Clovis Oncology, Inc.
Form 10-K
March 14, 2013
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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, 2012.**

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

**For the transition period from to .**

**Commission file number: 001-35347**

# Clovis Oncology, Inc.

**(Exact name of Registrant as specified in its charter)**

| Delaware | 90-0475355 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| 2525 28th Street, Suite 100 | |
| Boulder, Colorado | 80301 |
| (Address of principal executive offices) | (Zip Code) |

(303) 625-5000

(Registrant s telephone number, including area code)

**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 ¨ No x

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. x

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

| | |
|---|---|
| Large accelerated filer ¨ | Accelerated filer x |
| 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 29, 2012, the last business day of the registrant s most recently completed second quarter, was approximately $248,179,524 based on the closing price of the registrant s common stock on the NASDAQ Global Market on that date of $21.68 per share.

The number of outstanding shares of the registrant s common stock, par value $0.001 per share, as of March 11, 2013 was 26,215,503.

**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 2013 Annual Meeting of Stockholders, which is to be filed within 120 days after the end of the registrant s fiscal year ended December 31, 2012, 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 thereon or 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 preclinical studies and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.*

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

*Any forward-looking statements that we make in this 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 refer to Clovis Oncology, Inc.*

## 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 additional international markets. We target our development programs for the treatment of specific subsets of cancer populations, and seek to simultaneously develop, with partners, companion diagnostics that direct our product candidates to the patients that are most likely to benefit from their use. We currently have two clinical development programs and one drug discovery program underway: **CO-1686**, an oral epidermal growth factor receptor (EGFR), mutant-selective covalent inhibitor that is currently the subject of a development program for the treatment of non-small cell lung cancer (NSCLC), in patients with activating EGFR mutations, as well as the primary resistance mutation, T790M; **rucaparib**, an oral inhibitor of poly (ADP-ribose) polymerase (PARP), currently the subject of a development program for ovarian cancer patients with BRCA mutations and other DNA repair deficiencies; and lastly, our **mutant cKit inhibitor discovery program**, targeting the resistance mutations that occur in the majority of gastrointestinal stromal tumor (GIST) patients and result in disease progression. We hold global development and commercialization rights for each of our programs.

On November 12, 2012, we reported results from a pivotal study in metastatic pancreatic cancer of CO-101, our lipid-conjugated form of the anti-cancer drug gemcitabine. In this study, CO-101 failed to demonstrate a difference in overall survival as compared to gemcitabine. Based on the results of the study, we ceased further development of CO-101.

We believe that discovery productivity exceeds development capacity in oncology, and we have built our organization to meet the need for innovative patient-specific oncology drug development. 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. As our product candidates mature, we intend to build our own commercial organizations in major global markets and partner with local distributors in smaller markets.

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The most common anti-cancer drug therapies typically address cancers within a specific organ as a single disease as opposed to a collection of different disease subtypes, often resulting in poor response rates and minimal effect on overall survival. We believe the oncology community is increasingly recognizing that tumors in a particular organ have unique pathologic and molecular characteristics that may warrant different treatment strategies. By better understanding differences in tumor biology and underlying disease pathways, researchers are identifying biomarkers to guide development of targeted oncology therapies, with streamlined clinical trials, stratified patient populations and improved patient outcomes. We believe that targeted therapies and companion diagnostics offer a patient-tailored approach to the treatment of cancers with improved diagnosis and outcomes.

**Our Strategy**

Our strategy is to acquire, develop, and commercialize innovative anti-cancer agents in the United States, Europe and additional international markets in oncology indications with significant unmet medical need. The critical components of our business strategy include the following:

***Focus on oncology***. The oncology market is characterized by a number of disorders with high rates of recurrence and a limited response from current therapies or treatments. Many of these therapies include severe side effects. New oncology product candidates addressing unmet medical needs or providing superior safety profiles are frequently the subject of expedited regulatory reviews and, if approved, can experience rapid adoption rates. We believe that the increasing role of targeted therapies and companion diagnostics to identify selected patient subsets in oncology presents the potential for improved patient outcomes.

***Focus on compounds where improved outcomes are associated with specific biomarkers.*** Our licensing strategy to date has been to prioritize opportunities in which a strong biological hypothesis has been established linking a specific characteristic or biological state of a cell, or biomarker, with improved outcomes for the product candidate. As evidenced by the proliferation of studies focused on the biomarkers of specific cancers, significant progress has been made over the last several years in the identification of molecular targets and pathways that more narrowly specify the causes of cancer and the variation in responses to different therapies experienced by patient subsets with a particular cancer or tumor type. In certain cases, the underlying science has progressed to the point that subset patient populations deriving little or no benefit from existing therapies can be identified and targeted by newly-developed therapies, such as our product candidates. We believe that the identification of such subsets, and the correlation of their specific characteristics to the drug under development, should increase the clinical benefit to targeted patients and the probability of success in our clinical trials. Such patient identification should also enable us to design clinical trials that may be completed more rapidly than has traditionally been the case, and, if successful, to achieve clinical outcomes for the targeted group that are sufficiently attractive to support the risk/benefit metrics of healthcare payors.

***Combine companion diagnostics with drug development efforts to realize superior clinical outcomes***. A companion diagnostic is a test or measurement intended to assist physicians in making treatment decisions for their patients. Companion diagnostics do so by identifying the presence of biomarkers, and physicians use this information to select a specific drug or treatment to which their patient will most likely respond. Our development strategy is based on the premise that we can utilize effective companion diagnostics to identify different subsets of patients who we believe will uniquely benefit from our product candidates. We are partnering to develop these companion diagnostics for use in the clinical development and ultimate commercial utilization of our product candidates. Because we do not develop diagnostics internally, we are able to select from among all available technologies when choosing a partner for our programs under development. This flexibility allows us to choose the most appropriate partner and diagnostic platform for each program under development and affords us the best chance of clinical success. We have partnered with experienced diagnostic companies that we believe have the ability and commitment to gain the required regulatory approvals and support global commercialization for these companion diagnostics.

***Manage and control global development activities and regulatory operations.*** We believe our development and regulatory experience enables us to devise time- and cost-efficient strategies to develop and obtain regulatory approvals for new drugs, and to identify the regulatory pathway that allows us to get a product candidate to market as quickly as possible. Unlike many early-stage biotechnology and pharmaceutical companies that have development or regulatory capabilities only in the country

in which they are located, we have assembled an experienced team with a successful track record at managing global clinical development activities, and possesses multinational expertise in obtaining regulatory approvals for new drugs and in maintaining compliance with the regulations governing the sales, marketing and distribution of pharmaceutical products. We believe we can manage a global development program without local partners. We manage critical functions in house, including clinical development, biostatistics, pharmaceutical development, molecular diagnostics and clinical and regulatory operations, and we outsource certain activities where economically and strategically appropriate.

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***Seek and maintain global commercial rights.*** We believe that it is very important to maintain global rights to our product candidates, and that we can build our own commercial organizations in major pharmaceutical markets as well as a network of third-party distributors in smaller markets. We believe there are a relatively small number of oncologists practicing in each of the major pharmaceutical markets and an even smaller number of oncology opinion leaders who significantly influence the types of drugs prescribed in cancer therapy. We therefore believe that we can effectively reach the oncology markets with a relatively small sales and marketing organization focused on these physicians and oncology opinion leaders. As a result, we plan to maintain commercial autonomy and will not require a pharmaceutical partner for commercialization activities. By managing the global sales and marketing of our products on our own, we believe we can provide uniform marketing programs and consistent product positioning, pricing and labeling. Finally, by controlling commercial activities ourselves in major markets, we will retain the vast majority of the revenues from our product candidates.

**Product Candidates**

Consistent with our strategy, we hold global rights for each of our product candidates and are developing them for selected patient subsets. The following table summarizes the status of our pipeline:

***CO-1686 - an Oral EGFR Mutant-Selective Inhibitor***

*Overview*

CO-1686 is a new chemical entity we in-licensed in May 2010 from Avila Therapeutics, Inc., a privately-held biotechnology company which was acquired by Celgene Corporation in March 2012. It is a novel, oral, small molecule selective covalent inhibitor of the cancer-causing mutant forms of EGFR for the treatment of NSCLC. Because CO-1686 targets both the initial activating EGFR mutations as well as the primary resistance mutation, T790M, it has the potential to treat NSCLC patients with EGFR mutations both as a first-line or second-line therapy. According to a study published in *Clinical Cancer Research* in 2008, EGFR initiating activating mutations occur in approximately 10% to 15% of NSCLC cases in Caucasian patients and approximately 30% to 35% of NSCLC cases in East Asian patients. Based on multiple published reports, including a study in *Nature Reviews Cancer* in 2007, following treatment with Tarceva® (erlotinib) or Iressa® (gefitinib), approximately half of these patients experience disease progression due to the emergence of a secondary EGFR mutation known as the T790M mutation. In January 2012, our IND to begin clinical investigation of CO-1686 became effective, and we initiated our first Phase I/II study of CO-1686 in the U.S. and Europe in the first quarter of 2012.

*Market Overview: Resistance to EGFR Tyrosine Kinase Inhibitors, or TKIs, Represents an Unmet Medical Need*

*Lung Cancer and EGFR TKIs.* According to the American Cancer Society, there were an estimated 223,000 new cases of lung cancer in the United States in 2010, making it the most common type of cancer. In addition, according to Cancer Research UK, there are an estimated 288,000 new cases of lung cancer in the European Union each year and, according to a white paper entitled Cancer White Paper Incidence/Death/Prognosis 2004 (Shinoharashinsha Inc.), there are an estimated 85,000 new cases in Japan each year. Lung cancer typically presents relatively late in its clinical course, when locally-directed therapy (surgery and radiation) is not curative.

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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, and can be subdivided into further histologic subsets, with adenocarcinoma, bronchioalveolar, squamous cell, anaplastic and large cell being the most common. Until recently, treatment was similar for all of these subsets. 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, specifically for non-squamous cell, 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 24% and 4%, respectively, according to the Survival Epidemiology and End Results program of the National Cancer Institute.

Approximately 10 years ago, orally active small molecule inhibitors of the tyrosine kinase activity of EGFR were introduced into the treatment of lung cancer. The growth-promoting EGFR was known to be frequently expressed on lung cancer cells, often at high levels, and preclinical work had suggested that EGFR TKIs, such as gefitinib and erlotinib, could provide effective cancer therapy in certain patient subsets. Clinical trials were conducted in humans with NSCLC and the drugs were approved by the FDA in 2003 (Iressa ® (gefitinib)) and 2004 (Tarceva ® (erlotinib)) for patients who had failed to respond to conventional chemotherapy. It was noted in a study published in *Nature Reviews Cancer* in 2010 that a small subset of patients experienced profound tumor responses to TKI therapy.

In 2004, it was discovered that the subset of NSCLC patients who experienced dramatic clinical responses to the 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 have suggested that the majority, if not all, of their therapeutic benefit can be attributed to the subset of patients with activating EGFR mutations. Recent clinical trials have shown that for patients with activating EGFR mutations, treatment with TKIs is superior to standard cytotoxic chemotherapy as it has resulted in superior progression free survival and improved quality of life. Consequently, many cancer therapy guidelines (National Comprehensive Cancer Network and American Society for Clinical Oncology) suggest that patients with adenocarcinoma histology NSCLC should undergo genetic testing for EGFR mutations and TKIs should be used in those patients with identified activating mutations. Molecular testing of NSCLC tissues for EGFR mutations has become standard across many countries, although no specific diagnostic test is included in the regulatory labels for any of the approved TKIs to date, although submissions were made in 2012 that may remedy this situation.

*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 have shown that approximately 50% 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.

An early approach to therapy for this important resistance mutation was to develop covalent inhibitors, drugs that bind irreversibly through a covalent bond to their receptor target, and permanently inactivate it. There is a specific location on the EGFR protein, a cysteine residue, that is close to the protein s active site, and is where most covalent drugs bind to in order to achieve their inhibitory effect. We are aware of two product candidates currently in clinical development that bind to this cysteine residue in EGFR, which are referred to as second generation TKIs. Both drugs have been tested in patients with the T790M mutation in their EGFR, but no responses have been reported to date. We believe the likely explanation for this effect is that these drugs are extremely potent inhibitors of the normal form of the EGFR, and cause very substantial toxicity in the skin (rash) and intestine (diarrhea) which limits dosing significantly. Patients appear to be unable to tolerate the dose of drug needed to inhibit the T790M mutant EGFR in a lung tumor. Consequently, at present, patients who develop TKI resistance receive standard cytotoxic chemotherapy that carries toxicity and only modest palliative efficacy, and all patients will ultimately succumb to their disease. Thus, patients with mutant EGFR-related NSCLC who also carry the T790M mutation represent a defined subset of patients with a clear unmet medical need.

