research and development expenses for the year ended December 31, 2015 compared to 2014 was primarily due to increased development activities for the rociletinib and rucaparib programs. Costs associated with non-clinical and clinical development activities for rociletinib were $35.6 million higher than 2014 driven by increased patient enrollment in the TIGER program of studies in NSCLC. In addition, market research, disease education and other commercial product planning activities for rociletinib were $18.2 million higher in 2015 due to the preparation for the potential commercial launch of rociletinib.

Clinical trial costs for rucaparib were $10.3 million higher than the prior year primarily due to higher enrollment in the ARIEL2 and ARIEL3 studies in ovarian cancer, as well as the expansion of Study 010 in 2015. Development costs for rucaparib were $5.9 million higher than 2014 due to the advancement of our collaboration with Foundation Medicine, Inc. to develop a novel companion diagnostic test to identify patients most likely to respond to rucaparib.

Clinical supply and related manufacturing development costs for both programs were $3.2 million higher than 2014, as we increased production to support the expanded clinical studies.

Salaries, share-based compensation expense and other personnel-related costs were $49.4 million higher in 2015, including a $15.8 million increase in share-based compensation expense, driven by increased headcount to support our expanded development and commercial planning activities. During 2015, we completed the hiring of our U.S. sales and marketing and medical affairs organizations in preparation for the potential commercial launch of rociletinib.

The increase in research and development expenses for the year ended December 31, 2014 compared to 2013 was primarily due to expanded development activities for the rociletinib and rucaparib programs. Costs associated with

non-clinical and clinical development activities for rociletinib were $29.4 million higher than 2013 driven by higher enrollment in the ongoing Phase I/II study in NSCLC, as well as the initiation of the TIGER-1, TIGER-2 and Japanese Phase I studies in 2014. Clinical trial costs for rucaparib were $11.8 million higher than the prior year primarily due to the initiation of the ARIEL2 and ARIEL3 studies in ovarian cancer.

Development costs for rucaparib were $3.4 million higher than 2013 due to the expansion of our collaboration with Foundation Medicine, Inc. to incorporate a coordinated regulatory strategy for the development of a novel companion diagnostic test.

Clinical supply and related manufacturing development costs for both programs were $13.8 million higher than 2013, as we increased production to support expanded clinical studies. In addition, salaries, share-based compensation expense and other personnel related costs were $13.2 million higher in 2014 driven by higher headcount to support our expanded development activities. These increases were partially offset by $4.4 million lower costs due to the termination of the cKIT program in late 2013.

General and Administrative Expenses. General and administrative expenses for the years ended December 31, 2015, 2014 and 2013 were as follows:

	Year Ended December 31,		
	2015	2014	2013
	(in thousands)		
General and administrative expenses	$30,524	$21,457	$16,567
Increase from prior year	$9,067	$4,890	$5,929
% Change from prior year	42.3 %	29.5 %	55.7 %

The increase in general and administrative expenses for the year ended December 31, 2015 over 2014 was primarily due to $3.0 million higher share-based compensation expense, $1.4 million higher facilities expense, $1.2 million higher personnel costs, $1.1 million higher legal expense and $1.0 million higher consulting fees.

The increase in general and administrative expenses for the year ended December 31, 2014 over 2013 was primarily due to $4.8 million higher share-based compensation expense.

Acquired In-Process Research and Development Expenses. Acquired in-process research and development expenses for the years ended December 31, 2015, 2014 and 2013 were as follows:

	Year Ended December 31,		
	2015	2014	2013
	(in thousands)		
Acquired in-process research and development	$12,000	$8,806	$250
Increase (decrease) from prior year	$3,194	$8,556	$(4,000)
% Change from prior year	36.3 %	3,422.4%	(94.1)%

The increase in acquired in-process research and development expenses for the year ended December 31, 2015 compared to 2014 was due to higher payments made to partners related to in-licensing agreements. During the third quarter of 2015, we made milestone payments totaling $12.0 million to Celgene upon acceptance of the NDA and MAA for rociletinib by the FDA and EMA, respectively. During the first quarter of 2014, we made a $5.0 million milestone payment to Celgene upon initiation of the Phase II study for rociletinib, and we recorded a $3.4 million charge for a milestone payment to Advenchen, representing 25% of the sublicense agreement consideration of $13.6 million received from Servier upon the end of opposition and appeal of the lucitanib patent by the European Patent Office. During the second quarter of 2014, we also made a $0.4 million milestone payment to Pfizer upon initiation of a pivotal registration study for rucaparib.

The increase in acquired in-process research and development expenses for the year ended December 31, 2014 compared to 2013 was also due to higher payments made to partners related to in-licensing agreements. During the year ended December 31, 2014, we made $8.8 million in milestone payments, as detailed above. In January 2013, we made a $0.25 million upfront payment to Gatekeeper upon execution of the license agreement.

Impairment of Intangible Asset. During the fourth quarter of 2015, the Company recorded an $89.6 million impairment charge to the IPR&D intangible asset relating to our lucitanib product candidate. This reduction in the estimated fair value of lucitanib was the result of 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. During the first quarter of 2014, the Company recorded a $3.4 million reduction to the intangible asset’s expected future cash flows resulting from the receipt of a lucitanib milestone payment from Servier.

Change in Fair Value of Contingent Purchase Consideration. Change in fair value of contingent purchase consideration totaled ($24.6) million for the year ended December 31, 2015 compared to $0.7 million in 2014. During the fourth quarter of 2015, the Company recorded a $26.9 million reduction in the fair value of the contingent purchase consideration liability due to a change in the estimated probability-weighted future milestone payments, as well as the timing of such payments, for the lucitanib program.

Other Income (Expense), Net. Other income (expense), net for the years ended December 31, 2015, 2014 and 2013 was as follows:

	Year Ended December 31,		
	2015	2014	2013
	(in thousands)		
Other income (expense), net	$(5,216)	$736	$(713)
(Decrease) increase from prior year	$(5,952)	$1,449	$485
% Change from prior year	(808.7%)	(203.2%)	212.7%

Other expense increased for the year ended December 31, 2015 compared to 2014 primarily due to higher interest expense related to the Company's convertible senior notes issued in September 2014.

Other income increased for the year ended December 31, 2014 compared to 2013 driven by $4.1 million net currency gains primarily due to fluctuations in the foreign currency rate utilized to translate our Euro-denominated contingent purchase consideration liability into U.S. dollars. The net currency gains were partially offset by $2.6 million interest expense related to the Company's convertible senior notes issued in September 2014.

Income Tax Benefit (Expense). For the year ended December 31, 2015, the Company recognized a $29.1 million deferred tax benefit primarily associated with the impairment of the IPR&D intangible assets recorded in the fourth quarter of 2015. For the year ended 2014, the Company recognized income tax expense primarily due to recording foreign tax provisions during the first quarter of 2014 related to milestone revenue recognized under the Servier license agreement, partially offset by a deferred tax benefit recognized upon the reduction of the carrying value of the IPR&D intangible assets in the first quarter of 2014.

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. As of December 31, 2015, we had cash, cash equivalents and available-for-sale securities totaling $528.6 million.

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Year Ended December 31,		
	2015	2014	2013
	(in thousands)		
Net cash used in operating activities	$(253,066)	$(117,051)	$(71,712)
Net cash used in investing activities	(254,578)	(2,286)	(10,034)
Net cash provided by financing activities	304,480	279,476	260,842
Effect of exchange rate changes on cash and cash equivalents	(757)	(690)	35
Net (decrease) increase in cash and cash equivalents	$(203,921)	$159,449	$179,131

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 $136.0 million for the year ended December 31, 2015 compared to 2014 driven by higher rociletinib and rucaparib research and development costs associated with the expansion of the clinical trials, as well as the preparation for the potential commercial launch of rociletinib, and higher salaries, benefits and personnel-related costs resulting from increased headcount to support the expanded development activities and commercial planning for our product candidates. During the third quarter of 2015, we made milestone payments totaling $12.0 million to Celgene upon acceptance of the NDA and MAA for rociletinib by the FDA and EMA, respectively. During the year ended December 31, 2015, we also paid $7.3 million in interest related to the convertible senior notes. The net loss for the year ended December 31, 2014 was partially offset by a $13.6 million milestone revenue payment received from Servier.

Net cash used in operating activities increased $45.3 million for the year ended December 31, 2014 compared to 2013 driven by higher rociletinib and rucaparib research and development costs associated with the expansion of the clinical trials, drug formulation and manufacturing costs and higher salaries, benefits and personnel-related costs resulting from higher headcount to support the expanded development activities of our product candidates, partially offset by the milestone revenue payment received from Servier.

Investing Activities

Net cash used in investing activities increased $252.3 million for the year ended December 31, 2015 compared to 2014 primarily due to net purchases of available-for-sale securities.

Net cash used in investing activities decreased $7.7 million for the year ended December 31, 2014 compared to 2013 primarily due to the cash portion of the EOS acquisition price paid in November 2013, partially offset by higher purchases of property and equipment in 2014.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2015 includes $298.5 million in net proceeds received from our common stock offering in July 2015 and $6.0 million received from employee stock option exercises and stock purchases under the employee stock purchase plan.