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*Opportunity for Clovis*

We partnered with Avila to discover and develop an oral, small molecule selective covalent inhibitor of the mutant forms of EGFR that does not bind potently to unmutated or normal EGFR. We identified CO-1686 as a potential product candidate because it has three important potential advantages:

- it has the potential to effectively treat NSCLC patients with T790M mutant EGFR, a large number of patients for whom there is no effective therapy;
- it has the potential to effectively treat patients with initial activating EGFR mutations who receive first-generation TKIs but develop resistance due to the acquired T790M mutation; CO-1686 would be expected to prevent resistance through this mechanism and may thus result in responses of greater duration than seen with first-generation TKIs and extend progression-free survival; and
- at therapeutic doses, it would not be expected to inhibit normal EGFR in skin or intestine, and thus would be less likely to cause skin rash and diarrhea, which are dose-limiting toxicities associated with all other EGFR inhibitors.

*Design of CO-1686 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.

Covalent drugs have been developed by the pharmaceutical industry for decades, with several successfully commercialized, including Nexium®, Plavix ® and penicillins. However, these drugs were not intentionally designed to be covalent drugs. CO-1686 was developed using a proprietary platform to purposefully and systematically design and develop targeted covalent inhibitors.

There are a number of drugs both on the market and being developed that inhibit various kinases, including EGFR. Because kinases are structurally similar to each other, it is difficult to design small molecules that selectively inhibit a single kinase that do not also inhibit other kinases to some degree. Most kinase inhibitors are only modestly selective and inhibit a variety of kinases; these are typically referred to as multi-kinase inhibitors.

However, because of the design of its bond-forming capability, a targeted covalent drug is potent against the disease target of interest, including EGFR, and due to its selectiveness, it is not potent against other targets, even related targets. This is important to avoid undesired off-target side effects which can occur with reversible small molecules, such as multi-kinase inhibitors which are not highly selective.

CO-1686 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.

*Preclinical Development*

CO-1686 has demonstrated up to 200-fold greater binding selectivity for EGFR activating mutations and the T790M resistance mutation relative to the normal receptor when evaluated *in vitro*. Binding to normal EGFR can cause significant side effects, such as rash and diarrhea, which have been observed upon treatment with first- and second-generation EGFR inhibitors. Furthermore, experiments have been conducted in which human tumor tissue or cells have been implanted in mice or rats. These experiments, known as xenograft models, have demonstrated that CO-1686 can lead to tumor regression in two relevant models of EGFR-driven lung cancer tumors. The H1975 model employs tumors that contain both the L858R activating EGFR mutation and the T790M resistance mutation. This model represents EGFR-driven NSCLC that is resistant to first generation TKIs such as erlotinib and gefitinib. Use of CO-1686 in this model demonstrated a dose response with drug activity

at doses of 30mg/kg and greater activity at doses of 100mg/kg. In addition, because CO-1686 was designed to spare the normal EGFR receptor, the drug was well tolerated at all dose levels with no apparent body weight loss in the mice, which is a surrogate measure for intestinal toxicity.

*Clinical Development*

We have designed an accelerated clinical development program for CO-1686, and if successful, our goal is to file an NDA for an initial indication in 2016. We intend to pursue the development of CO-1686 as both a second-line 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. In January 2012, our IND to begin clinical investigation of CO-1686 became effective. We initiated our first Phase I/II study of CO-1686 in the U.S. and Europe in the first quarter of 2012. Data from this study will be used to determine the tolerability and pharmacokinetics of CO-1686, as well as provide evidence of efficacy in selected NSCLC patients with the T790M mutation. We are currently in the dose escalation portion of the Phase I/II study, and once we have established the recommended dose and schedule for CO-1686 we will proceed into two planned Phase II expansion cohorts of the study. These will test the efficacy of CO-1686 in two selected patient subsets: NSCLC patients with the T790M mutation immediately after progression on TKI therapy; and first-line NSCLC patients with confirmed EGFR mutations. If initial data from the second-line cohort are encouraging, we expect to commence a single-arm pivotal study in T790M positive NSCLC patients during the first half of 2014. The primary endpoint of this study will be disease response rate, and pending positive data, we would expect to submit an NDA to the U.S. FDA in 2016. In addition, if the data from the ongoing Phase I/II study are positive, we may initiate a study comparing CO-1686 to erlotinib and gefitinib as a first-line therapy for NSCLC patients with activating mutations of EGFR.

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To date, we have used a freebase capsule formulation of CO-1686, which is simply active drug in a capsule form, in our clinical study. We are currently developing a hydrobromide salt tablet formulation of CO-1686, which we intend to use in our pivotal studies for CO-1686. In animal models, this salt formulation has demonstrated much better exposure levels as compared to the freebase formulation. If we successfully complete the development of the salt formulation, we anticipate that the human dose of the salt will be lower than we are currently exploring with the freebase formulation.

Concurrent with our drug development program, we are collaborating with Roche Molecular Systems (RMS) for the development of a companion diagnostic to enable identification of patients with the T790M mutation. The eventual goal of the collaboration is to commence a pivotal trial of CO-1686 in patients selected for the T790M mutation using a PCR-based tool. The diagnostic test is being developed in parallel with the clinical development of CO-1686, with the 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 CO-1686 would be approved.

***Rucaparib - a PARP Inhibitor***

*Overview*

Rucaparib is a new chemical entity we in-licensed from Pfizer Inc. in June 2011. Rucaparib is a novel, oral, small molecule poly (ADP-ribose) polymerase, or PARP, inhibitor that is currently being explored in Phase I/II clinical trials for ovarian and breast cancer patients with BRCA mutations and other DNA repair deficiencies.

Rucaparib is currently in the dose escalation portion of a Phase I/II monotherapy study in the U.S. and U.K. to determine the appropriate dosing schedule for the drug. The Phase II portion of the study will assess preliminary efficacy in patients with ovarian cancer, including in patients with hereditary, or germ-line, mutations in BRCA genes. We also have an ongoing clinical trial to determine the maximum tolerated dose of rucaparib that can be combined with intravenous, or IV, platinum chemotherapy in the treatment of solid tumors. These clinical studies are supplemented by two ongoing investigator-initiated trials: a Phase I/II monotherapy study in germ-line BRCA mutant breast and ovarian cancer and a Phase II randomized study of the chemotherapy drug cisplatin, with or without rucaparib, in the adjuvant treatment of high-risk germ-line BRCA mutant and triple-negative breast cancer, a particularly difficult to treat form of breast cancer. We plan to initiate, by the end of 2013, a pivotal study of rucaparib as maintenance therapy for ovarian cancer patients who have responded to platinum-based chemotherapy treatment.

We are also collaborating with Foundation Medicine, Inc. for the development of a companion diagnostic utilizing next-generation sequencing to identify germ-line as well as somatic BRCA mutations and other DNA repair deficiencies to identify patients most likely to benefit from rucaparib.

*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) (PAR) 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.

As small molecule inhibitors of PARP became available, they were tested for their ability to inhibit DNA damage repair and potentiate the effects of radiation or cytotoxic chemotherapy, and were shown to be potent enhancers of these anti-cancer therapies in preclinical studies. Subsequently, PARP inhibitors have been explored in clinical trials as chemopotentiators, often in combination with drugs that add alkyl groups to DNA, such as temozolamide. Results to date have demonstrated anti-cancer activity, but have clearly demonstrated the need for patient

selection in order to show compelling data.

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*Synthetic Lethality*

A large advance in the field came when it was recognized that germ-line 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 advanced that 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 a study conducted by H. Farmer, et al., published in *Nature* in 2005 to be true *in vitro*, and then, in a study conducted by Peter C. Fong, M.D. et al., published in the *New England Journal of Medicine* in 2009, it was shown to be valid in humans, as evidenced by women with advanced breast and ovarian cancer and germ-line BRCA mutations experiencing objective tumor responses when treated with monotherapy PARP inhibitors.

Germ-line and somatic BRCA mutations are a minority subset of all breast and ovarian cancers, representing approximately 20-25% of those cancers, and the hypothesis was explored that some tumors might have defective DNA repair function for reasons other than germ-line (hereditary) or somatic (acquired) gene mutation. This notion has been called BRCA-ness. Subsequent work has shown that BRCA-ness exists, and that cancer patients with normal BRCA genes can respond to monotherapy with PARP inhibitors. Work is underway to identify a molecular signature for BRCA-ness that could enable patient selection for therapy. As a complement to the work to identify a BRCA-ness signature, clinical criteria have been developed to identify patients likely to respond to PARP inhibitors. If the notion of synthetic lethality is accepted, then PARP inhibitors should work well in patients with pre-existing defective DNA repair in their tumors. Defective DNA repair in a tumor would likely mean that the tumor is responsive to DNA-damaging chemotherapy, since the therapeutic DNA damage that triggers apoptosis cannot be effectively repaired by the tumor cell. Platinum chemotherapy drugs are a good example of one such DNA-damaging agent. To examine the hypothesis that platinum-sensitive tumors will respond to PARP inhibition, ovarian cancer patients have recently been studied since ovarian cancer typically responds well to initial platinum-based chemotherapy, although relapses are expected after several months. Data from a study conducted by Jonathan Ledermann, M.D., et al., published in the *New England Journal of Medicine* in 2012 demonstrated that in women with advanced ovarian cancer who have responded twice to platinum chemotherapy, maintenance therapy with an oral PARP inhibitor approximately doubled the time until disease progression versus a placebo-treated arm. This study was not conducted in all ovarian cancer subtypes, but specifically in high-grade serous ovarian cancer (HGSOC). According to the National Cancer Institute, there are approximately 22,000 new cases of ovarian cancer each year, and according to *Cancer*: *Principles and Practice of Oncology* (7th Edition, 2005), HGSOC accounts for approximately 90% of ovarian cancers.

*Rucaparib Development Strategy*

Initial clinical development of rucaparib was done by Pfizer using an IV formulation of the drug. Following the completion of a Phase I study to identify the dose of rucaparib to be used in combination with the chemotherapy drug temozolomide, or TMZ, a Phase II study was performed to evaluate the efficacy of rucaparib plus TMZ in patients with metastatic melanoma. Forty-six patients were treated in this study, and 34% of the patients achieved a partial response or stable disease of at least 24 weeks. The most common adverse events for the rucaparib and TMZ combination were gastrointestinal, including nausea and vomiting.

Based upon the basic science observations and clinical data for PARP inhibitors described above, we intend to initially develop the oral formulation of rucaparib as a monotherapy treatment for ovarian cancer patients with BRCA mutations or other DNA repair deficiencies. This development approach will require a patient selection strategy, and we have entered into a collaboration with Foundation Medicine, Inc. to develop a companion diagnostic for rucaparib. The goal of the collaboration is to develop an in-vitro diagnostic to identify biomarkers to select cancer patients most likely to respond to rucaparib, more specifically, to identify the genetic mutations in addition to those in germ-line and somatic BRCA that are associated with defective DNA repair that may define appropriate tumor targets for rucaparib. If successful, this work has the potential to increase the percentage of HGSOC patients eligible for rucaparib therapy from the approximately 20-25% typically found to have germ-line or somatic BRCA mutations to an estimated 40-50% who have certain DNA repair deficiencies, also known as homologous recombination deficiencies (HRD), caused by somatic mutations in a variety of genes.

In 2011, we commenced development efforts for rucaparib with the objective of identifying the optimal dose and schedule for oral rucaparib as monotherapy. Our Phase I/II monotherapy study is currently in the dose escalation phase, and we expect to identify a Phase II/III recommended dose by mid 2013. Once the appropriate dose and schedule has been determined, we intend to expand this study to enroll selected ovarian cancer patients to assess the efficacy of rucaparib in this patient population.

We plan to initiate two additional rucaparib trials during the second half of 2013. First, we intend to initiate a Phase II HRD biomarker study in women with relapsed, platinum-sensitive HGSOC. Both archived and current tumor samples will be collected from patients and will be DNA sequenced. The patients response to rucaparib will be assessed and those clinical responses will be correlated to patient genotypes, including germ-line BRCA mutant, somatic BRCA mutant, and other non-BRCA mutations identified through the genetic diagnostic sequencing. These data will be utilized to inform the definition of HRD for our pivotal study, which we intend to initiate in late 2013.