Net cash provided by financing activities for the year ended December 31, 2014 includes $278.3 million in net proceeds received from our convertible senior notes offering in September 2014 and $1.2 million received from employee stock option exercises and stock purchases under the employee stock purchase plan.

Net cash provided by financing activities for the year ended December 31, 2013 includes $259.1 million in net proceeds received from our common stock offering in June 2013 and $1.8 million received from employee stock option exercises and stock purchases under the employee stock purchase plan.

Operating Capital Requirements

Assuming we successfully complete clinical trials and obtain requisite regulatory approvals, we do not anticipate commercializing any of our product candidates until at least the second half 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 each of 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 December 31, 2015, we had cash, cash equivalents and available-for-sale securities totaling $528.6 million and total current liabilities of $75.6 million. 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 the next 12 months. We expect that we will need to raise additional capital during 2016 in order to fully implement our business plan to further the development and commercialization of our product candidates, as well as to fund our other operating expenses, milestone payments to licensors and capital expenditures. 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 outcome of such litigation; and
- the timing, receipt and amount of sales, if any, of our product candidates.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2015 (in thousands):

	Total

	Less than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 Years	
Convertible senior notes	$—	$—	$—	$287,500	$287,500
Interest on convertible senior notes	7,187	14,375	14,376	5,091	41,029
Operating lease commitments	1,795	3,529	3,728	2,547	11,599
Purchase obligations (a)	6,455	9,682	—	—	16,137
Total	$15,437	$27,586	$18,104	$295,138	$356,265

(a) 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 this 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.

Royalty and License Fee Commitments

We have certain obligations under licensing agreements with third parties contingent upon achieving various development, regulatory and commercial milestones. Pursuant to our license agreement for the development and commercialization of rociletinib, we may be required to pay up to an additional aggregate of $98.0 million in regulatory milestone payments if certain clinical study objectives and regulatory filings, acceptance and approvals are achieved. Further, we may be required to pay up to an aggregate of $120.0 million in sales milestone payments if certain annual sales targets are met for rociletinib.

Pursuant to our license agreements for the development of rucaparib, we may be required to pay up to an aggregate $258.5 million in milestone payments upon the successful attainment of development, regulatory and sales milestones. We are also obligated to pay to Advenchen 25% of any consideration, excluding royalties, received pursuant to any sublicense agreements for lucitanib, including the agreement with Servier.

The Company is obligated to pay additional consideration to the former EOS shareholders if certain future regulatory and lucitanib-related sales milestones are achieved. The estimated fair value of these payments was recorded as contingent purchase consideration on our Consolidated Balance Sheets. The potential contingent milestone payments range from a zero payment, which assumes lucitanib fails to achieve any of the regulatory milestones, to $190.5 million ($65.0 million and €115.0 million) if all regulatory and sales milestones are met, utilizing the translation rate at December 31, 2015. The estimated fair value of the liability was $24.7 million at December 31, 2015.

Finally, pursuant to terms of each of our product license agreements, we will pay royalties to our licensors on sales, if any, of the respective products.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under the rules promulgated by the U.S. Securities and Exchange Commission.

Tax Loss Carryforwards

As of December 31, 2015, we have net operating loss (“NOL”) carryforwards of approximately $504.8 million to offset future federal income taxes. We also have research and development and orphan drug tax credit carryforwards of $177.7 million to offset future federal income taxes. The federal net operating loss carryforwards and research and development and orphan drug tax credit carryforwards expire at various times through 2035.

We believe that a change in ownership as defined under Section 382 of the U.S. Internal Revenue Code occurred as a result of the Company’s public offering of common stock completed in April 2012. Future utilization of the federal net operating losses and tax credit carryforwards accumulated from inception to the change in ownership date will be subject to annual limitations to offset future taxable income. We do not, however, believe this limitation prevents utilization prior to expiration. It is possible that a change in ownership will occur in the future, which will limit the NOL amounts generated since the last estimated change in ownership against future taxable income. At December 31, 2015, we recorded a 100% valuation allowance against our net deferred tax assets in the U.S. of approximately $446.9 million and a $2.2 million valuation allowance against tax assets in foreign jurisdictions, as we believe it is more likely than not that the tax benefits will not be fully realized. In the future, if we determine that a portion or all of the tax benefits associated with our tax carryforwards will be realized, net income would increase in the period of determination.

Recently Adopted Accounting Standards

In April 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2015-03, "Interest – Imputation of Interest (Subtopic 835-30) – Simplifying the Presentation of Debt Issuance Costs." ASU No. 2015-03 requires debt issuance costs to be presented as a deduction from the corresponding debt liability rather than as an asset. This update is effective for fiscal years beginning after December 15, 2015, including interim periods within those years. Early adoption is permitted. Upon adoption, the guidance must be applied retrospectively to all periods presented in the financial statements. The Company elected to early adopt this standard effective December 31, 2015. Adoption of the standard resulted in the reclassification of the Company's debt issuance costs from other assets to convertible senior notes on its Consolidated Balance Sheets. As of December 2014, the reclassification resulted in a decrease of $8.8 million to other assets with a corresponding decrease to convertible senior notes.

In November 2015, the FASB issued ASU No. 2015-17, “Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes.” ASU No. 2015-17 requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as noncurrent on the balance sheet. This update is effective for fiscal years beginning after December 15, 2016, including interim periods within those years. Early adoption is permitted. Upon adoption, the guidance may be applied either prospectively, for all deferred tax assets and liabilities, or retrospectively to all periods presented in the financial statements. The Company elected to early adopt the standard effective December 31, 2015. Adoption of the standard was applied retrospectively and resulted in no change to the Company’s Consolidated Balance Sheets.

Recently Issued Accounting Standards

In May 2014, the FASB issued ASU No. 2014-09, “Revenue from Contracts with Customers (Topic 606).” ASU 2014-09 specifies the accounting for revenue from contracts with customers and establishes disclosure requirements relating to the nature, timing and uncertainty of revenue and cash flows arising from an entity’s contracts with customers. In August 2015, the FASB issued ASU 2015-14, “Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date,” which delayed the effective date of the standard to annual and interim periods beginning after December 15, 2017. Early application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods. ASU 2014-09 allows for either full retrospective or modified retrospective adoption. 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.

In August 2014, the FASB issued ASU No. 2014-15, “Disclosure of Uncertainties About an Entity’s Ability to Continue as a Going Concern,” which requires management to evaluate whether there are conditions or events that raise substantial doubt about an entity’s ability to continue as a going concern and to provide disclosures when certain criteria are met. The guidance is effective for annual periods beginning in 2016 and interim reporting periods starting in the first quarter of 2017. Early application is permitted. The Company is currently evaluating the impact the standard may have on its disclosures.

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842),” which requires lessees to recognize assets and liabilities for the rights and obligations created by most leases on their balance sheet. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. ASU 2016-02 requires modified retrospective adoption for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. The Company is currently evaluating the impact the standard may have on its consolidated financial statements and related disclosures.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of December 31, 2015, we had cash, cash equivalents and available-for-sale securities of $528.6 million, consisting of bank demand deposits, money market funds and U.S. treasury securities. The primary objectives of our investment policy are to preserve principal and maintain proper liquidity to meet operating needs. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Our available-for-sale securities are subject to interest rate risk and will decline in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair value of our portfolio.

We contract with contract research organizations, investigational sites and contract manufacturers globally where payments are made in currencies other than the U.S. dollar. In addition, a significant portion of the contingent

purchase consideration liability will be settled with Euro-denominated payments if certain future milestones are achieved. We may be subject to fluctuations in foreign currency rates in connection with these agreements and future contingent payments. While we periodically hold foreign currencies, primarily Euro and Pound Sterling, we do not use other financial instruments to hedge our foreign exchange risk. Transactions denominated in currencies other than the functional currency are recorded based on exchange rates at the time such transactions arise. As of December 31, 2015 and 2014, approximately 3% and 7%, respectively, of our total liabilities were denominated in currencies other than the functional currency.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this Item are included in Item 15 of this report and are presented beginning on page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Securities Exchange Act of 1934, as amended ("Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective.

As of December 31, 2015, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2015, the design and operation of our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining effective internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, a company's principal executive officer and principal financial officer and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of the consolidated financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or the degree of compliance with the policies or procedures may deteriorate.

As of December 31, 2015, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as defined in Rules 13a-15(f) or 15d-15(f) of the Exchange Act. In making its assessment, management used the criteria established in Internal Control—Integrated Framework (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its assessment, our management determined that, as of December 31, 2015, we maintained effective internal control over financial reporting based on those criteria.

In addition, the effectiveness of our internal control over financial reporting as of December 31, 2015 has been audited by Ernst & Young, LLP, an independent registered public accounting firm.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal controls over financial reporting during the quarter ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Report of Independent Registered Public Accounting Firm

The Stockholders and Board of Directors of Clovis Oncology, Inc.:

We have audited Clovis Oncology, Inc.'s internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). Clovis Oncology, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Clovis Oncology, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Clovis Oncology, Inc. as of December 31, 2015 and 2014 and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2015 and our report dated February 29, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Denver, Colorado

February 29, 2016

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ITEM 9B. OTHER INFORMATION

None.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K and is incorporated herein by reference from our definitive proxy statement relating to our 2016 annual meeting of stockholders, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, also referred to in this Form 10-K as our 2016 Proxy Statement, which we expect to file with the SEC no later than April 30, 2016.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information regarding our directors, including the audit committee and audit committee financial experts, and executive officers and compliance with Section 16(a) of the Exchange Act will be included in our 2016 Proxy Statement and is incorporated herein by reference.

We have adopted a Code of Business Ethics for all of our directors, officers and employees as required by NASDAQ governance rules and as defined by applicable SEC rules. Stockholders may locate a copy of our Code of Business Ethics on our website at www.clovisoncology.com or request a copy without charge from:

Clovis Oncology, Inc.

Attention: Investor Relations

5500 Flatiron Parkway, Suite 100

Boulder, CO 80301

We will post to our website any amendments to the Code of Business Ethics and any waivers that are required to be disclosed by the rules of either the SEC or NASDAQ.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item regarding executive compensation will be included in our 2016 Proxy Statement and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item regarding security ownership of certain beneficial owners and management will be included in the 2016 Proxy Statement and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item regarding certain relationships and related transactions and director independence will be included in the 2016 Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item regarding principal accounting fees and services will be included in the 2016 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are being filed as part of this report:

(1) Financial Statements.

Reference is made to the Index to Financial Statements of Clovis Oncology, Inc. appearing on page F-1 of this report.

(2) Financial Statement Schedules.

All financial statement schedules have been omitted because they are not applicable or not required or because the information is included elsewhere in the Financial Statements or the Notes thereto.

(3) Exhibits.

Reference is made to the Index to Exhibits filed as a part of this Annual Report on Form 10-K.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CLOVIS ONCOLOGY, INC.

By: /S/ PATRICK J. MAHAFFY
Patrick J. Mahaffy
Date: February 29, 2016 President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Name	Title	Date
/S/ PATRICK J. MAHAFFY	President and Chief Executive Officer; Director	February 29, 2016
	(Principal Executive Officer)	
Patrick J. Mahaffy		
/S/ ERLE T. MAST	Executive Vice President and Chief Financial Officer	February 29, 2016
	(Principal Financial Officer and Principal Accounting Officer)	
Erle T. Mast		
/S/ BRIAN G. ATWOOD	Director	February 29, 2016
Brian G. Atwood		
/S/ M. JAMES BARRETT	Director	February 29, 2016
M. James Barrett		
/S/ JAMES C. BLAIR	Director	February 29, 2016
James C. Blair		
/S/ KEITH FLAHERTY	Director	February 29, 2016

Keith Flaherty		
/S/ GINGER L. GRAHAM	Director	February 29, 2016
Ginger L. Graham		
/S/ PAUL KLINGENSTEIN	Director	February 29, 2016
Paul Klingenstein		
/S/ EDWARD J. MCKINLEY	Director	February 29, 2016
Edward J. McKinley		
/S/ THORLEF SPICKSCHEN	Director	February 29, 2016
Thorlef Spickschen		

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

The Stockholders and Board of Directors

Clovis Oncology, Inc.

We have audited the accompanying consolidated balance sheets of Clovis Oncology, Inc. as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Clovis Oncology, Inc. at December 31, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015 in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, the Company changed its classification of debt issuance costs.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Clovis Oncology, Inc.'s internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 29, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Denver, Colorado

February 29, 2016

CLOVIS ONCOLOGY, INC.

Consolidated Statements of Operations

	For the Year Ended December 31,		
	2015	2014	2013
	(in thousands, except per share amounts)		
Revenues:			
License and milestone revenue	$—	$13,625	$—
Operating expenses:			
Research and development	269,251	137,705	66,545
General and administrative	30,524	21,457	16,567
Acquired in-process research and development	12,000	8,806	250
Impairment of intangible asset	89,557	3,409	—
Change in fair value of contingent purchase consideration	(24,611)	707	405
Total expenses	376,721	172,084	83,767
Operating loss	(376,721)	(158,459)	(83,767)
Other income (expense):			
Interest expense	(8,372)	(2,604)	—
Foreign currency gains (losses)	2,740	3,580	(535)
Other income (expense)	416	(240)	(178)
Other income (expense), net	(5,216)	736	(713)
Loss before income taxes	(381,937)	(157,723)	(84,480)
Income tax benefit (expense)	29,076	(2,308)	(52)
Net loss	$(352,861)	$(160,031)	$(84,532)
Basic and diluted net loss per common share	$(9.79)	$(4.72)	$(2.95)
Basic and diluted weighted average common shares outstanding	36,026	33,889	28,672

See accompanying Notes to Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

Consolidated Statements of Comprehensive Loss

	For the Year Ended December 31,		
	2015	2014	2013
	(in thousands)		
Net loss	$(352,861)	$(160,031)	$(84,532)
Other comprehensive (loss) income			
Foreign currency translation adjustments	(22,629)	(29,144)	4,643
Net unrealized loss on available-for-sale securities	(383)	—	—
Other comprehensive (loss) income	(23,012)	(29,144)	4,643
Comprehensive loss	$(375,873)	$(189,175)	$(79,889)

See accompanying Notes to Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

Consolidated Balance Sheets

	December 31,	
	2015	2014
	(in thousands, except for share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$278,756	$482,677
Available-for-sale securities	249,832	—
Prepaid research and development expenses	3,377	3,765
Other current assets	7,736	4,730
Total current assets	539,701	491,172
Property and equipment, net	4,946	2,718
Intangible assets	101,500	212,900
Goodwill	59,327	66,055
Other assets	7,912	4,541
Total assets	$713,386	$777,386
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$11,260	$2,917
Accrued research and development expenses	53,011	37,257
Other accrued expenses	11,305	7,598
Total current liabilities	75,576	47,772
Contingent purchase consideration	24,661	52,453
Deferred income taxes, net	31,133	66,851
Convertible senior notes	279,885	278,680
Deferred rent, long-term	1,481	—
Total liabilities	412,736	445,756
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, par value $0.001 per share; 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2015 and 2014	—	—
Common stock, $0.001 par value per share, 100,000,000 shares authorized at December 31, 2015 and 2014; 38,359,454 and 33,977,187 shares issued and outstanding at December 31, 2015 and 2014, respectively	38	34
Additional paid-in capital	1,129,978	785,089
Accumulated other comprehensive loss	(47,460)	(24,448)
Accumulated deficit	(781,906)	(429,045)
Total stockholders' equity	300,650	331,630
Total liabilities and stockholders' equity	$713,386	$777,386

See accompanying Notes to Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

Consolidated Statements of Stockholders' Equity

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive Income	Accumulated	
	Shares	Amount	Capital	(Loss)	Deficit	Total
	(in thousands, except for share amounts)					
Balance at January 1, 2013	26,207,190	$ 26	$317,899	$ 53	$ (184,482)	$133,496
Issuance of common stock, net of issuance costs of $15,929	3,819,444	4	259,067	—	—	259,071
Issuance of common stock related to EOS acquisition	3,713,731	4	173,650	—	—	173,654
Issuance of common stock under employee stock purchase plan	16,324	—	378	—	—	378
Exercise of stock options	140,632	—	1,671	—	—	1,671
Share-based compensation expense	—	—	9,505	—	—	9,505
Foreign currency translation adjustments	—	—	—	4,643	—	4,643
Net loss	—	—	—	—	(84,532)	(84,532)
Balance at December 31, 2013	33,897,321	34	762,170	4,696	(269,014)	497,886
Issuance of common stock under employee stock purchase plan	13,633	—	481	—	—	481
Exercise of stock options	66,233	—	921	—	—	921
Share-based compensation expense	—	—	21,517	—	—	21,517
Foreign currency translation adjustments	—	—	—	(29,144)	—	(29,144)
Net loss	—	—	—	—	(160,031)	(160,031)
Balance at December 31, 2014	33,977,187	34	785,089	(24,448)	(429,045)	331,630
Issuance of common stock, net of issuance costs of $17,741	4,054,487	4	298,505	—	—	298,509
Issuance of common stock under employee stock purchase plan	32,021	—	493	—	—	493
Exercise of stock options	295,759	—	5,534	—	—	5,534
Share-based compensation expense	—	—	40,357	—	—	40,357
Net unrealized loss on available-for-sale securities	—	—	—	(383)	—	(383)
Foreign currency translation adjustments	—	—	—	(22,629)	—	(22,629)
Net loss	—	—	—	—	(352,861)	(352,861)
Balance at December 31, 2015	38,359,454	$ 38	$1,129,978	$ (47,460)	$ (781,906)	$300,650