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In this Phase III study, rucaparib will be evaluated as maintenance therapy for HGSOC patients who have responded to platinum-based therapy and in their most recent therapy, demonstrated a complete or partial response. Patients will be randomized to receive either placebo or rucaparib and the primary endpoint of the study will be progression-free survival (PFS). The primary efficacy analysis will evaluate the following subgroups, in an ordered step-down procedure: mutant BRCA patients; all HRD patients (including BRCA and non-BRCA); and all patients.

Rucaparib is also the subject of an additional ongoing company-sponsored clinical trial to determine the maximum tolerated dose of oral rucaparib that can be combined with a platinum chemotherapy in the treatment of solid tumors. Our rucaparib clinical development plan is supplemented by two investigator-sponsored trials of rucaparib. One is a Phase I/II monotherapy trial in the treatment of germ-line BRCA mutation breast and ovarian cancer; the second is a Phase II randomized trial in the adjuvant treatment of patients with high-risk germ-line BRCA-defective breast cancer and triple-negative breast cancer. In both of these studies, we have transitioned from the IV formulation to the oral dosage form for monotherapy, although the latter trial continues with IV formulation of rucaparib during the platinum-combination dosing period.

***Mutant cKIT Inhibitor Discovery Program***

We have a drug discovery agreement with Array BioPharma Inc. for the discovery of a novel inhibitor of the receptor tyrosine kinase KIT targeting the resistance mutations that occur in the majority of gastrointestinal stromal tumor (GIST) patients and result in disease progression. Our goal is to identify a lead compound in late 2013 or early 2014. In the event a clinical candidate is identified, we are solely responsible for all aspects of the pre-clinical and clinical development and commercialization, including development of a companion diagnostic to prospectively identify patients with specific KIT mutations.

GIST is a gastrointestinal cancer diagnosed each year in more than 12,000 patients in the US and EU and 2,500 in Japan. Currently approved therapies for GIST include tyrosine kinase inhibitors (TKIs), typically used first- and second-line, which inhibit some KIT mutations, but acquired resistance due to secondary KIT mutations occurs in the majority of GIST patients, resulting in disease progression. Exon 17 resistance mutations are considered the most difficult to treat, and typically emerge after other TKI therapy in at least 50 percent of patients with progressive disease. None of the currently-approved therapies inhibit exon 17 mutations, nor do the current development-stage drugs targeting GIST. The goal of our collaboration is to discover a potent, oral inhibitor of KIT mutations, including all exon 17 resistance mutations.

**Competition**

The development and commercialization of new drugs is competitive and we will 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.

***CO-1686 Competition***

Tarceva® and Iressa® are two of the currently approved drugs that are used to treat EGFR mutant NSCLC. In addition, we are aware of five products in development targeting cancer-causing mutant forms of the epidermal growth factor receptor (EGFR), for the treatment of NSCLC patients. These products include, Boehringer Ingelheim s BIBW-2992 (afatinib), which has been submitted for approval to the FDA and EMA, Pfizer s PF-299804 (dacomitinib), currently in Phase III trials, Ariad s AP26113, currently in Phase I trials, Taiho s TAS-2913, currently in preclinical development and Hanmi Pharmaceutical s HM61713, currently in Phase I trials. We believe CO-1686 potentially offers several important advantages over the second-generation EGFR inhibitors, including superior efficacy due to activity against the T790M resistance mutation and higher selectivity for the T790M mutation with relative sparing of normal EGFR, therefore avoiding the significant skin rash and gastro-intestinal toxicities associated with other first- and second-generation inhibitors, including Tarceva and Iressa.

***Rucaparib Competition***

There are currently no approved drugs that target the PARP pathway. However, there are a number of PARP inhibitors in clinical development including Abbott s ABT-888 (veliparib) currently in Phase II clinical trials, Tesaro s niraparib, currently in Phase I trials, Eisai s E-7016, currently in Phase II trials, Biomarin s BMN-673, currently in Phase I/II trials and Astra Zeneca s olaparib, currently in Phase II trials.

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**License Agreements**

***Avila Therapeutics, Inc.***

In May 2010, we entered into an exclusive worldwide license agreement with Avila (now part of Celgene Corporation) to discover, develop and commercialize a covalent inhibitor of mutant forms of the EGFR gene product discovered by Avila and selected by us. As a result of the collaboration contemplated by the agreement, CO-1686 was identified as the lead inhibitor candidate which we are proceeding to develop under the terms of the license agreement. Under the agreement, we are required to use commercially reasonable efforts to develop and commercialize CO-1686, and we are responsible for all preclinical, clinical, regulatory and other activities necessary to develop and commercialize CO-1686. We made an up-front payment of $2.0 million to Avila upon execution of the license agreement and an additional $4.0 million payment upon the acceptance of the IND for CO-1686, both of which were recognized as acquired in-process research and development expenses. When and if commercial sales of CO-1686 commence, we will pay Celgene tiered royalties at percentage rates ranging from mid-single digits to low-teens based on annual net sales achieved. Celgene has the option to increase royalty rates on annual net sales in the United States and the European Union by electing to reimburse us for a share of our development expenses for CO-1686. This option must be exercised within a limited period of time of Celgene being notified by us of our intent to pursue regulatory approval of CO-1686 in the United States or the European Union as a first-line treatment. Under the agreement, we are required to make regulatory milestone payments to Celgene of up to $115.0 million if specified clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, we are obligated to make sales milestone payments to Celgene if specified annual sales targets for CO-1686 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 $120.0 million.

We have full sublicensing rights under the license agreement, subject to our sharing equally with Celgene any up-front 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 CO-1686 and an obligation to assign or license to Celgene any intellectual property rights or other rights we may have in CO-1686, including our regulatory filings, regulatory approvals, patents and trademarks for CO-1686.

***Pfizer Inc.***

In June 2011, we entered into a license agreement with Pfizer, 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 an up-front payment by issuing to Pfizer $7.0 million principal amount of a 5% convertible promissory note, which prior to becoming due was converted into shares of our common stock in connection with our initial public offering. 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 $89.0 million if specified clinical study objectives and regulatory filings, acceptances and approvals are achieved. 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.

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***Array BioPharma Inc.***

In July 2012, we entered into a drug discovery collaboration agreement with Array BioPharma Inc. for the discovery of a novel inhibitor of the receptor tyrosine kinase KIT targeting resistance mutations for the treatment of GIST, a gastrointestinal cancer. Under the terms of the agreement, we are responsible for funding all costs of the discovery program, as well as costs to develop and commercialize any clinical candidates discovered. If any clinical candidates are discovered and we seek to pursue clinical development of such clinical candidates, we may be required to pay Array up to an aggregate of $192.0 million in milestone payments if certain development and regulatory objectives and annual net sales targets are achieved. The agreement will remain in effect until the expiration of all of our clinical, regulatory and sales milestone obligations to Array, determined on a product-by-product and country-by-country basis, unless we elect to terminate the license agreement earlier. Array may terminate the agreement if we fail to meet our obligations under the agreement and are unable to cure such failure within specified time periods.

**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, or 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 preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA s Good Laboratory Practice, or GLP, 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, or API, and finished drug product are produced and tested to assess compliance with cGMP regulations; 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, or 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 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.

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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 II 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 preclinical 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 ten 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.

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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, preclinical 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, or REMS, 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, or 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.

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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 Committee for Medicinal Products for Human Use, or 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. An 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 an 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 an 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, or COMP, 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 5 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 7 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 6 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 dug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

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*Pediatric Development*

In the United States, the FDCA provides for an additional 6 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.

*Priority Review/Standard Review (United States) and Accelerated Review (European Union)*

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. 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. If criteria are not met for priority review, the NDA is subject to the standard FDA review period of 10 months. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

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, excluding clock stops.

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*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 approved. 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.

In 2003, the United States government enacted legislation providing a partial prescription drug benefit for Medicare beneficiaries, which became effective at the beginning of 2006. 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. Further, the Healthcare Reform Law substantially changes the way healthcare is financed in the United States by both government and private insurers. Among other cost containment measures, the Healthcare Reform Law establishes:

- An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;

- A new 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 new 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, an increasing emphasis on managed care 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.

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***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 Healthcare Reform Law, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b, effective March 23, 2010. 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 Healthcare Reform Law 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 healthcare program. 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 of $5,500 to $11,000 for each separate false claim.

Also, the Health Insurance Portability and Accountability Act of 1996, or 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, or 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, preclinical 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.

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PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, 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, or CDRH, at 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, or CDER, 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 for comment a draft guidance document addressing the development and approval process for In Vitro Companion Diagnostic Devices . According to the draft 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. While this draft guidance is not yet finalized, we believe our programs for the development of our companion diagnostics are consistent with the draft guidance as proposed.

In the 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.

We acquired an exclusive, worldwide license to CO-1686 from Avila in May 2010. Multiple patent applications are pending that claim CO-1686 generically and specifically (including with respect to composition of matter) that, if issued, would have expiration dates between 2029 and 2033.

We obtained an exclusive, worldwide license from Pfizer to develop and commercialize rucaparib in June 2011. 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 2022-2024 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, and various

salt and polymorphic forms have expiration dates ranging from 2020 through 2031.

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

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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, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the U.S. PTO or a foreign patent office to determine priority of invention, or in opposition proceedings in 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 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. To the extent prudent, we intend to bring litigation against third parties that we believe are infringing one or more of our patents.

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 an 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, or the 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 avoid infringing third-party patent and proprietary rights. 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.

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 preclinical studies and clinical trials and intend to do so in the future. We have not entered into long-term agreements with all of our current contract manufacturers. We currently obtain our supplies of 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.

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The active pharmaceutical ingredient for CO-1686 is currently being manufactured at a single third-party contract manufacturer. The current 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. Drug product formulation work for CO-1686 is in progress, including the development of a hydrobromide salt tablet formulation. We have engaged two third-party manufacturers capable of both formulation development and drug product manufacturing. Definition of an acceptable formulation and suitable manufacturing process to prepare that formulation are critical to the successful development of CO-1686.

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 third-party contract manufacturer. 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. Definition of an acceptable commercial formulation and suitable manufacturing process to prepare that formulation are critical to the successful development of rucaparib. 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.

**Sales and Marketing**

We intend to build the commercial infrastructure in the United States and Europe necessary to effectively support the commercialization of CO-1686 and rucaparib, if and when we believe a regulatory approval of the first of such product candidates in a particular geographic market appears imminent. 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 will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that CO-1686 or rucaparib will be approved.

Outside of the United States and Europe, we may elect in the future to utilize strategic partners, distributors, or contract sales forces to assist in the commercialization of our products.

**Employees**

As of March 12, 2013, we had 61 full-time employees. None of our employees is represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

**Research and Development**

We invested $58.9 million, $40.7 million, and $22.3 million in research and development in the years ended December 31, 2012, 2011 and 2010, 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 and a subsequent offering of common stock in April 2012. Our common stock is listed on the NASDAQ Global Select Market, under the symbol CLVS . Our principal executive offices are located at 2525 28th Street, Suite 100, Boulder, Colorado 80301, and our telephone number is (303) 625-5000. We maintain additional offices in San Francisco, California and Cambridge, UK. 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, or the 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 and information statements and other information regarding us and other issuers that file electronically with the SEC.

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**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. Because we were only recently formed, we have only a limited operating history upon which you can evaluate our business and prospects. In addition, as an early stage company, we have limited experience and 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, 2012, 2011 and 2010, we had net losses of $74.0 million, $55.6 million, and $37.8 million, respectively. As of December 31, 2012, we had an accumulated deficit of $184.5 million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase 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 in 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. We will require additional capital for the further development and commercialization of our product candidates, as well as to fund our other operating expenses and capital expenditures.

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. We may also seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available. Any of these events could significantly harm our business, financial condition and prospects.

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**Risks Related to Our Business and Industry**

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

To date, we have invested a significant portion of our efforts and financial resources in the acquisition and development of our product candidates. Our future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize such product candidates. Our product candidates 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 will require additional clinical development, management of clinical, preclinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization, and significant marketing efforts before we 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 United States Food and Drug Administration, or 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 our 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 we may commercialize our product candidates.

We have not previously submitted a New Drug Application, or NDA, to the FDA, or similar drug approval filings to comparable foreign authorities, for any product candidate, and 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 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 both in the United States, the European Union and in additional foreign countries. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply 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 preclinical 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 preclinical 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, or 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, or 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.

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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, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such 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.

Our product candidates could fail to receive regulatory approval 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 preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;

- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;

- the FDA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with partners; and

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. 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.***

Undesirable side effects caused by 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. To date, patients treated with rucaparib have experienced drug-related side effects such as nausea and vomiting. The clinical evaluation of CO-1686 is still in the early stages, but as is the case with all oncology drugs, it is likely that there may be side effects associated with its use. 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 side effects 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.