See accompanying Notes to Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

Consolidated Statements of Cash Flows

	Year ended December 31,		
	2015	2014	2013
	(in thousands)		
Operating activities			
Net loss	$(352,861)	$(160,031)	$(84,532)
Adjustments to reconcile net loss to net cash used in operating activities:			
Share-based compensation expense	40,357	21,517	9,505
Depreciation and amortization	761	444	250
Amortization of premiums and discounts on available-for-sale securities	1,400	—	—
Amortization of debt issuance costs	1,205	368	—
Impairment of intangible asset	89,557	3,409	—
Change in fair value of contingent purchase consideration	(27,792)	(3,301)	1,028
Loss on disposal of equipment	39	67	—
Deferred income taxes	(28,874)	761	—
Changes in operating assets and liabilities, net of acquisition of a business:			
Prepaid and accrued research and development expenses	14,122	18,112	3,276
Other operating assets	(4,380)	(910)	(995)
Accounts payable	8,105	(1,369)	958
Other accrued expenses	5,295	3,882	(1,202)
Net cash used in operating activities	(253,066)	(117,051)	(71,712)
Investing activities			
Purchases of property and equipment	(3,035)	(2,286)	(121)
Purchases of available-for-sale securities	(392,540)	—	—
Sales of available-for-sale securities	140,997	—	—
Acquisition of business, net of cash acquired	—	—	(9,913)
Net cash used in investing activities	(254,578)	(2,286)	(10,034)
Financing activities			
Proceeds from the sale of common stock, net of issuance costs	298,509	—	259,071
Proceeds from the issuance of convertible senior notes, net of issuance costs	—	278,313	—
Proceeds from the exercise of stock options and employee stock purchases	5,971	1,163	1,771
Net cash provided by financing activities	304,480	279,476	260,842
Effect of exchange rate changes on cash and cash equivalents	(757)	(690)	35
(Decrease) increase in cash and cash equivalents	(203,921)	159,449	179,131
Cash and cash equivalents at beginning of period	482,677	323,228	144,097
Cash and cash equivalents at end of period	$278,756	$482,677	$323,228
Supplemental disclosure of cash flow information:			
Cash paid for interest	$7,307	$—	$—
Non-cash investing and financing activities:			
Issuance of shares for acquisition of business	$—	$—	$173,654
Contingent consideration for acquisition of business	$—	$—	$55,754

See accompanying Notes to Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business

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 clinical 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, and they are currently under active review. In December 2015, the FDA extended the Prescription Drug User Fee Act goal date for the rociletinib NDA by three months to June 28, 2016 to allow additional time for review of additional clinical data submitted by the Company in a Major Amendment in November 2015. The FDA has scheduled the NDA for rociletinib for discussion by the Oncologic Drugs Advisory Committee ("ODAC") on April 12, 2016. 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.

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 and 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 December 31, 2015 is sufficient to meet the cash requirements to fund planned operations through the next 12 months, although there can be no assurance that this can, in fact, be accomplished.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

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.

Fair Value of Financial Instruments

Cash, cash equivalents, available-for-sale securities and contingent purchase consideration are carried at fair value (see Note 5). Financial instruments, including other current assets and accounts payable, are carried at cost, which approximates fair value given their short-term nature.

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.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets. Equipment purchased for use in manufacturing and clinical trials is evaluated to determine whether the equipment is solely beneficial for a drug candidate in the development stage or whether it has an alternative use. Equipment with an alternative use is capitalized. Leasehold improvements are amortized over the economic life of the asset or the lease term, whichever is shorter. Maintenance and repairs are expensed as incurred. The estimated useful lives of our capitalized assets are as follows:

	Estimated Useful Life
Computer hardware and software	3 to 5 years
Leasehold improvements	6 years
Laboratory, manufacturing and office equipment	5 to 7 years
Furniture and fixtures	10 years

Long-Lived Assets

The Company reviews long-lived assets for impairment when events or changes in circumstances indicate that the carrying value of the assets may not be recoverable. Recoverability is measured by comparison of the assets' book value to future net undiscounted cash flows that the assets are expected to generate. If the carrying value of the assets exceed their future net undiscounted cash flows, an impairment charge is recognized for the amount by which the carrying value of the assets exceeds the fair value of the assets.

Intangible Assets

Intangible acquired in-process research and development ("IPR&D") assets were established as part of the acquisition of Ethical Oncology Science, S.p.A. ("EOS") (see Note 3) 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 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. During the fourth quarter of 2015, the Company recorded an $89.6 million impairment charge to the IPR&D intangible assets (see Note 7).

Goodwill

Goodwill represents the excess of the purchase price over the fair value of net assets acquired in a business combination accounted for under the acquisition method of accounting and is not amortized, but is subject to impairment testing at least annually in the fourth quarter or when a triggering event is identified that could indicate a potential impairment. We are organized as a single reporting unit and perform impairment testing by comparing the carrying value of the reporting unit to the fair value of the Company.

Other Current Assets

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

	December 31,	
	2015	2014
Receivable from partners	$3,241	$1,991
Prepaid insurance	1,231	1,190
Receivable from landlord	1,153	—
Prepaid expenses - other	1,023	1,168
Receivable - other	889	281
Other	199	100
Total	$7,736	$4,730

Other Accrued Expenses

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

	December 31,	
	2015	2014
Accrued personnel costs	$8,250	$4,726
Accrued interest payable	2,096	2,236
Accrued expenses - other	959	636
Total	$11,305	$7,598

Valuation of Contingent Consideration Resulting from a Business Combination

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 IPR&D assets, including changes in timeline and likelihood of success, and the passage of time. In the absence of new information, changes in fair value reflect only the passage of time. During the fourth quarter of 2015, the Company recorded a $26.9 million reduction in the fair value of the contingent purchase consideration liability (see Note 5).

Research and Development Expense

Research and development costs are charged to expense as incurred and include, but are not limited to, salary and benefits, share-based compensation, clinical trial activities, drug development and manufacturing, companion diagnostic development and third-party service fees, including clinical research organizations and investigative sites. During 2015, we completed the hiring of our U.S. sales and marketing and medical affairs organizations in preparation for the potential commercial launch of rociletinib. These costs are also included in research and development expense.

Costs for certain development activities, such as clinical trials, 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 on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred and are reflected on the Consolidated Balance Sheets as prepaid or accrued research and development expenses.

Acquired In-Process Research and Development Expense

The Company has acquired and expects to continue to acquire the rights to develop and commercialize new drug candidates. The upfront payments to acquire a new drug compound, as well as subsequent milestone payments, are immediately expensed as acquired in-process research and development provided that the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use.

Share-Based Compensation Expense

Share-based compensation is recognized as expense for all share-based awards made to employees and directors and is based on estimated fair values. The Company determines equity-based compensation at the grant date using the Black-Scholes option pricing model. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period. Any changes to the estimated forfeiture rates are accounted for prospectively.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash, cash equivalents and available-for-sale securities. The Company maintains its cash and cash equivalent balances in the form of money market accounts with financial institutions that management believes are creditworthy. Available-for-sale securities are invested in accordance with the Company's investment policy. The investment policy includes guidelines on the quality of the institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk. The Company has no financial instruments with off-balance sheet risk of accounting loss.

Foreign Currency

The assets and liabilities of the Company's foreign operations are translated into U.S. dollars at current exchange rates and the results of operations are translated at the average exchange rates for the reported periods. The resulting translation adjustments are included in accumulated other comprehensive loss on the Consolidated Balance Sheets. Transactions denominated in currencies other than the functional currency are recorded based on exchange rates at the time such transactions arise. Transaction gains and losses are recorded to foreign currency gains (losses) on the Consolidated Statements of Operations. As of December 31, 2015 and 2014, approximately 3% and 7%, respectively, of the Company's total liabilities were denominated in currencies other than the functional currency.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Tax benefits are recognized when it is more likely than not that a tax position will be sustained during an audit. Deferred tax assets are reduced by a valuation allowance if current evidence indicates that it is considered more likely than not that these benefits will not be realized.

Revenue Recognition

Revenue is recognized from license milestone payments when the following criteria have been met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the price is fixed or determinable; and (4) collectability is reasonably assured. We exercise judgment in determining that collectability is reasonably assured or that services have been delivered in accordance with the arrangement. We assess whether the fee is fixed or determinable based on the payment terms associated with the transaction and whether the sales price is

subject to refund or adjustment. We assess collectability based primarily on the customer's payment history and creditworthiness of the customer. Payments that are contingent upon the achievement of a substantive milestone will be recognized in the period in which the milestone is achieved.

Recently Adopted Accounting Standards

In April 2015, the FASB issued ASU No. 2015-03, “Interest – Imputation of Interest (Subtopic 835-30) – Simplifying the Presentation of Debt Issuance Costs.” ASU No. 2015-03 requires debt issuance costs to be presented as a deduction from the corresponding debt liability rather than as an asset. This update is effective for fiscal years beginning after December 15, 2015, including interim periods within those years. Early adoption is permitted. Upon adoption, the guidance must be applied retrospectively to all periods presented in the financial statements. The Company elected to early adopt this standard effective December 31, 2015. Adoption of the standard resulted in the reclassification of the Company’s debt issuance costs from other assets to convertible senior notes on its Consolidated Balance Sheets. As of December 31, 2014, the reclassification resulted in a decrease of $8.8 million to other assets with a corresponding decrease to convertible senior notes.

In November 2015, the FASB issued ASU No. 2015-17, “Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes.” ASU No. 2015-17 requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as noncurrent on the balance sheet. This update is effective for fiscal years beginning after December 15, 2016, including interim periods within those years. Early adoption is permitted. Upon adoption, the guidance may be applied either prospectively, for all deferred tax assets and liabilities, or retrospectively to all periods presented in the financial statements. The Company elected to early adopt this standard effective December 31, 2015. Adoption of this standard was applied retrospectively and resulted in no change to the Company’s Consolidated Balance Sheets.