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***We rely on third parties to conduct our preclinical 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 preclinical and clinical programs. We rely on these parties for execution of our preclinical 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 current good clinical practices, or cGCP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the European Medicines Agency, or 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 cGCP regulations. In addition, our clinical trials must be conducted with product produced under current good manufacturing practices, or cGMP, 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, nonclinical and preclinical 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 impact 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 impact 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 cGMP 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 impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

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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 for 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 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 impact upon our business. We currently obtain our supplies of finished drug product through individual purchase orders.

***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, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, 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 cGMPs and cGCPs 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 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 policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

***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;

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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 of treatment 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, health care 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, Tarceva® and Iressa® are two of the currently approved drugs that are used to treat EGFR mutant NSCLC, and in addition, we are aware of five products in development targeting EGFR for the treatment of NSCLC: Boehringer Ingelheim s BIBW-2992 (afatinib) and Pfizer s PF-299804 (dacomitinib), Ariad s AP26113, Taiho s TAS-2913, and Hanmi Pharmaceutical s HM61713. Also, we believe the products in development targeting the PARP pathway consist of Abbott s ABT-888 (velaparib), Tesaro, Inc. s niraparib, Eisai s E-7016, Teva s CEP-9722, Biomarin s BMN-673, and Astra Zeneca s olaparib.

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 impact 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 health care 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.

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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. 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 impact 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 Healthcare Reform Law, was enacted. The Healthcare Reform Law substantially changes the way healthcare is financed by both governmental and private insurers. Such government-adopted reform measures may adversely impact 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.***

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, Andrew R. Allen, our Executive Vice President of Clinical and Pre-Clinical Development and Chief Medical Officer, Steven L. Hoerter, our Senior Vice President of Commercial, and Gillian C. Ivers-Read, our Executive Vice President of Technical Operations and Chief Regulatory Officer, whose services are critical to the successful implementation of our product candidate acquisition, development and regulatory strategies. We are not aware of any present intention of any of these individuals to leave our company. 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.

Despite our efforts to retain valuable employees, members of our management, scientific and development 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, other than those with our executive officers, 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. 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.

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. 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.

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***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 impact 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 impact, 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;

- the federal Health Insurance Portability and Accountability Act of 1996, or 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 the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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

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

decreased demand for our product candidates or products that we may develop;

injury to our reputation;

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;

product recalls, withdrawals or labeling, marketing or promotional restrictions;

loss of revenues from product sales; and

the inability to commercialize our product candidates.

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 currently carry $10.0 million of product liability insurance, which we believe is adequate for our clinical trials. 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 business and operations would suffer in the event of system failures.***

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 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 drug development programs. 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.

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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, or the U.S. PTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

With respect to rucaparib, we have an exclusive, worldwide license from Pfizer to a portfolio of patents and patent applications directed to the rucaparib composition of matter that expire in 2020. While patent term extensions under the Hatch-Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend our patent exclusivity for rucaparib, we cannot provide any assurances that any such patent term extension will be obtained.

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 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 may be third-party patents of which we are currently unaware 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.

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***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 CO-1686 , 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 CO-1686. While we have the right to jointly prosecute and maintain the patent rights for the composition of matter for CO-1686, 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.

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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**

***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. Since our initial public offering in November 2011 the price of our common stock on the NASDAQ Global Select Market has ranged from $11.19 per share to $27.55 per share. In addition to the factors discussed in this Risk Factors section and elsewhere in this report, these factors include:

our failure to 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;

adverse regulatory decisions;

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;

our dependence on third parties, including CROs as well as our partners that provide us with companion diagnostic products;

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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 impact on the market price of our common stock.

***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 61.9% of our voting stock as of December 31, 2012. 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.

Certain holders of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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***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, 2012, the number of shares of our common stock available for future grant under our 2011 Stock Incentive Plan, or the 2011 Plan, is 1,669,894. 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.

***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.

***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 will depend 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 downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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**ITEM 1B. UNRESOLVED STAFF COMMENTS**
Not Applicable.

**ITEM 2. PROPERTIES**
Our offices are located at three leased facilities, a 14,892 square foot facility in Boulder, Colorado used primarily for corporate functions, a 19,234 square foot facility in San Francisco, California used for clinical development operations and research laboratory space, and a 1,350 square foot facility in Cambridge, United Kingdom used for our European regulatory and clinical operations. These leases expire in December 2015, April 2014, and May 2013, respectively. We believe that our existing facilities are sufficient for our needs for the foreseeable future.

**ITEM 3. LEGAL PROCEEDINGS**
We are not currently a party to any material legal proceedings.

**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 is traded on the NASDAQ Global Select Market under the symbol CLVS. Trading of our common stock commenced on November 16, 2011, following the completion of our initial public offering. 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, 2011** | | |
| Fourth Quarter (beginning November 16, 2011) | $ 14.85 | $ 11.45 |
| **Year Ended December 31, 2012** | | |
| First Quarter | $ 27.55 | $ 13.41 |
| Second Quarter | $ 25.18 | $ 16.91 |
| Third Quarter | $ 23.42 | $ 13.24 |
| Fourth Quarter | $ 23.34 | $ 11.19 |

On March 11, 2013, there were approximately 39 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.

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**Securities Authorized for Issuance Under Equity Compensation Plans**

**Equity Compensation Plan Information**

**As of December 31, 2012**

| | 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) |
|---|---|---|---|
| **Plan Category** | | | |
| **Equity compensation plans approved by security holders (1)(2)** | 1,599,044 | $ 14.05 | 2,108,103 |
| **Equity compensation plans not approved by security holders** | | | |
| **Total** | 1,599,044 | $ 14.05 | 2,108,103 |

(1) As of December 31, 2012, 2,473,592 shares were authorized for issuance under our 2011 Stock Incentive Plan, or the 2011 Plan, which became effective on November 15, 2011, the effective date of our initial public offering, including 178,112 remaining shares available for future issuance under the 2009 Equity Incentive Plan, or 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, 2012, 438,209 shares were reserved for issuance under our 2011 Employee Stock Purchase Plan, or ESPP, which became effective on November 15, 2011, the effective date of our initial public offering. 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.

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**Performance Graph**[1]

The following graph shows a comparison from November 16, 2011 through December 31, 2012 of cumulative total return on assumed investment of $100.00 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.

**COMPARISON OF ONE YEAR CUMULATIVE TOTAL RETURN**

**Among Clovis Oncology, Inc., the NASDAQ Cumulative Index, and the NASDAQ Biotechnology Index**

[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.*

**Recent Sales of Unregistered Securities**

Set forth below is information regarding certain shares of common stock and preferred stock issued by us within the past three years that were not registered under the Securities Act of 1933, as amended, which we refer to as the Securities Act. Also included is the consideration, if any, received by us for such shares and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

(1) On May 25, 2011, we sold $20,000,000 aggregate principal amount of our 5% convertible promissory notes due 2012 to accredited investors, for an aggregate purchase price of $20,000,000.

(2) On June 2, 2011, we sold $15,000,000 aggregate principal amount of our 5% convertible promissory notes due 2012 to Pfizer Inc., an accredited investor, $7.0 million of which were issued as consideration for the execution of our license agreement with Pfizer Inc. for rucaparib and $8.0 million of which were issued for an investment of $8.0 million of cash by Pfizer Inc.

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(3) From January 1, 2010 through November 15, 2011, we issued an aggregate of 351,888 shares of our common stock at prices ranging from $0.29 to $3.28 per share to certain of our employees and directors pursuant to the exercise of stock options under the Clovis Oncology, Inc. 2009 Equity Incentive Plan for an aggregate purchase price of $1,118,459.

(4) From January 1, 2010 through November 15, 2011, we granted options to purchase 1,073,341 shares of common stock to our employees and directors at a weighted average exercise price of $4.91 per share.

No underwriters were involved in the foregoing issuances of securities. The securities described in paragraphs (1) and (2) above were issued to accredited investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act, and, in certain cases, in reliance on Regulation D promulgated thereunder, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. The securities described in paragraph (3) and (4) above were issued pursuant to written compensatory plans or arrangements with our employees and directors in reliance on the exemption provided by Rule 701 promulgated under Section 3(b) of the Securities Act, or pursuant to Section 4(2) under the Securities Act, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. The certificates representing the issued shares of capital stock described above included appropriate legends setting forth that the applicable securities have not been registered and the applicable restrictions on transfer.

**Use of Proceeds from Sales of Registered Securities**

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-175080) that was declared effective by the Securities and Exchange Commission on November 15, 2011, which registered an aggregate of 11,500,000 shares of our common stock. On November 21, 2011, 10,000,000 shares of common stock were sold on our behalf at an initial public offering price of $13.00 per share, for aggregate gross proceeds of $130,000,000, managed by J.P. Morgan Securities LLC and Credit Suisse Securities (USA) LLC. On November 30, 2011, in connection with the exercise of the underwriters over-allotment option, 700,000 additional shares of common stock were sold on our behalf at the initial public offering price of $13.00 per share, for aggregate gross proceeds of $9,100,000. Following the sale of the 10,700,000 shares of common stock, the offering terminated.

We paid to the underwriters underwriting discounts and commissions of approximately $6.9 million in connection with the offering. In addition, we incurred expenses of approximately $2.8 million in connection with the offering, which when added to the underwriting discounts and commissions paid by us, amounts to total expenses of approximately $9.7 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and commissions and offering expenses, were approximately $129.4 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

As of December 31, 2012, we had used approximately $69.3 million of the net proceeds from our initial public offering to fund operations, capital expenditures, working capital and other general corporate purposes. The remainder of the proceeds have been invested into money market funds.

**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, 2012, 2011, 2010 and the period from April 20, 2009 (inception) to December 31, 2012 and the historical balance sheet data as of December 31, 2012 and 2011 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 period from April 20, 2009 (inception) to December 31, 2009 and the historical balance sheet date as of December 31, 2010 and 2009 have been derived from our audited financial statements that do not appear in this report.

The financial information presented from April 20, 2009 (inception) to December 31, 2010 is based solely on the results of Clovis Oncology, Inc. Subsequent to January 1, 2011, the financial information is consolidated and includes the results of our wholly owned subsidiary in the United Kingdom. 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.

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**Statement of Operations Data:**

| | Year Ended December 31, | | | Period from April 20, 2009 (Inception) to | Cumulative from April 20, 2009 (Inception) to |
|---|---|---|---|---|---|
| | 2012 | 2011 | 2010 | December 31, 2009 | December 31, 2012 |
| | (in thousands, except share and per share data) | | | | |
| Revenue | $ | $ | $ | $ | $ |
| Operating expenses: | | | | | |
| Research and development | 58,894 | 40,726 | 22,323 | 1,762 | 123,705 |
| General and administrative | 10,638 | 6,860 | 4,302 | 2,209 | 24,009 |
| Acquired in-process research and development | 4,250 | 7,000 | 12,000 | 13,085 | 36,335 |
| Operating loss | (73,782) | (54,586) | (38,625) | (17,056) | (184,049) |
| Other income (expense), net | (228) | (957) | 795 | (43) | (433) |
| Loss before income taxes | (74,010) | (55,543) | (37,830) | (17,099) | (184,482) |
| Income taxes | 27 | (27) | | | |
| Net loss | $ (73,983) | $ (55,570) | $ (37,830) | $ (17,099) | $ (184,482) |
| Basic and diluted net loss per common share | $ (2.97) | $ (14.42) | $ (28.55) | $ (15.38) | $ (22.15) |
| Common shares used in the computation of basic and diluted net loss per common share | 24,915 | 3,854 | 1,325 | 1,112 | 8,327 |

| | As of December 31, | | | |
|---|---|---|---|---|
| | 2012 | 2011 | 2010 | 2009 |
| | (in thousands) | | | |
| **Balance Sheet Data:** | | | | |
| Cash, cash equivalents and available for sale securities | $ 144,097 | $ 140,248 | $ 22,299 | $ 57,311 |
| Working capital | 132,712 | 130,519 | 19,886 | 57,349 |
| Total assets | 145,994 | 143,445 | 26,200 | 59,574 |
| Convertible preferred stock | | | 75,499 | 75,499 |
| Common stock and additional paid-in capital | 317,925 | 242,243 | 138 | 41 |
| Total stockholders equity (deficit) | 133,496 | 131,793 | (54,749) | (17,058) |

**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 additional international markets. We target our development programs for the treatment of specific subsets of cancer populations, and seek to simultaneously develop, with partners, companion diagnostics that direct our product candidates to the patients that are most likely to benefit from their use. We are currently developing two product candidates for which we hold global marketing rights: CO-1686, an orally available, small molecule epidermal growth factor receptor, or EGFR, covalent inhibitor that is in Phase I/II clinical development for the treatment of non-small cell lung cancer, or NSCLC, in patients with activating EGFR mutations, including the initial activating mutations, as well as the primary resistance mutation, T790M; and rucaparib, an orally available, small molecule poly (ADP-ribose) polymerase, or PARP, inhibitor being developed for various solid tumors that is currently in Phase I/II clinical trials. We have also entered into a drug discovery agreement for the discovery of a novel KIT inhibitor targeting resistance mutations for the treatment of GIST, a gastrointestinal cancer. If any clinical candidates are discovered, we would seek to pursue clinical development of such clinical candidates.

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We were incorporated in Delaware in April 2009 and commenced operations in May 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. We have generated no revenues and, through December 31, 2012, have principally funded our operations using the $75.5 million of net proceeds from the sale of convertible preferred stock, the issuance of $35.0 million aggregate principal amount of convertible promissory notes, and $199.3 million of net proceeds from public offerings of our common stock completed in November 2011 and April 2012. The convertible preferred stock and outstanding principal amount of the convertible promissory notes and all accrued and unpaid interest converted into shares of our common stock immediately prior to the closing of our initial public offering in November 2011.

We have never been profitable and, as of December 31, 2012, we had an accumulated deficit of $184.5 million. We incurred losses of $17.1 million, $37.8 million, $55.6 million and $74.0 million for the period from April 20, 2009 (inception) through December 31, 2009 and for the years ended December 31, 2010, 2011, and 2012, respectively. We expect to incur significant and increasing losses for the foreseeable future as we advance our product candidates through clinical development to seek regulatory approval and, if approved, commercialize such product candidates. We will need additional financing to support our operating activities. We will seek to fund our operations through public or private equity or debt financings or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We expect that research and development expenses will increase as we continue the development of our product candidates. We will need to generate significant revenues to achieve profitability and we may never do so.

The financial information presented from April 20, 2009 (inception) to December 31, 2010 was based solely on the results of Clovis Oncology, Inc. Subsequent to January 1, 2011, the financial information is consolidated and includes the results of our wholly owned subsidiary in the United Kingdom. All intercompany transactions and balances are eliminated in this consolidation.

**Product License Agreements**

***CO-101***

In November 2009, we entered into a license agreement with Clavis to develop and commercialize CO-101 in North America, Central America, South America and Europe. Under the terms of the license agreement, we made an up-front payment to Clavis in the amount of $15.0 million, which was comprised of $13.1 million for development costs incurred prior to the execution of the agreement, which we recognized as acquired in-process research and development and $1.9 million for the prepayment of preclinical activities to be performed by Clavis. In November 2010, the license agreement was amended to expand the license territory to include Asia and other international markets. We paid Clavis $10.0 million for the territory expansion and recognized that payment as acquired in-process research and development expense. As part of the amendment to the license agreement, Clavis agreed to reimburse up to $3.0 million of our research and development costs for certain CO-101 development activities subject to our incurring such costs. We are responsible for all remaining development and commercialization costs of the compound.

On November 12, 2012, the Company reported results from a pivotal study of CO-101 versus gemcitabine in metastatic pancreatic cancer, which failed to demonstrate a difference in overall survival between the two study arms. Based on the results of the study, the Company has ceased development of CO-101.

***CO-1686***

In May 2010, we entered into a worldwide license agreement with Avila (now part of Celgene Corporation) to discover, develop and commercialize a covalent inhibitor of mutant forms of the EGFR gene product. CO-1686 was identified as the lead inhibitor candidate developed by Avila under the license agreement. We are responsible for all preclinical, clinical, regulatory and other activities necessary to develop and commercialize CO-1686. We made an up-front payment of $2.0 million to Avila upon execution of the license agreement and an additional $4.0 million milestone payment in the first quarter of 2012 upon the acceptance by the U.S. Food and Drug Administration, or FDA, of our investigational new drug, or IND, application for CO-1686. We recognized both payments as acquired in-process research and development expense. We are obligated to pay royalties on net sales of CO-1686, based on the volume of annual net sales achieved. Celgene has the option to increase royalty rates by electing to reimburse a portion of our development expenses. This option must be exercised within a limited period of time after Celgene is notified by us of our intent to pursue regulatory approval of CO-1686 in the United States or the European Union as a first-line treatment. We may be required to pay up to an additional aggregate of $115.0 million in additional development and regulatory milestone payments if certain clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, we may be required to pay up to an aggregate of $120.0 million in sales milestone payments if certain annual sales targets are achieved.

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***Rucaparib***

In June 2011, we entered into a license agreement with Pfizer to acquire exclusive global development and commercialization rights to Pfizer s drug candidate PF-01367338, also known as rucaparib. This drug candidate is a small molecule PARP inhibitor which we are developing for the treatment of selected solid tumors. Pursuant to the terms of the license agreement, we made an up-front payment by issuing Pfizer $7.0 million principal amount of a 5% convertible promissory note due in 2012, which was subsequently converted to common stock immediately prior to our initial public offering. We are responsible for all development and commercialization costs of rucaparib and, if approved, we will be required to pay Pfizer royalties on sales of the product. In addition, we may be required to pay Pfizer up to an aggregate of $259.0 million in milestone payments if certain development, regulatory and sales milestones are achieved.

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 up-front payment of $250,000 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 sales of rucaparib.

***Drug Discovery Collaboration Agreement***

In July 2012, the Company entered into a drug discovery collaboration agreement with Array BioPharma Inc. for the discovery of a novel KIT inhibitor targeting resistance mutations for the treatment of GIST, a gastrointestinal cancer. Under the terms of the agreement, the Company is responsible to fund all costs of the discovery program, as well as costs to develop and commercialize any clinical candidates discovered. If any clinical candidates are discovered and the Company seeks to pursue clinical development of such clinical candidates, the Company may be required to pay Array up to an aggregate of $192.0 million in milestone payments if certain development and regulatory objectives and annual net sales targets are achieved.

**Financial Operations Overview**

***Revenue***

To date, we have not generated any revenues. In the future, we may generate revenue from the sales of product candidates that are currently under development. Based on our current development plans, we do not expect to generate significant revenues for the foreseeable future. If we fail to complete the 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 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 CROs and investigative sites that conduct our clinical trials and preclinical studies;
- the cost of acquiring, developing and manufacturing clinical trial materials;

costs associated with preclinical activities and regulatory operations; 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, 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.

Research and development activities are central to our business model. 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 CO-1686 and rucaparib product candidates and perform drug discovery activities for a novel KIT inhibitor targeting resistance mutations for the treatment of GIST.

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The following table identifies research and development costs and acquired in-process research and development costs on a program-specific basis for our product candidates in-licensed through December 31, 2012, their companion diagnostics, and the KIT inhibitor drug discovery program. 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, 2012 | Year Ended December 31, 2011 | Year Ended December 31, 2010 | Cumulative from April 20, 2009 (Inception) to December 31, 2012 |
|---|---|---|---|---|
| | | | (in thousands) | |
| **CO-101 Expenses** | | | | |
| Acquired in-process R&D | $ | $ | $ 10,000 | $ 23,085 |
| Research and development | 23,966 | 21,703 | 14,461 | 60,501 |
| CO-101 Total | 23,966 | 21,703 | 24,461 | 83,586 |
| **CO-1686 Expenses** | | | | |
| Acquired in-process R&D | 4,000 | | 2,000 | 6,000 |
| Research and development | 7,741 | 6,196 | 2,432 | 16,369 |
| CO-1686 Total | 11,741 | 6,196 | 4,432 | 22,369 |
| **Rucaparib Expenses** | | | | |
| Acquired in-process R&D | 250 | 7,000 | | 7,250 |
| Research and development | 8,953 | 2,861 | | 11,814 |
| Rucaparib Total | 9,203 | 9,861 | | 19,064 |
| **KIT Inhibitor Expenses** | | | | |
| Acquired in-process R&D | | | | |
| Research and development | 2,097 | | | 2,097 |
| KIT Inhibitor Total | 2,097 | | | 2,097 |
| Personnel and other expenses | 16,137 | 9,966 | 5,430 | 32,924 |
| Total | $ 63,144 | $ 47,726 | $ 34,323 | $ 160,040 |

***General and Administrative Expenses***

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

We anticipate that our general and administrative expenses will increase due to increased personnel expenses to support the growth in research and development activities.

***Other Income and Expense***

Other income is comprised of interest income earned on cash, cash equivalents and available for sale securities, gain on the sale of available for sale securities, and a federal grant awarded to us under the Qualifying Therapeutic Discovery Project Program in 2010. Other expense includes interest expense associated with the convertible notes payable outstanding during 2011. In addition, we hold cash balances at financial institutions denominated in currencies other than the U.S. dollar to fund research and development activities performed by various third-party vendors. The translation of these currencies into U.S. dollars results in foreign currency gains or losses, depending on the change in value of these currencies against the U.S. dollar. These gains and losses are included in Other Income and Expense.

**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 and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses 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.

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Our significant accounting policies are described in more detail in the notes to our 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 preclinical 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, 2012, 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 $358,000.

***Share-Based Compensation***

Described below is the methodology we have utilized in measuring share-based compensation expense. Following the consummation of our initial public offering in November 2011, stock option values are determined based on the quoted market price of our common stock.

Since our inception in 2009, we applied the fair value recognition provisions of Financial Accounting Standards Board Accounting Standards Codification, or ASC, 718 Accounting for Stock Based Compensation , which we refer to as ASC 718. 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 share option awards. Use of this valuation methodology requires that we make assumptions as to the price volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. Because we are a company with a limited operating history, we utilize data from several peer companies to estimate expected stock price volatility and the expected term of our options.

We selected peer companies from the biopharmaceutical industry with similar characteristics as us, including stage of product development, market capitalization, number of employees and therapeutic focus. 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 risk-free interest rate used for each grant is based on the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life. The fair value of stock options was estimated at the grant date using the following weighted average assumptions:

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| | Year Ended December 31, 2012 | Year Ended December 31, 2011 | Year Ended December 31, 2010 | Period from April 20, 2009 (Inception) Through December 31, 2009 |
|---|---|---|---|---|
| Dividend yield | | | | |
| Volatility | 71% | 74% | 80% | 80% |
| Risk-free interest rate | 1.14% | 2.13% | 2.10% | 2.33% |
| Expected term (years) | 6.3 | 6.0 | 5.6 | 5.3 |

In accordance with ASC 718, we recognized share-based compensation expense of approximately $4.9 million, $1.3 million, $68,000 and $4,000 for the years ended December 31, 2012, 2011, and 2010, respectively, and for the period April 20, 2009 (inception) through December 31, 2009. As of December 31, 2012, we had $12.0 million in total unrecognized compensation expense, net of related forfeiture estimates, which is expected to be recognized over a weighted-average remaining vesting period of approximately 2.8 years. We expect our share-based compensation to grow in future periods due to the potential increases in the value of our common stock and headcount.

Under ASC 718, 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.

As there was no public market for our common stock until our initial public offering in November 2011, the estimated fair value of our common stock from April 2009 through the initial public offering date effective November 15, 2011 was determined contemporaneously by our board of directors based on valuation estimates provided by management and prepared in accordance with the framework of the 2004 AICPA Technical Practice Aid, Valuation of Privately-Held-Company Equity Practice Aids, or the Practice Aid.

**Results of Operations**

***Comparison of Years Ended December 31, 2012, 2011 and 2010:***

***Research and Development Expenses.*** Research and development expenses for the years ended December 31, 2012, 2011 and 2010 were as follows:

| | Years Ended | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| | | (in thousands) | |
| Research and development expenses | $ 58,894 | $ 40,726 | $ 22,323 |
| Increase from prior year | $ 18,168 | $ 18,403 | $ 20,561 |
| % Change from prior year | 44.6% | 82.4% | 1166.9% |

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The increase in research and development expenses for the year ended December 31, 2012 over 2011 was primarily due to development expenses associated with our rucaparib and CO-1686 product candidates. Clinical trial and drug development expenses increased by $7.7 million due to growth in preclinical development, diagnostic development activities and in the number of patients, active sites and investigators participating in the clinical trials that support these two product candidates. In the third quarter of 2012, we initiated a drug discovery program for KIT, resulting in an increase of $2.1 million over the prior year. CO-101 costs increased by $2.2 million due mainly to drug development, manufacturing activities, and expenses incurred to wind down this program. The remaining increase of $6.2 million was due primarily to an increase in salaries, benefits, stock compensation expense and personnel-related costs resulting from additional headcount hired to support the expanding development activities of our products.