Recently Issued Accounting Standards

In May 2014, the FASB issued ASU No. 2014-09, “Revenue from Contracts with Customers (Topic 606).” ASU 2014-09 specifies the accounting for revenue from contracts with customers and establishes disclosure requirements relating to the nature, timing and uncertainty of revenue and cash flows arising from an entity’s contracts with customers. In August 2015, the FASB issued ASU 2015-14, “Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date,” which delayed the effective date of the standard to annual and interim periods beginning after December 15, 2017. Early application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods. ASU 2014-09 allows for either full retrospective or modified retrospective adoption. 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.

In August 2014, the FASB issued ASU No. 2014-15, “Disclosure of Uncertainties About an Entity’s Ability to Continue as a Going Concern,” which requires management to evaluate whether there are conditions or events that raise substantial doubt about an entity’s ability to continue as a going concern and to provide disclosures when certain criteria are met. The guidance is effective for annual periods beginning in 2016 and interim reporting periods starting in the first quarter of 2017. Early application is permitted. The Company is currently evaluating the impact the standard may have on its disclosures.

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842),” which requires lessees to recognize assets and liabilities for the rights and obligations created by most leases on their balance sheet. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. ASU 2016-02 requires modified retrospective adoption for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. The Company is currently evaluating 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 EOS (now known as Clovis Oncology Italy S.r.l.). EOS was a biopharmaceutical company located in Italy that focused on the development of novel medicines for the treatment of cancer. The primary reason for the business acquisition was to obtain development and commercialization rights to lucitanib, an oral, selective tyrosine kinase inhibitor.

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 regulatory and sales milestones are achieved. The results of operations for EOS were included in our consolidated financial statements from the acquisition date, and the assets acquired and liabilities assumed of EOS were recorded as of the acquisition date at their respective fair values and consolidated with those of the Company.

As part of the acquisition of EOS, the Company recorded intangible assets on the Consolidated Balance Sheets to reflect the fair value of IPR&D, which was based on two components. The first was the estimated fair value of lucitanib development and commercialization rights sublicensed by EOS to Servier (see Note 12 – Lucitanib). The estimated fair value of these rights was $56.1 million at the date of the acquisition based on probability-weighted cash flow payments due from Servier upon the achievement of certain development, regulatory and commercial milestones, as well as future royalty payments resulting from the sale of lucitanib in the sublicensed territories.

The second component was based on the fair value of the expected net cash flows for the development and commercialization rights of lucitanib in the United States and Japan held by EOS at acquisition. The estimated fair value of $183.8 million for these rights was based on probability-weighted net cash flows of the anticipated lucitanib development and sales activities.

Key assumptions used in the discounted cash flow models include estimates related to the timing of development, probability of development and regulatory success, sales and commercialization factors and estimated product life. Net cash flows were discounted at a risk-adjusted rate of 18.9%.

The excess purchase price over the fair value of amounts assigned to the assets acquired and liabilities assumed was recorded as goodwill on the Consolidated Balance Sheets.

The Company is obligated to pay additional consideration to the former EOS shareholders if certain future regulatory and lucitanib-related sales milestones are achieved. The estimated fair value of these payments was recorded as contingent purchase consideration on the Consolidated Balance Sheets. The initial estimated fair value of the contingent purchase consideration was $54.7 million at the acquisition date, which was determined based on the assumptions described below.

Pursuant to the sublicense agreement with Servier, the Company is eligible to receive future milestone payments based on the achievement of development, regulatory and sales milestones. Certain of the contingent consideration payments owed from the Company to the former EOS shareholders are tied to the receipt of milestone payments from Servier.

A summary of the contingent payment obligations is as follows (in thousands and payment currency):

	Amount
Initial approval of an NDA for lucitanib in the U.S.	$65,000
Obligations associated with the receipt of milestone payments from Servier:	
Initial filing of a MAA for lucitanib in the E.U.	€15,000
Initial approval of a MAA for lucitanib in the E.U.	€45,000
Initial achievement of lucitanib net sales in Servier licensed territory of €500 million in any four consecutive quarters	€55,000
Total	€115,000

The fair value of the MAA filing and approval obligations of $52.5 million was based on the discounting of the probability-weighted future milestone payments using an estimated borrowing rate ranging from 5.2% to 5.8%, which represented our estimated borrowing rate for the various terms the payment obligations were expected to be outstanding. The sales milestone fair value of $2.2 million was based on the probability-weighted future milestone payments using the risk-adjusted discount rate of 18.7%. The potential contingent milestone payments range from a zero payment, which assumes lucitanib fails to achieve any of the regulatory milestones, to $190.5 million ($65.0 million and €115.0 million) if all regulatory and sales milestones are met, utilizing the translation rate at December 31, 2015.

During the fourth quarter of 2015, the Company recorded an $89.6 million impairment charge to the IPR&D intangible assets and a $26.9 million reduction in the fair value of the contingent purchase consideration liability (see

Note 5 and Note 7).

4. Property and Equipment

Property and equipment consisted of the following (in thousands):

	December 31,	
	2015	2014
Laboratory, manufacturing and office equipment	$2,556	$2,452
Leasehold improvements	1,861	260
Furniture and fixtures	1,487	667
Computer hardware and software	833	414
Total property and equipment	6,737	3,793
Less: accumulated depreciation	(1,791)	(1,075)
Total property and equipment, net	$4,946	$2,718

Depreciation expense related to property and equipment was approximately $761 thousand, $444 thousand and $250 thousand for the years ended December 31, 2015, 2014 and 2013, respectively.

5. 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 for further discussion of the valuation methodology.

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
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
December 31, 2014				
Assets:				
Money market	$447,994	$447,994	$—	$—
Total assets at fair value	$447,994	$447,994	$—	$—
Liabilities:				
Contingent purchase consideration	$52,453	$—	$—	$52,453
Total liabilities at fair value	$52,453	$—	$—	$52,453

There were no transfers between the Level 1 and Level 2 categories or into or out of the Level 3 category during the year ended December 31, 2015.

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

	Year Ended December 31, 2015
Liabilities:	
Balance at beginning of period	$ 52,453
Change in fair value (a)	(24,611)
Change in foreign currency gains and losses	(3,181)
Balance at end of period	$ 24,661

(a) The decrease in the fair value of the contingent purchase consideration was due to a change in the estimated probability-weighted future milestone payments discounted using an estimated borrowing rate ranging from 8.5% to 8.6%, as well as the timing of such payments, for the lucitanib program.

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 December 31, 2015, the carrying amount of the convertible senior notes was $287.5 million, which represents the aggregate principal amount, and the fair value was $248.7 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 convertible senior notes, which are not listed on any securities exchange or quoted on an inter-dealer automated quotation system. See Note 8 for discussion of the convertible senior notes.

6. Available-for-Sale Securities

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 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)

The Company's investments have been in an unrealized loss position for between two to three months. Based upon our evaluation of all relevant factors, we believe that the decline in fair value of securities held at December 31, 2015 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 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	$200,147	$199,912
Due in one year to two years	50,068	49,920
Total	$250,215	$249,832

7. Intangible Assets and Goodwill

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):

	December 31,	
	2015	2014
IPR&D assets:		
Balance at beginning of period	$212,900	$244,518
Impairment of intangible asset (a)	(89,557)	(3,409)
Change in foreign currency gains and losses	(21,843)	(28,209)
Balance at end of period	$101,500	$212,900
Goodwill:		
Balance at beginning of period	$66,055	$74,811
Change in foreign currency gains and losses	(6,728)	(8,756)
Balance at end of period	$59,327	$66,055

(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.

During the first quarter of 2014, the Company recorded a $3.4 million reduction in the intangible assets driven by lower expected future milestone revenue from the lucitanib development activities due to the receipt of a lucitanib milestone payment from Servier (see Note 12 - Lucitanib).

These reductions were included in impairment of intangible asset on the Consolidated Statements of Operations. As of December 31, 2015, no impairment to the carrying value of the goodwill was identified.

8. 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, which was included in other assets on the Consolidated Balance Sheets. Pursuant to its adoption of ASU No. 2015-03 on December 31, 2015, the Company reclassified the debt issuance costs from other assets to convertible senior notes

(see Note 2 – Recently Adopted Accounting Standards).

The debt issuance costs are amortized as interest expense over the expected life of the Notes using the effective interest method. The Company determined the expected life of the debt was equal to the seven-year term of the Notes. As of December 31, 2015 and 2014, the balance of unamortized debt issuance costs was $7.6 million and $8.8 million, respectively.

The following table sets forth total interest expense recognized related to the Notes during the years ended December 31, 2015 and 2014 (in thousands):

	Year Ended December 31,	
	2015	2014
Contractual interest expense	$7,167	$2,236
Amortization of debt issuance costs	1,205	368
Total interest expense	$8,372	$2,604

9. Stockholders' Equity

Common Stock

In June 2013, the Company sold 3,819,444 shares of its common stock in a public offering at $72.00 per share. The net offering proceeds realized after deducting offering expenses and underwriters' discounts and commissions were $259.1 million.