The increase in research and development expenses for the year ended December 31, 2011 over 2010 was due primarily to development expenses associated with CO-101 and rucaparib clinical trials. Clinical trial expenses increased by $9.6 million due to growth in the number of patients, active sites and investigators that were participating in our CO-101 clinical trials and costs incurred for the development of companion diagnostics for our CO-101 drug product, as well as the assumption of clinical development costs for rucaparib following the in-licensing of that product candidate in June 2011. Drug product development and manufacturing activities also increased by $470,000 in support of the CO-101 development. In addition, $3.8 million of the increase was the result of discovery, formulation development, manufacturing, and the commencement of preclinical activities associated with CO-1686, a compound that was in-licensed in May 2010. The remaining increase of $4.5 million was due primarily to an increase in salaries, benefits and personnel-related costs resulting from additional headcount hired to support the expanding development activities of CO-101, CO-1686 and rucaparib.

***General and Administrative Expenses.*** General and administrative expenses for the years ended December 31, 2012, 2011 and 2010 were as follows:

| | Years Ended | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| | | (in thousands) | |
| General and administrative expenses | $ 10,638 | $ 6,860 | $ 4,302 |
| Increase from prior year | $ 3,778 | $ 2,558 | $ 2,093 |
| % Change from prior year | 55.1% | 59.5% | 94.7% |

The increase in general and administrative expenses for the year ended December 31, 2012 over 2011 was primarily attributable to increased personnel, professional services, facilities and information system costs associated with being a publicly traded company. Additionally, share-based compensation increased by $1.8 million due to the increase in the value of stock options granted in 2012.

The increase in general and administrative expenses for the year ended December 31, 2011 over 2010 was primarily attributable to a full year s lease expense in 2011 associated with office space in San Francisco, California and Cambridge, England where the leases commenced in May 2010 and August 2010, respectively, as well as legal fees associated with patent review and analysis activities for two of our product candidates, and increased personnel, travel and information system costs to support company growth. Additionally, stock compensation expense increased by $701,000 relative to the increase in the valuation of our common stock in 2011.

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***Acquired In-Process Research and Development Expenses.*** Acquired in-process research and development expenses for the years ended December 31, 2012, 2011 and 2010 were as follows:

| | Years Ended | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| | | (in thousands) | |
| Acquired in-process research and development | $ 4,250 | $ 7,000 | $ 12,000 |
| Decrease from prior year | $ (2,750) | $ (5,000) | $ (1,085) |
| % Change from prior year | -39.3% | -41.7% | -8.3% |

The decrease in acquired in-process research and development expenses for the year ended December 31, 2012 in comparison to 2011 was due to a reduction in payments made to partners related to in-licensing agreements. In January 2012, we made a regulatory milestone payment of $4.0 million to Avila Therapeutics, Inc. for the FDA s acceptance of our IND application to begin clinical investigation of CO-1686. In June 2011, we made an up-front payment to Pfizer to acquire the licensing rights to rucaparib by issuing a $7.0 million convertible promissory note.

The decrease in acquired in-process research and development expenses for the year ended December 31, 2011 over 2010 was due to the difference in up-front acquisition costs for the development and commercialization rights of rucaparib in comparison to CO-1686 and CO-101. In May 2010, we acquired the global rights to develop and commercialize CO-1686 and made a $2.0 million up-front payment which was recognized as acquired in-process research and development expense. Additionally, in November 2010, we made a payment of $10.0 million to Clavis to expand the territory rights under the license agreement to include Asia and other international markets and we recorded this payment as acquired in-process research and development expense.

***Other Income (Expense), Net.*** Other income (expense), net for the years ended December 31, 2012, 2011 and 2010 were as follows:

| | Years Ended | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| | | (in thousands) | |
| Other income (expense), net: | $ (228) | $ (957) | $ 795 |
| Increase (decrease) from prior year | $ 729 | $ (1,752) | $ 838 |
| % Change from prior year | 76.2% | -220.4% | 1948.8% |

The decrease in other expense for the year ended December 31, 2012 over 2011 was due to the decrease in interest expense and debt issuance costs of $948,000, resulting from the conversion of our convertible promissory notes issued in 2011 into common stock upon the effective date of our initial public offering in November 2011. The increase was partially offset by a reduction to foreign currency transaction gains realized in 2012 resulting from a change in the value of Euro and British Pound transactions in relation to the U.S. Dollar.

The decrease in other income (expense), net for the year ended December 31, 2011 over 2010 was due to interest expense increasing by $851,000, resulting from the convertible promissory notes issued to our existing investors and Pfizer during the second quarter of 2011, which were subsequently converted to common stock upon the effective date of our initial public offering in November 2011. We also recorded $97,000 of debt issuance costs in 2011 associated with the issuance of convertible promissory notes. In addition, other expense increased in 2011 due to a $489,000 award received in 2010 under the Qualifying Therapeutic Discovery Project Program that did not occur in 2011, as well as a $183,000 reduction in foreign currency transaction gains in 2011 due primarily to a change in the value of the Euro in relation to the U.S. Dollar.

**Liquidity and Capital Resources**

We have funded our operations primarily through the private placement of equity, convertible debt securities and public offerings of our common stock in November 2011 and April 2012. As of December 31, 2012 we have received $75.5 million in net proceeds from the issuance of convertible preferred stock, $27.9 million through the issuance of convertible promissory notes, and $199.3 million in net proceeds from the issuance of common stock. The outstanding principal amount and all accrued and unpaid interest associated with the convertible promissory notes were converted into shares of our common stock immediately prior to the closing of our initial public offering at the initial public offering price of $13.00 per share, in November 2011. As of December 31, 2012, we had cash and cash equivalents totaling $144.1 million.

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

| | Year Ended December 31, 2012 | Year Ended December 31, 2011 | Year Ended December 31, 2010 |
|---|---|---|---|
| | | (in thousands) | |
| Net cash used in operating activities | $ (65,384) | $ (39,828) | $ (34,011) |
| Net cash provided by (used in) investing activities | 942 | 9,168 | (12,821) |
| Net cash provided by financing activities | 70,291 | 158,346 | 29 |
| Effect of exchange rate changes on cash and cash equivalents | 12 | 42 | |
| Net increase (decrease) in cash and cash equivalents | $ 5,861 | $ 127,728 | $ (46,803) |

***Operating Activities***

The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. The increase of $25.6 million to cash used in operating activities for the year ended December 31, 2012 in comparison to prior year was due to the growth in rucaparib and CO-1686 research and development costs associated with the expansion of clinical trials, drug formulation and manufacturing costs; initiation of the KIT drug discovery program in the third quarter of 2012; increased CO-101 program expenses related to the closedown of clinical studies and manufacturing development activities upon the discontinuation of the CO-101 program in late 2012; and increased internal salaries, benefits and personnel-related costs resulting from additional headcount hired to support the expanding development activities of our product candidates.

The increase of $5.8 million to cash used in operating activities for the year ended December 31, 2011 in comparison to the prior year was due to an increase in clinical trial costs for CO-101 resulting from an increase in the number of patients enrolled and sites activated for our ongoing LEAP trial, commencement of CO-1686 research and development activities, in-licensed by us in May 2010, and commencement of product development and clinical trial activities for rucaparib, in-licensed by us in June 2011.

***Investing Activities***

The cash provided by (used in) investing activities for all periods primarily reflects the purchase of available for sale securities offset by maturities and sales of available for sale securities. The decrease of $8.2 million in cash provided by investing activities for the year ended December 31, 2012 in comparison to the prior year was due to a reduction in available for sale security maturities and sales of $7.6 million and an increase of $0.6 million for the purchase of property and equipment.

The increase of $22.0 million in cash provided by investing activities for the year ended December 31, 2011 compared to the prior year was due primarily to the maturities and sale of available for sale securities in 2011 to fund operations. The increase related to the sale and maturities of available for sale securities is partially offset by the purchase of $0.5 million in property and equipment in 2011 compared to $0.8 million in 2010.

***Financing Activities***

Cash provided by financing activities for the year ended December 31, 2012 reflects the receipt of $70.0 million in net proceeds from the sale of our common stock in April 2012 and $0.3 million of proceeds from the exercise of stock options. Cash provided by financing activities for the year ended December 31, 2011 was due to the issuance of $28.0 million of 5% convertible promissory notes for cash in the second quarter of 2011, the receipt of $129.4 million in net cash proceeds in the fourth quarter of 2011 from the sale of common stock during our initial public offering, and the exercise of stock options for $1.1 million.

***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 2016 at the earliest. As such, we anticipate that we will continue to generate significant losses for the foreseeable future

as we incur expenses to complete our development activities for each of our programs, including clinical trial activities, companion diagnostic development, drug development, establishing our commercial capabilities, and expanding our general and administrative functions to support the growth in our research and development and commercial organizations.

The net proceeds raised from the sale of securities to date will not be sufficient to fund our operations through successful development and commercialization of our product candidates. As a result, we will need to raise additional capital to fund our operations and continue to conduct clinical trials to support additional development and potential regulatory approval, make milestone payments to our licensors and commercialize our product candidates.

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We believe that our existing cash and cash equivalents, will allow us to fund our operating plan through at least the next 12 months. If our available cash and cash equivalents are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or obtain a credit facility. The sale of additional equity and debt securities may result in additional dilution to our shareholders.

In addition, if we raise additional funds through the issuance of debt securities or convertible preferred stock, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations. Furthermore, any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay, or eliminate some or all of our planned development and commercialization activities, which could harm our business.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including but not limited to:

- the number and characteristics of the product candidates, companion diagnostics, and indications we pursue;
- the achievement of various development, regulatory and commercial milestones resulting in required payments to partners pursuant to the terms of our license agreements;
- the scope, progress, results and costs of researching and developing our product candidates and related companion diagnostics and conducting clinical and preclinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates and companion diagnostics;
- the cost of commercialization activities, if any, assuming our product candidates are approved for sale, including marketing and distribution costs;
- the cost of manufacturing any of our product candidates we successfully commercialize;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and 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, 2012 (in thousands):

| | | Payments due by Period | | | |
|---|---|---|---|---|---|
| | Total | Less than 1 Year | 1 to 3 Years | 3 to 5 Years | More than 5 Years |
| Operating lease obligations | $ 1,813 | $ 994 | $ 819 | $ | $ |

In addition, 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 CO-1686, we may be required to pay an additional aggregate of $115.0 million if certain clinical study objectives and regulatory approvals are achieved. Further, we

may be required to pay an aggregate of up to $120.0 million in sales milestone payments if certain annual sales targets are met for CO-1686. Pursuant to our license agreements for the development of rucaparib, we may be required to pay up to an aggregate $259.7 million in milestone payments upon the successful attainment of development, regulatory and sales milestones. Pursuant to our drug discovery collaboration agreement for the discovery of a novel KIT inhibitor, if any clinical candidates are discovered and we seek to pursue clinical development of such clinical candidates, we may be required to pay up to an aggregate of $192.0 million in milestone payments if certain development and regulatory objectives and annual net sales targets are achieved. Finally, pursuant to terms of each of these 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 SEC.

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**Tax Loss Carryforwards**

As of December 31, 2012, we have net operating loss carryforwards of approximately $136.1 million to offset future federal income taxes. We also have federal research and development tax credit carryforwards of $32.0 million to offset future federal income taxes. The federal net operating loss carryforwards and research and development tax credit carryforwards expire at various times through 2032. 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. At December 31, 2012, we recorded a 100% valuation allowance against our net operating losses and research and development tax credit carryforwards of approximately $85.9 million, 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**

On January 1, 2012, the Company adopted Accounting Standards Update (ASU) No. 2011-05, Presentation of Comprehensive Income. The standard eliminates the option to report other comprehensive income and its components in the statement of changes in equity. The Company elected to present the statement of operations and statement of comprehensive loss in two separate, but consecutive statements.

Other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force) and the SEC did not or are not believed by management to have a material impact on the Company s present or future financial statements.

## 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, 2012, we had cash and cash equivalents of $144.1 million, consisting of bank demand deposits and money market funds that primarily invest in U.S. government obligations. 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 fall 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 market value of our portfolio.

We contract with CROs, investigational sites, and contract manufacturers globally. We may be subject to fluctuations in foreign currency rates in connection with these agreements. 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, 2012 and December 31, 2011, approximately 26% and 31%, 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 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.

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As of December 31, 2012, 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, 2012, the design and operation of our disclosure controls and procedures were effective.

**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, 2012, 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* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its assessment, our management determined that, as of December 31, 2012, 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, 2012 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, 2012 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

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**Report of Independent Registered Public Accounting Firm**

The Stockholders and Board of Directors

Clovis Oncology, Inc.

We have audited Clovis Oncology, Inc. s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (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, 2012, 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., a corporation in the development stage, as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders equity (deficit), and cash flows for each of the three years in the period ended December 31, 2012 and for the period from April 20, 2009 (Inception) to December 31, 2012 and our report dated March 14, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Denver, Colorado

March 14, 2013

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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 2013 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 2013 Proxy Statement, which we expect to file with the SEC no later than April 30, 2013.

**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 2013 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

2525 28th Street, 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 2013 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 2013 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 2013 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 2013 Proxy Statement and is incorporated herein by reference.

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## 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.

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**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
*President and Chief Executive Officer*

Date: March 14, 2013

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 | March 14, 2013 |
| **Patrick J. Mahaffy** | *(Principal Executive Officer)* | |
| /s/ ERLE T. MAST | Executive Vice President and Chief Financial Officer | March 14, 2013 |
| **Erle T. Mast** | *(Principal Financial Officer and Principal Accounting Officer)* | |
| /s/ BRIAN G. ATWOOD | Director | March 14, 2013 |
| **Brian G. Atwood** | | |
| /s/ M. JAMES BARRETT | Director | March 14, 2013 |
| **M. James Barrett** | | |
| /s/ JAMES C. BLAIR | Director | March 14, 2013 |
| **James C. Blair** | | |
| /s/ PAUL KLINGENSTEIN | Director | March 14, 2013 |
| **Paul Klingenstein** | | |
| /s/ EDWARD J. MCKINLEY | Director | March 14, 2013 |
| **Edward J. McKinley** | | |
| /s/ THORLEF SPICKSCHEN | Director | March 14, 2013 |
| **Thorlef Spickschen** | | |

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**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

**Index to Consolidated Financial Statements**


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**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., a corporation in the development stage, as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive loss**,** convertible preferred stock and stockholders equity (deficit), and cash flows for each of the three years in the period ended December 31, 2012 and for the period from April 20, 2009 (Inception) to December 31, 2012. 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, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012 and for the period from April 20, 2009 (Inception) to December 31, 2012, in conformity with U.S. generally accepted accounting principles.

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, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 14, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Denver, Colorado

March 14, 2013

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**CLOVIS ONCOLOGY, INC.**

**(A Development Stage Enterprise)**

**Consolidated Statements of Operations**

| | For the Year Ended December 31, 2012 | For the Year Ended December 31, 2011 | For the Year Ended December 31, 2010 | Cumulative from April 20, 2009 (Inception) to December 31, 2012 |
|---|---|---|---|---|
| | (in thousands, except per share amounts) | | | |
| Revenues | $ | $ | $ | $ |
| Operating Expenses: | | | | |
| Research and development | 58,894 | 40,726 | 22,323 | 123,705 |
| General and administrative | 10,638 | 6,860 | 4,302 | 24,009 |
| Acquired in-process research and development | 4,250 | 7,000 | 12,000 | 36,335 |
| Operating loss | (73,782) | (54,586) | (38,625) | (184,049) |
| Other income (expense), net | (228) | (957) | 795 | (433) |
| Loss before income taxes | (74,010) | (55,543) | (37,830) | (184,482) |
| Income taxes | 27 | (27) | | |
| Net loss | $ (73,983) | $ (55,570) | $ (37,830) | $ (184,482) |
| Basic and diluted net loss per common share | $ (2.97) | $ (14.42) | $ (28.55) | $ (22.15) |
| Basic and diluted weighted average common shares outstanding | 24,915 | 3,854 | 1,325 | 8,327 |

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**CLOVIS ONCOLOGY, INC.**

**(A Development Stage Enterprise)**

**Consolidated Statements of Comprehensive Loss**

| | For the Year Ended December 31, 2012 | For the Year Ended December 31, 2011 | For the Year Ended December 31, 2010 | Cumulative from April 20, 2009 (Inception) to December 31, 2012 |
|---|---|---|---|---|
| | | (in thousands) | | |
| Net loss | $ (73,983) | $ (55,570) | $ (37,830) | $ (184,482) |
| Other comprehensive income | | | | |
| Foreign currency translation adjustments | 5 | 47 | | 52 |
| Net unrealized gain (loss) on available for sale securities | (1) | (40) | 42 | 1 |
| Other comprehensive income | 4 | 7 | 42 | 53 |
| Comprehensive loss | $ (73,979) | $ (55,563) | $ (37,788) | $ (184,429) |

See accompanying notes.

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**CLOVIS ONCOLOGY, INC.**

**(A Development Stage Enterprise)**

**Consolidated Balance Sheets**

| | December 31, 2012 | 2011 |
|---|---|---|
| | (in thousands, except for share amounts) | |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 144,097 | $ 138,236 |
| Available for sale securities | | 2,012 |
| Prepaid research and development expenses | 116 | 1,020 |
| Other current assets | 659 | 247 |
| Total current assets | 144,872 | 141,515 |
| Property and equipment, net | 1,084 | 1,896 |
| Other assets | 38 | 34 |
| Total assets | $ 145,994 | $ 143,445 |
| **Liabilities and stockholders equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,297 | $ 3,036 |
| Accrued research and development expenses | 7,161 | 5,071 |
| Other accrued expenses | 2,702 | 2,889 |
| Total current liabilities | 12,160 | 10,996 |
| Non-current liabilities | 338 | 656 |
| Commitments and contingencies (Note 9) | | |
| Stockholders equity: | | |
| Preferred stock, par value $0.001 per share; 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2012 and 2011, respectively | | |
| Common stock, $0.001 par value per share, 100,000,000 shares authorized at December 31, 2012 and 2011, respectively; 26,207,190 and 22,375,757 shares issued and outstanding at December 31, 2012 and 2011, respectively | 26 | 22 |
| Additional paid-in capital | 317,899 | 242,221 |
| Accumulated other comprehensive income | 53 | 49 |
| Deficit accumulated during development stage | (184,482) | (110,499) |
| Total stockholders equity | 133,496 | 131,793 |
| Total liabilities and stockholders equity | $ 145,994 | $ 143,445 |

See accompanying notes.

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**CLOVIS ONCOLOGY, INC.**

**(A Development Stage Enterprise)**

**Consolidated Statements of Convertible Preferred Stock and Stockholders Equity (Deficit)**

| | Convertible Preferred Stock | | Common Stock | | Additional Paid-In Capital | Accumulated Other Comprehensive Income | Deficit Accumulated During Development Stage | Total Stockholders Equity (Deficit) |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | | |
| | | | | | (in thousands, except per share amounts) | | | |
| Balance at April 20, 2009 (inception) | | $ | | $ | $ | $ | $ | $ |
| Issuance of common stock to founders at $.0029 per share | | | 1,206,899 | 1 | 2 | | | 3 |
| Issuance of convertible preferred stock; $2.00, $3.00 and $4.62 per share for series A-1, A-2 and B, respectively, net of issuance costs of $174 | 21,009,196 | 75,499 | | | | | | |
| Exercise of stock options | | | 114,659 | | 33 | | | 33 |
| Share-based compensation expense | | | | | 4 | | | 4 |
| Net loss | | | | | | | (17,099) | (17,099) |
| Balance at December 31, 2009 | 21,009,196 | 75,499 | 1,321,558 | 1 | 39 | | (17,099) | (17,059) |
| Exercise of stock options | | | 15,518 | | 29 | | | 29 |
| Share-based compensation expense | | | | | 68 | | | 68 |
| Net unrealized gain on available for sale securities | | | | | | 42 | | 42 |
| Net loss | | | | | | | (37,830) | (37,830) |
| Balance at December 31, 2010 | 21,009,196 | 75,499 | 1,337,076 | 1 | 136 | 42 | (54,929) | (54,750) |
| Issuance of common stock, net of issuance costs of $9,745 | | | 10,700,000 | 11 | 129,344 | | | 129,355 |
| Exercise of stock options | | | 336,370 | | 76 | | | 76 |
| Share-based compensation expense | | | | | 1,325 | | | 1,325 |
| Conversion of convertible promissory notes and accrued interest into common stock | | | 2,757,788 | 3 | 35,848 | | | 35,851 |
| Conversion of convertible preferred stock into common stock | (21,009,196) | (75,499) | 7,244,523 | 7 | 75,492 | | | 75,499 |
| Net unrealized loss on available for sale securities | | | | | | (40) | | (40) |
| Currency translation adjustment | | | | | | 47 | | 47 |
| Net loss | | | | | | | (55,570) | (55,570) |
| Balance at December 31, 2011 | | | 22,375,757 | 22 | 242,221 | 49 | (110,499) | 131,793 |
| Issuance of common stock, net of issuance costs of $5,024 | | | 3,750,000 | 4 | 69,972 | | | 69,976 |
| Issuance of common stock under employee stock purchase plan | | | 12,817 | | 174 | | | 174 |
| Exercise of stock options | | | 68,616 | | 583 | | | 583 |
| Share-based compensation expense | | | | | 4,949 | | | 4,949 |
| Net unrealized loss on available for sale securities | | | | | | (1) | | (1) |
| Currency translation adjustment | | | | | | 5 | | 5 |
| Net loss | | | | | | | (73,983) | (73,983) |
| Balance at December 31, 2012 | | $ | 26,207,190 | $ 26 | $ 317,899 | $ 53 | $ (184,482) | $ 133,496 |

See accompanying notes.

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**CLOVIS ONCOLOGY, INC.**

**(A Development Stage Enterprise)**

**Consolidated Statements of Cash Flows**

| | Year Ended December 31, | | | Cumulative from April 20, 2009 (Inception) to December 31, 2012 |
|---|---|---|---|---|
| | 2012 | 2011 | 2010 | |
| | (in thousands) | | | |
| **Operating activities** | | | | |
| Net loss | $ (73,983) | $ (55,570) | $ (37,830) | $ (184,482) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | | |
| Depreciation | 353 | 185 | 83 | 627 |
| Share-based compensation expense | 4,949 | 1,325 | 68 | 6,346 |
| Amortization of premiums and discounts on available for sale securities | 10 | 141 | 320 | 471 |
| Loss on disposal of equipment | 1,162 | | | 1,162 |
| Gain on sale of available for sale securities | | (16) | (18) | (34) |
| Non-cash acquired in-process research and development | | 7,000 | | 7,000 |
| Changes in operating assets and liabilities: | | | | |
| Prepaid and accrued research and development expenses | 2,993 | 2,682 | 2,896 | 7,044 |
| Other operating assets | (17) | 924 | (1,040) | (217) |
| Accounts payable | (758) | 1,656 | 866 | 2,298 |
| Other accrued expenses | (93) | 1,845 | 644 | 2,607 |
| Net cash used in operating activities | (65,384) | (39,828) | (34,011) | (157,178) |
| **Investing activities** | | | | |
| Purchases of property and equipment | (1,058) | (446) | (770) | (2,544) |
| Purchases of available for sale securities | | | (27,008) | (27,008) |
| Maturities and sales of available for sale securities | 2,000 | 9,614 | 14,957 | 26,571 |
| Net cash provided by (used in) investing activities | 942 | 9,168 | (12,821) | (2,981) |
| **Financing activities** | | | | |
| Proceeds from sale of convertible preferred stock, net of issuance costs | | | | 75,499 |
| Proceeds from sale of common stock, net of issuance costs | 69,976 | 129,355 | | 199,335 |
| Proceeds from the exercise of common stock options and employee stock purchase plan | 315 | 1,089 | 29 | 1,466 |
| Proceeds from issuance of convertible promissory notes, net of issuance costs | | 27,902 | | 27,902 |
| Net cash provided by financing activities | 70,291 | 158,346 | 29 | 304,202 |
| Effect of exchange rate changes on cash and cash equivalents | 12 | 42 | | 54 |
| Increase (decrease) in cash and cash equivalents | 5,861 | 127,728 | (46,803) | 144,097 |
| Cash and cash equivalents at beginning of period | 138,236 | 10,508 | 57,311 | |
| Cash and cash equivalents at end of period | $ 144,097 | $ 138,236 | $ 10,508 | $ 144,097 |
| **Non-cash items:** | | | | |
| Conversion of convertible preferred stock to common stock | $ | $ 75,499 | $ | $ 75,499 |
| Conversion of convertible promissory notes and accrued interest to common stock | $ | $ 35,851 | | $ 35,851 |
| Assets recorded for which payment (has)/has not yet occurred | $ (621) | $ 684 | | $ 63 |

See accompanying notes.