In November 2013, the Company issued 3,713,731 shares of its common stock at a value of $173.7 million to acquire all of the outstanding common and preferred stock of EOS.

In July 2015, the Company sold 4,054,487 shares of its common stock in a public offering at $78.00 per share. The net proceeds to the Company from the offering were $298.5 million, after deducting underwriting discounts and commissions and offering expenses.

The holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders of the Company. Subject to the preferences that may be applicable to any outstanding shares of preferred stock, the holders of common stock are entitled to receive ratably such dividends, if any, as may be declared by the Company's Board of Directors.

Accumulated Other Comprehensive Loss

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

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

	Foreign Currency Translation Adjustments	Unrealized Losses	Total Accumulated Other Comprehensive Income (Loss)
Balance December 31, 2013	$ 4,696	$ —	$ 4,696
Period change	(29,144)	—	(29,144)
Balance December 31, 2014	(24,448)	—	(24,448)
Period change	(22,629)	(383)	(23,012)
Balance December 31, 2015	$ (47,077)	$ (383)	$ (47,460)

The period change between December 31, 2015 and 2014 was primarily due to the currency translation of the IPR&D intangible assets, goodwill and deferred income taxes associated with the acquisition of EOS (see Note 3 and Note 7).

10. Share-Based Compensation

Stock Options

In May 2009, the Company's Board of Directors approved the 2009 Equity Incentive Plan (the "2009 Plan"). The 2009 Plan provided for the granting of stock options and other share-based awards, including restricted stock, stock appreciation rights and restricted stock units to its employees, directors and consultants. Common shares authorized for issuance under the 2009 Plan were 1,317,125 at December 31, 2015. Options to purchase common stock under the 2009 Plan were designated as incentive stock options or non-statutory stock options. Stock options granted under the 2009 Plan vest over either a one-year period or three-year period for Board of Director grants and over a four-year period for employee grants and expire 10 years from the date of grant. Upon the closing of the Company's initial public offering in November 2011, the 2009 Plan was closed, resulting in the termination of new grants from this plan and the transfer of all shares available for future issuance to the 2011 Stock Incentive Plan. Future forfeitures and cancellations of options previously granted under the 2009 Plan were transferred to the 2011 Stock Incentive Plan and are available for grant under the 2011 Plan.

In August 2011, the Company's Board of Directors approved the 2011 Stock Incentive Plan (the "2011 Plan"), which became effective upon the closing of the Company's initial public offering in November 2011. The 2011 Plan provides for the granting of incentive and nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, performance awards and other share-based awards to its employees, directors and consultants. Common shares authorized for issuance under the 2011 Plan were 6,262,641 at December 31, 2015, which represents the initial reserve of 1,250,000 shares of common stock plus 191,496 shares of common stock remaining for future grant from the 2009 Equity Incentive Plan and 4,821,145 new shares authorized by the Board of Directors at the annual meetings of stockholders. Stock options granted vest over either a one-year period or three-year period for Board of Director grants or over a four-year period for employee grants and expire 10 years from the date of grant.

Share-based compensation expense for the years ended December 31, 2015, 2014 and 2013, respectively, was recognized in the accompanying Consolidated Statements of Operations as follows (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Research and development (a)	$27,321	$11,474	$4,289
General and administrative	13,036	10,043	5,216
Total share-based compensation expense	$40,357	$21,517	$9,505

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

The Company did not recognize a tax benefit related to share-based compensation expense during the years ended December 31, 2015, 2014 and 2013, respectively, as the Company maintains net operating loss carryforwards and has established a valuation allowance against the entire net deferred tax asset as of December 31, 2015.

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

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (Thousands)
Outstanding at December 31, 2014	4,159,362	$ 37.69		
Granted (a)	1,600,593	80.04		
Exercised	(295,759)	18.52		
Forfeited	(103,939)	56.93		
Outstanding at December 31, 2015	5,360,257	$ 51.53	7.1	$ 33,927
Vested and expected to vest at December 31, 2015	5,030,757	$ 50.22	7.0	$ 33,678
Exercisable at December 31, 2015	2,608,239	$ 34.56	6.0	$ 29,607

(a) Includes 120,000 performance-based stock options granted to executives of the Company in the first quarter of 2015. Fifty percent of the grant vests contingent on approval by the FDA to commercially distribute, sell or market

rociletinib and 50% 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 $35.00 as of December 31, 2015, which would have been received by the option holders had all option holders with in-the-money options exercised their options as of that date.

The following table summarizes information about our stock options as of and for the years ended December 31, 2015, 2014 and 2013:

	Year Ended December 31,		
	2015	2014	2013
Weighted-average grant date fair value per share	$52.70	$38.47	$18.59
Intrinsic value of options exercised	$19,976,769	$2,906,304	$6,114,436
Cash received from stock option exercises	$5,478,211	$682,678	$1,393,053

The fair value of each share-based award is estimated on the grant date using the Black-Scholes option pricing model based upon the weighted-average assumptions provided in the following table:

	Year Ended December 31,		
	2015	2014	2013
Dividend yield	—	—	—
Volatility (a)	72%	70%	69%
Risk-free interest rate (b)	1.77%	1.92%	1.16%
Expected term (years) (c)	6.1	6.2	6.2

(a) Volatility: The expected volatility was estimated using peer data of companies in the biopharmaceutical industry with similar equity plans.
(b) Risk-free interest rate: The rate is based on the yield on the grant date of a zero-coupon U.S. Treasury bond whose maturity period approximates the option's expected term.
(c) Expected term: The expected term of the award was estimated using peer data of companies in the biopharmaceutical industry with similar equity plans.

Unrecognized share-based compensation expense related to non-vested options, adjusted for expected forfeitures, was $88.6 million as of December 31, 2015. The unrecognized share-based compensation expense is expected to be recognized over the weighted-average remaining vesting period of 2.7 years.

Common Stock Reserved for Issuance

As of December 31, 2015, the Company reserved shares of common stock for future issuance as follows:

	Options Outstanding	Available for Grant or Future Issuance	Total Shares of Common Stock Reserved
2009 Equity Incentive Plan	494,031	—	494,031
2011 Stock Incentive Plan	4,866,226	1,181,722	6,047,948
2011 Employee Stock Purchase Plan	—	376,231	376,231
Total	5,360,257	1,557,953	6,918,210

Employee Stock Purchase Plan

In August 2011, our Board of Directors approved the Clovis Oncology, Inc. 2011 Employee Stock Purchase Plan (the "Purchase Plan"). Each year, on the date of our annual meeting of stockholders and at the discretion of our board of directors, the amount of shares reserved for issuance under the Purchase Plan may be increased by up to the lesser of (1) a number of additional shares of our common stock representing 1% of our then-outstanding shares of common stock, (2) 344,828 shares of our common stock and (3) a lesser number of shares as approved by the Board. The Purchase Plan provides for consecutive six-month offering periods, during which participating employees may elect to have up to 10% of their compensation withheld and applied to the purchase of common stock at the end of each offering period. The purchase price of the common stock is 85% of the lower of the fair value of a share of common

stock on the first trading date of each offering period or the fair value of a share of common stock on the last trading day of the offering period. The Purchase Plan will terminate on August 24, 2021, the tenth anniversary of the date of initial adoption of the Purchase Plan. We sold 32,021 and 13,633 shares to employees in 2015 and 2014, respectively. There were 376,231 shares available for sale under the Purchase Plan as of December 31, 2015. The weighted-average estimated grant date fair value of purchase awards under the Purchase Plan during the years ended December 31, 2015 and 2014 was $26.80 and $17.31 per share, respectively. The total share-based compensation expense recorded as a result of the Purchase Plan was approximately $858 thousand, $236 thousand and $169 thousand during the years ended December 31, 2015, 2014 and 2013, respectively.

The fair value of purchase awards granted to our employees during the years ended December 31, 2015, 2014 and 2013, respectively, was estimated using the Black-Scholes option pricing model based upon the weighted-average assumptions provided in the following table:

	Year Ended December 31,		
	2015	2014	2013
Dividend yield	—	—	—
Volatility (a)	71%	71%	72%
Risk-free interest rate (b)	0.11%	0.07%	0.09%
Expected term (years) (c)	0.5	0.5	0.5

(a) Volatility: The expected volatility was estimated using peer data of companies in the biopharmaceutical industry with similar equity plans.
(b) Risk-free interest rate: The rate is based on the U.S. Treasury yield in effect at the time of grant with terms similar to the contractual term of the purchase right.
(c) Expected term: The expected life of the award represents the six-month offering period for the Purchase Plan.

11. Commitments and Contingencies

The Company leases office space in Boulder, Colorado, San Francisco, California, Cambridge, UK and Milan, Italy under non-cancelable operating lease agreements that expire through 2023.

The lease agreements contain periodic rent increases that result in the Company recording deferred rent over the terms of certain leases. In June 2015, the Company entered into a seven-year lease agreement for new office space in Boulder, Colorado. Pursuant to the terms of the lease, the landlord will reimburse the Company for $1.1 million of leasehold improvement expenditures (the “Tenant Improvement Allowance”). In December 2015, upon completion of construction, the Company recorded the Tenant Improvement Allowance as deferred rent, which is being amortized as a reduction to rental expense over the lease term.

Rental expense under these leases was $2.4 million, $1.4 million and $1.1 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Future minimum rental commitments, by fiscal year and in the aggregate, for the Company’s operating leases are provided below (in thousands):

	December 31, 2015
2016	$ 1,795
2017	1,746
2018	1,783
2019	1,837
2020	1,891
Thereafter	2,547
Total future minimum lease payments	$ 11,599

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. During the years ended December 31, 2015, 2014 and 2013, $6.0 million, $3.3 million and $6.4 million, respectively, of purchases were performed under this agreement. As of December 31, 2015, $16.1 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. 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. 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 alleges 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 alleges claims for abuse of control and gross mismanagement. The Sanchez Complaint seeks, among other things, an award of money damages. The Company intends to vigorously defend against the allegations contained in the Sanchez Complaint, but there can be no assurance that the defense will be successful.

12. License Agreements

Rociletinib

In May 2010, we entered into an exclusive worldwide license agreement with Avila Therapeutics, Inc. (now Celgene Avilomics Research Inc., part of Celgene Corporation ("Celgene")) to discover, develop and commercialize a covalent inhibitor of mutant forms of the epidermal growth factor receptor ("EGFR") 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 the acceptance by the FDA of our Investigational New Drug application for rociletinib and a $5.0 million milestone payment in the first quarter of 2014 upon 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.

When and if commercial sales of rociletinib commence, we will pay Celgene tiered royalties at percentage rates ranging from mid-single digits to low teens based on 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, the majority of which relate to annual sales targets of $500.0 million and above.

In January 2013, the Company entered into an exclusive license agreement with Gatekeeper Pharmaceuticals, Inc. ("Gatekeeper") to acquire exclusive rights under patent applications associated with mutant EGFR inhibitors and methods of treatment. Pursuant to the terms of the license agreement, the Company made an upfront payment of $0.25 million upon execution of the agreement, which was recognized as acquired in-process research and development expense. If rociletinib is approved for commercial sale, the Company will pay royalties to Gatekeeper on future net sales.

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 ("PARP"), which the Company is developing for the treatment of selected solid tumors. Under the terms of the license agreement, we made a $7.0 million upfront payment to Pfizer. In April 2014, 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 obligated under the license agreement to use commercially reasonable efforts to develop and commercialize rucaparib, and we are responsible for all remaining development and commercialization costs of rucaparib. When and if commercial sales of rucaparib begin, we will pay Pfizer tiered royalties at a mid-teen percentage rate on our net sales, with standard provisions for royalty offsets to the extent we need to obtain any rights from third parties to commercialize rucaparib. 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.

In April 2012, the Company entered into a license agreement with AstraZeneca UK Limited to acquire exclusive rights associated with rucaparib under a family of patents and patent applications that claim methods of treating patients with PARP inhibitors in certain indications. The license enables the development and commercialization of rucaparib for the uses claimed by these patents. Pursuant to the terms of the license agreement, the Company made an upfront payment of $0.25 million upon execution of the agreement, which was recognized as acquired in-process research and development expense. The Company may be required to pay up to an aggregate of $0.7 million in milestone payments if certain regulatory filings, acceptances and approvals are achieved. If approved, AstraZeneca will also receive royalties on any net sales of rucaparib.

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 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. If and when commercial sales commence, we are obligated to pay Advenchen tiered royalties at percentage rates in the mid-single digits on net sales of lucitanib, based on the volume of annual net sales achieved. In addition, we are required to pay to Advenchen 25% of any consideration, excluding royalties, received pursuant to any sublicense agreements for lucitanib, including the agreement with Servier. We are obligated under the agreement to use commercially reasonable efforts to develop and commercialize at least one product candidate containing lucitanib, and we are also responsible for all remaining development and commercialization costs for lucitanib.

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 €90.0 million in the aggregate. In addition, we are entitled to receive sales milestone payments if specified annual sales targets for lucitanib are met, which, in the aggregate, could total €250.0 million. We are also entitled to receive royalties at percentage rates ranging from low to mid-teens 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 late 2016 or 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 on the Consolidated Statements of Operations.

The Company recorded a $3.2 million and $2.0 million receivable at December 31, 2015 and 2014, respectively, for the reimbursable development costs incurred under the global development plan, which is included in other current assets on the Consolidated Balance Sheets. During the years ending December 31, 2015, 2014 and 2013, we incurred $13.7 million, $9.5 million and $1.4 million, respectively, in research and development costs and recorded reductions in research and development expense of $11.8 million, $10.0 million and $1.3 million, respectively, for reimbursable development costs due from Servier.

13. Net Loss Per Common Share

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

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

	Year ended December 31,		
	2015	2014	2013
Common shares under option	2,031	2,973	2,344
Convertible senior notes	4,646	4,646	—
Total potential dilutive shares	6,677	7,619	2,344

14. Income Taxes

The geographical components of income (loss) before income taxes consisted of the following (in thousands):

	Year ended December 31,		
	2015	2014	2013
Domestic	$(290,342)	$(165,220)	$(84,534)
Foreign	(91,595)	7,497	54
Total loss before income taxes	$(381,937)	$(157,723)	$(84,480)

The income tax provision consists of the following current and deferred foreign tax expenses (in thousands). No U.S. tax expense was recognized in the 2015 and 2014 and the 2013 tax provisions are not significant.

	Year ended December 31,	
	2015	2014
Foreign:		
Current expense	$—	$1,547
Deferred (benefit) expense	(29,076)	761
Total income tax (benefit) expense	$(29,076)	$2,308

A reconciliation of the U.S. statutory income tax rate to the Company's effective tax rate is as follows:

	Year Ended December 31,		
	2015	2014	2013
Federal income tax benefit at statutory rate	(34.0)%	(34.0)%	(34.0)%
State income tax benefit, net of federal benefit	(3.0)	(3.5)	(3.0)
Tax credits	(13.6)	(20.5)	(15.5)
Change in tax status of foreign subsidiary	—	(13.5)	—
Limitation on future foreign tax credits	(5.0)	—	—

Other	0.4	1.0	2.1
Change in valuation allowance	47.6	72.0	50.5
Effective income tax rate	(7.6)%	1.5 %	0.1 %

The components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2015	2014
Deferred tax assets:		
Net operating loss carryforward	$189,663	$111,309
Tax credit carryforwards	179,865	101,469
Intangible assets	26,766	—
Deductible foreign taxes	10,836	22,729
Share-based compensation expense	23,844	10,777
Foreign currency translation	17,471	9,092
Product acquisition costs	10,470	6,866
Accrued liabilities and other	4,147	2,051
Total deferred tax assets	463,062	264,293
Valuation allowance	(449,080)	(259,004)
Deferred tax assets, net of valuation allowance	13,982	5,289
Deferred tax liabilities:		
Intangible assets	(31,871)	(70,084)
Contingent purchase consideration	(11,142)	(843)
Prepaid expenses and other	(2,102)	(1,213)
Total deferred tax liabilities	(45,115)	(72,140)
Net deferred tax liability	$(31,133)	$(66,851)

The realization of deferred tax assets is dependent upon a number of factors including future earnings, the timing and amount of which is uncertain. A valuation allowance was established for the net deferred tax asset balance due to management's belief that the realization of these assets is not likely to occur in the foreseeable future. The Company recorded an increase to the valuation allowance of $190.1 million and $122.7 million during the years ended December 31, 2015 and 2014, respectively, primarily due to an increase in net operating loss and tax credit carryforwards and future tax deductions associated with EOS acquisition intangible assets.

As of December 31, 2015, the Company had approximately $504.8 million, $728.1 million and $2.7 million of U.S. federal, state and foreign net operating loss carryforwards, respectively. The U.S. net operating losses will expire from 2029 to 2035 if not utilized. Included in the U.S. net operating loss was approximately $16.7 million of stock compensation expense, the benefit of which, if realized, will be an increase to additional paid-in-capital and a reduction to taxes payable. In addition, the Company has research and development and orphan drug tax credit carryforwards of $177.7 million that will expire from 2029 through 2035 if not utilized.

We believe that a change in ownership as defined under Section 382 of the U.S. Internal Revenue Code occurred as a result of the Company's public offering of common stock completed in April 2012. Future utilization of the federal net operating losses ("NOL") and tax credit carryforwards accumulated from inception to the change in ownership date will be subject to annual limitations to offset future taxable income. At this time, we do not believe, however, this limitation will prevent the utilization of the federal NOL or credit carryforward prior to expiration. It is possible that a change in ownership will occur in the future, which will limit the NOL amounts generated since the last estimated change. The Company's federal and state income taxes for the period from inception to December 31, 2015 remain open to an audit. Our foreign subsidiaries are also subject to tax audits by tax authorities in the jurisdictions where they operate for the periods from December 31, 2010 to December 31, 2015.

Tax positions are initially recognized in the financial statements when it is more likely than not that the position will be sustained upon examination by the tax authorities. Such tax positions must initially and subsequently be measured at the largest amount of tax benefit that has a greater than 50% likelihood of being realized upon ultimate settlement

with the tax authority assuming full knowledge of the position and relevant facts. The Company has not identified any significant uncertain tax positions that require recognition in our financial statements. Our evaluation was performed from inception through December 31, 2015.