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**CLOVIS ONCOLOGY, INC.**

**(A Development Stage Enterprise)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Nature of Business**

Clovis Oncology, Inc. (the Company ), a corporation in the development stage, was incorporated in Delaware on April 20, 2009, and commenced operations in May 2009. 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 up-front payments, milestone payments and royalties on future sales. In addition, the Company generally expects to assume the responsibility for future drug development and commercialization costs. The Company currently operates in one segment. Since inception, the Company s operations have consisted primarily of developing in-licensed compounds and their companion diagnostics, evaluating new product acquisition candidates, raising capital and corporate organization activities. The Company has never earned revenue from these activities, and accordingly, the Company is considered to be in the development stage as of December 31, 2012.

On September 22, 2011, the Board of Directors and stockholders of the Company effectuated a 1 for 2.9 reverse split of the Company s common stock. The historical financial statements and related notes have been retrospectively adjusted to give effect to this change.

On November 12, 2012, the Company reported results from a pivotal study for CO-101 in metastatic pancreatic cancer. The study results failed to demonstrate a difference in overall survival between the two study arms, CO-101 versus gemcitabine. Based on the results of the study, the Company has terminated development of CO-101.

**Liquidity**

The Company has incurred significant net losses since inception and has relied on its ability to fund its operations through private equity financings and public offerings of common stock, and management expects operating losses and negative cash flows to continue for at least the next several years. 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 the Company s operating plan, existing working capital at December 31, 2012 is sufficient to meet the cash requirements to fund planned operations through at least December 31, 2013, without additional sources of cash, although there can be no assurance that this can, in fact, be accomplished.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The information reported within the Company s financial statements from April 20, 2009 to December 31, 2010 was based solely on the accounts of Clovis Oncology, Inc. Effective January 1, 2011, Clovis Oncology UK Limited, a wholly owned subsidiary of the Company, commenced operations. All financial information presented after December 31, 2010 was consolidated and includes the accounts of the Company and its wholly owned subsidiary. All significant intercompany balances and transactions have been eliminated in consolidation. The financial statements are prepared in conformity with U.S. generally accepted accounting principles ( GAAP ). Subsequent events have been evaluated through the date these financial statements were filed with the Securities & Exchange Commission.

**Use of Estimates**

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses, other comprehensive loss and related disclosures. On an ongoing basis, management evaluates its estimates, including estimates related to 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.

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**CLOVIS ONCOLOGY, INC.**

**(A Development Stage Enterprise)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Fair Value of Financial Instruments**

Cash, cash equivalents and available for sale securities are carried at fair value (see Note 4). Financial instruments, including prepaid expenses, accounts payable and accrued liabilities, 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, marketable securities with maturities of three months or less at purchase, and money market funds that invest primarily in certificate of deposits, commercial paper and U.S. government and U.S. government agency obligations. Cash equivalents are reported at fair value.

Marketable securities with original maturities greater than three months are considered to be available for sale securities and historically consisted of U.S. agency obligations, U.S. government obligations and corporate debt obligations. Available for sale securities are reported at fair market value and unrealized gains and losses are included as a separate component of stockholders equity. Realized gains, realized losses, the amortization of premiums and discounts, interest earned and dividends earned are included in other income (expense). The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Investments with maturities beyond one year are classified as short-term based on management s intent to fund current operations with these securities or to make them available for current operations. A decline in the market value of a security below its cost value that is deemed to be other than temporary is charged to earnings, and results in the establishment of a new cost basis for the security.

**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 following estimated useful lives were used to depreciate the Company s assets:

| | 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 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 such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the projected discounted future net cash flows arising from the assets. In the fourth quarter of 2012, an impairment of $1.2 million was recorded to research and development expenses for CO-101 manufacturing equipment no longer in use due to termination of the development activities for this product candidate. We have not found an active market to sell the equipment and the full carrying value at December 1, 2012 was impaired.

**Other Accrued Expenses**

Other accrued expenses are comprised of the following:

| | December 31, | |
|---|---|---|
| | 2012 | 2011 |
| Accrued personnel costs | $ 2,441 | $ 2,373 |
| Accrued corporate legal fees and professional services | 63 | 231 |
| Accrued expenses other | 198 | 285 |
| Other accrued expenses | $ 2,702 | $ 2,889 |

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**CLOVIS ONCOLOGY, INC.**

**(A Development Stage Enterprise)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**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. 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 in the financial statements as prepaid or accrued research and development.

**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 up-front payments to acquire a new drug compound, as well as future 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 in 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 income 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 other income (expense), net in the Consolidated Statements of Operations. As of December 31, 2012 and 2011, approximately 26% and 31% of the Company s total liabilities were denominated in currencies other than the functional currency, respectively.

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**CLOVIS ONCOLOGY, INC.**

**(A Development Stage Enterprise)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**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.

**Recently Adopted and Issued Accounting Standards**

On January 1, 2012, the Company adopted Accounting Standards Update (ASU) No. 2011-05, Presentation of Comprehensive Income. The standard eliminates the option to report other comprehensive income and its components in the statement of changes in equity. The Company elected to present the statement of operations and statement of comprehensive loss in two separate, but consecutive statements.

Other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force) and the SEC did not or are not believed by management to have a material impact on the Company s present or future financial statements.

**3. Property and Equipment**

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

| | December 31, | |
|---|---|---|
| | 2012 | 2011 |
| Laboratory, manufacturing and office equipment | $ 555 | $ 1,170 |
| Furniture and fixtures | 516 | 520 |
| Computer hardware and software | 381 | 340 |
| Leasehold improvements | 140 | 140 |
| Total property and equipment | 1,592 | 2,170 |
| Less: accumulated depreciation | (508) | (274) |
| Property and equipment, net | $ 1,084 | $ 1,896 |

Depreciation expense related to property and equipment was $353,000, $185,000, $83,000 and $627,000 for the years ended December 31, 2012, 2011 and 2010, respectively, and for the period from April 20, 2009 (inception) to December 31, 2012.

**4. 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 and liabilities consist of money market investments.

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 and liabilities represent U.S. government agency obligations.

Level 3: Unobservable inputs that are supported by little or no market activity. The Company does not have Level 3 assets or liabilities.

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**CLOVIS ONCOLOGY, INC.**

**(A Development Stage Enterprise)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

| | Balance | Level 1 | Level 2 | Level 3 |
|---|---|---|---|---|
| **December 31, 2012** | | | | |
| Money market | $ 135,385 | $ 135,385 | $ | $ |
| Total assets at fair value | $ 135,385 | $ 135,385 | $ | $ |
| **December 31, 2011** | | | | |
| Money market | $ 136,273 | $ 136,273 | $ | $ |
| U.S. agency obligations | 2,012 | | 2,012 | |
| Total assets at fair value | $ 138,285 | $ 136,273 | $ 2,012 | $ |

There were no security transfers between Levels 1 and 2 in 2012.

**5. Available for Sale Securities**

The Company s available for sale securities at cost or amortized cost value and fair market value by contractual maturity were (in thousands):

| | Cost or Amortized Cost Value | Fair Market Value |
|---|---|---|
| **December 31, 2011** | | |
| Due in one year or less | $ 2,010 | $ 2,012 |
| Total | $ 2,010 | $ 2,012 |

The types of securities included in the Company s available for sale investments were (in thousands):

| | Cost or Amortized Cost Value | Gross Unrealized Gains | Gross Unrealized (Losses) | Fair Market Value |
|---|---|---|---|---|
| **December 31, 2011** | | | | |
| U.S. government agencies | $ 2,010 | $ 2 | $ | $ 2,012 |

No securities have been in a continuous unrealized loss position for more than 12 months at December 31, 2012 and 2011, respectively, and no impairments have been recorded for the periods presented.

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**CLOVIS ONCOLOGY, INC.**

**(A Development Stage Enterprise)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**6. Convertible Promissory Notes**

In May 2011, the Company issued $20.0 million of 5% Convertible Promissory Notes to existing investors for cash. In June 2011, the Company issued $15.0 million of 5% Convertible Promissory Notes to Pfizer, which was comprised of a $7.0 million note issued to acquire the global rights to develop and market rucaparib and an $8.0 million note issued for cash (the Notes ). The Notes accrued interest at an annual rate of 5% and had a maturity date of May 25, 2012. In connection with the completion of the Company s initial public offering in November 2011, the principal balance and all accrued and unpaid interest due on the Notes was converted into 2,757,788 shares of the Company s common stock.

**7. Convertible Preferred Stock and Stockholders Equity**

**Common Stock**

In May 2009, the Company issued 1,206,899 shares of its common stock to the original founders at a purchase price of $.0029 per share. The shares were issued under restricted stock purchase agreements, which allow the Company, at its discretion, to repurchase unvested shares if the founders terminate their employment with the Company. In addition, if the founders employment is terminated by the Company without cause within six months following a change in control, 100% of the unvested shares of the restricted stock will immediately vest upon termination. Upon execution of the restricted stock purchase agreements, 25% of the shares vested immediately and the remaining shares vest ratably on a monthly basis over a four-year term. As of December 31, 2012 and 2011, 94,289 and 320,581 shares remained unvested, respectively.

In November 2011, the Company sold 10,700,000 shares of its common stock in an initial public offering at a price of $13.00 per share. The Company received net proceeds from the offering of $129.4 million, after deduction of $6.9 million of underwriting commissions and $2.8 million of offering expenses.

In April 2012, the Company sold 3,750,000 shares of its common stock in a public offering at $20.00 per share. The net offering proceeds realized after deducting offering expenses and underwriters discounts and commissions was $70.0 million.

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.

**Preferred Stock**

In May 2009, the Company entered into the Series A-1, A-2, B and C Preferred Stock Purchase Agreement with various investors (the Preferred Stock Purchase Agreement ). The Preferred Stock Purchase Agreement provided for the issuance of up to $146.3 million of the Company s convertible preferred stock, subject to various terms and conditions. During 2009, the Company issued shares of Series A-1, Series A-2 and Series B convertible preferred stock resulting in total aggregate cash proceeds to the Company of $75.5 million, net of $174,000 related stock issuance costs.

In connection with the completion of the Company s initial public offering in November 2011, all of the outstanding shares of convertible preferred stock were automatically converted into 7,244,523 shares of the Company s common stock. The Series A-1, A-2 and B convertible preferred stock converted at a rate of 2.9 for 1 into common stock based upon the election of the convertible preferred stock holders immediately prior to the closing of the initial public offering.

**8. 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 1,330,509 and 1,370,363 at December 31, 2012 and 2011, respectively. Options to purchase common stock under the 2009 Plan were designated as incentive stock options or non-statutory stock options. Stock options granted under this 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 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 will be transferred to the 2011 Stock Incentive Plan and will be available for grant under the 2011 Plan.

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**CLOVIS ONCOLOGY, INC.**

**(A Development Stage Enterprise)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 2,473,592 and 1,388,258 at December 31, 2012 and 2011, respectively, which represents the initial reserve of 1,250,000 shares of common stock plus 178,112 shares of common stock remaining for future grant from the 2009 Equity Incentive Plan and 1,045,480 new shares authorized by the Board of Directors at the 2012 annual meeting of stockholders. Stock options granted to date 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, 2012, 2011 and 2010, respectively, and the cumulative period from April 20, 2009 to December 31, 2012 has been recognized in the accompanying Statements of Operations as follows:

| | Year Ended December 31, | | | Cumulative Period from April 20, 2009 (Inception) to December 31, |
|---|---|---|---|---|
| | 2012 | 2011 | 2010 | 2012 |
| Research and development | $ 2,391 | $ 608 | $ 52 | $ 3,052 |
| General and administrative | 2,558 | 717 | 16 | 3,294 |
| Total share-based compensation expense | $ 4,949 | $ 1,325 | $ 68 | $ 6,346 |

The Company did not recognize a tax benefit related to share-based compensation expense during the years ended December 31, 2012, 2011 and 2010 and the cumulative period from April 20, 2009 (Inception) to December 31, 2012, 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, 2012. No share-based compensation expense was capitalized on our Consolidated Balance Sheets as of December 31, 2012 and December 31, 2011.

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

| | Option Shares Outstanding | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Balance at December 31, 2011 | 934,816 | $ 4.88 | | |
| Granted | 818,198 | 23.55 | | |
| Exercised | (68,616) | 2.06 | | |
| Forfeited | (85,354) | 14.35 | | |
| Balance at December 31, 2012 | 1,599,044 | $ 14.05 | 8.58 | $ 9,001,288 |
| Vested and expected to vest at December 31, 2012 | 1,485,859 | $ 13.55 | 8.54 | $ 8,810