In December 2014, the Company converted a non-U.S. entity into a U.S. entity for U.S. income tax purposes. As a result of this election, the subsidiary was treated as a flow through entity for U.S. federal tax purposes. The election generated deferred tax assets, calculated as the difference between the subsidiary's tax basis and the underlying financial statement basis of the assets.

The Company may be assessed interest and penalties related to the settlement of tax positions and such amounts will be recognized within income tax expense when assessed. To date, no interest and penalties have been recognized by the Company.

15. Employee Benefit Plan

We maintain a retirement plan, which is qualified under section 401(k) of the Internal Revenue Code for its U.S. employees. The plan allows eligible employees to defer, at the employee's discretion, pretax compensation up to the IRS annual limits. The Company matches contributions up to 4% of the eligible employee's compensation or the maximum amount permitted by law. Total expense for contributions made to U.S. employees was approximately $824 thousand, $425 thousand and $368 thousand for the years ended December 31, 2015, 2014 and 2013, respectively. The Company's international employees participate in retirement plans governed by the local laws in effect for the country in which they reside. The Company made matching contributions to international employees of approximately $171 thousand, $106 thousand and $81 thousand for the years ended December 31, 2015, 2014 and 2013, respectively.

16. Quarterly Information (Unaudited)

The results of operations on a quarterly basis for the years ended December 31, 2015 and 2014 were as follows (in thousands):

	March 31, 2015	June 30, 2015	Sept. 30, 2015 (1)	Dec. 31, 2015	March 31, 2014	June 30, 2014	Sept. 30, 2014	Dec. 31, 2014
Revenues:								
License and milestone revenue	$—	$—	$—	$—	$ 13,625	$—	$—	$—
Operating expenses:								
Research and development	56,750	60,368	76,138	75,995	24,151	28,440	34,965	50,149
General and administrative	6,751	7,204	8,331	8,238	5,320	5,265	5,267	5,605
Acquired in-process research and development	—	—	12,000	—	8,406	400	—	—
Impairment of intangible asset	—	—	—	89,557	3,409	—	—	—
Change in fair value of contingent purchase consideration	724	764	783	(26,882)	822	861	888	(1,864)
Total expenses	64,225	68,336	97,252	146,908	42,108	34,966	41,120	53,890
Operating loss	(64,225)	(68,336)	(97,252)	(146,908)	(28,483)	(34,966)	(41,120)	(53,890)
Other income (expense):								
Interest expense	(2,075)	(2,097)	(2,099)	(2,101)	—	—	(511)	(2,093)
Foreign currency gains (losses)	3,247	(1,142)	(101)	736	(60)	316	2,323	1,001
Other income (expense)	11	62	179	164	(46)	(46)	(42)	(106)
Other income (expense), net	1,183	(3,177)	(2,021)	(1,201)	(106)	270	1,770	(1,198)
Loss before income taxes	(63,042)	(71,513)	(99,273)	(148,109)	(28,589)	(34,696)	(39,350)	(55,088)
	(102)	(18)	628	28,568	(2,129)	(68)	(292)	181

Income tax (expense) benefit								
Net loss	$(63,144)	$(71,531)	$(98,645)	$(119,541)	$(30,718)	$(34,764)	$(39,642)	$(54,907)
Basic and diluted net loss per common share	$(1.86)	$(2.10)	$(2.62)	$(3.12)	$(0.91)	$(1.03)	$(1.17)	$(1.62)
Basic and diluted weighted average common shares outstanding	34,011	34,088	37,613	38,321	33,820	33,872	33,921	33,941

(1) In July 2015, the Company sold 4,054,487 shares of its common stock in a public offering at $78.00 per share. The net proceeds to the Company from the offering were $298.5 million after deducting underwriting discounts and commissions and offering expenses.

17. Subsequent Events

The Company evaluated events after the balance sheet date of December 31, 2015 and up to the date the Company filed this Annual Report and determined that no subsequent activity required disclosure.

INDEX TO EXHIBITS

Exhibit Number	Exhibit Description
3.1(5)	Amended and Restated Certificate of Incorporation of Clovis Oncology, Inc.
3.2(5)	Amended and Restated Bylaws of Clovis Oncology, Inc.
4.1(3)	Form of Common Stock Certificate of Clovis Oncology, Inc.
4.2(8)	Indenture, dated as of September 9, 2014, by and between the Company and The Bank of New York Mellon Trust Company, N.A.
10.1*(4)	Amended and Restated Strategic License Agreement, dated as of June 16, 2011, by and between Clovis Oncology, Inc. and Avila Therapeutics, Inc.
10.2*(4)	License Agreement, dated as of June 2, 2011, by and between Clovis Oncology, Inc. and Pfizer Inc.
10.3+(1)	Clovis Oncology, Inc. 2009 Equity Incentive Plan.
10.4+(4)	Clovis Oncology, Inc. 2011 Stock Incentive Plan.
10.5+(1)	Form of Clovis Oncology, Inc. 2009 Equity Incentive Plan Stock Option Agreement.
10.6+(4)	Form of Clovis Oncology, Inc. 2011 Stock Incentive Plan Stock Option Agreement.
10.7+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Patrick J. Mahaffy.
10.8+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Erle T. Mast.
10.9+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Gillian C. Ivers-Read.
10.10+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Andrew R. Allen.
10.11+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Paul Klingenstein.
10.12+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and James C. Blair.
10.13+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Edward J. McKinley.
10.14+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Thorlef Spickschen.

10.15+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and M. James Barrett.
10.16+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Brian G. Atwood.
10.17+(1)	Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Patrick J. Mahaffy.
10.18+(1)	Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Erle T. Mast.
10.19+(1)	Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Gillian C. Ivers-Read.
10.20+(1)	Indemnification Agreement, dated as of May 13, 2009, between Clovis Oncology, Inc. and Andrew R. Allen.
10.25+(4)	Clovis Oncology, Inc. 2011 Employee Stock Purchase Plan.
10.26+(4)	Clovis Oncology, Inc. 2011 Cash Bonus Plan.
10.27+(6)	Employment Agreement, dated as of March 22, 2012, by and between Clovis Oncology, Inc. and Steven L. Hoerter.
10.28+(6)	Indemnification Agreement, dated as of March 22, 2012, by and between Clovis Oncology, Inc. and Steven L. Hoerter.
10.29+(2)	Indemnification Agreement, dated as of June 13, 2013, between Clovis Oncology, Inc. and Ginger L. Graham.
10.30+(2)	Indemnification Agreement, dated as of June 13, 2013, between Clovis Oncology, Inc. and Keith Flaherty.
10.31(9)	Consulting Agreement, dated August 6, 2015, by and between Andrew Allen and Clovis Oncology, Inc.
10.32(7)	Stock Purchase Agreement, dated as of November 19, 2013, by and among the Company, EOS, the Sellers listed on Exhibit A thereto and Sofinnova Capital V FCPR, acting in its capacity as the Sellers' Representative.

Exhibit Number	Exhibit Description
10.33(7)	Registration Rights Agreement, dated as of November 19, 2013, by and between the Company and the Sellers signatory thereto.
10.34*(7)	Development and Commercialization Agreement, dated as of October 24, 2008, by and between Advenchen Laboratories LLC and Ethical Oncology Science S.p.A., as amended by the First Amendment, dated as of April 13, 2010 and the Second Amendment, dated as of July 30, 2012.
10.35*(7)	Collaboration and License Agreement, dated as of September 28, 2012, by and between Ethical Oncology Science S.p.A. and Les Laboratoires Servier and Institut de Recherches Internationales Servier.
10.36+	Indemnification Agreement, dated as of January 29, 2016, by and between Clovis Oncology, Inc. and Lindsey Rolfe.
10.37+	

	Employment Agreement, dated as of February 25, 2016, by and between Clovis Oncology, Inc. and Lindsey Rolfe.
10.38+	Indemnification Agreement, dated as of January 26, 2016, by and between Clovis Oncology, Inc. and Dale Hooks.
10.39+	Employment Agreement, dated as of January 26, 2016, by and between Clovis Oncology, Inc. and Dale Hooks.
21.1	List of Subsidiaries of Clovis Oncology, Inc.
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.

32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

(1) Filed as an exhibit with the Registrant's Registration Statement on Form S-1 (File No. 333-175080) on June 23, 2011.
(2) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on June 14, 2013.
(3) Filed as an exhibit with Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (File No. 333-175080) on August 31, 2011.
(4) Filed as an exhibit with Amendment No. 3 to the Registrant's Registration Statement on Form S-1 (File No. 333-175080) on October 31, 2011.

(5) Filed as an exhibit with the Registrant's Annual Report on Form 10-K on March 15, 2012.
(6) Filed as an exhibit with the Registrant's Registration Statement on Form S-1 (File No. 333-180293) on March 23, 2012.
(7) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on November 19, 2013.
(8) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on September 9, 2014.
(9) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on August 12, 2015.
+ Indicates management contract or compensatory plan.
* Confidential treatment has been granted with respect to portions of this exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission.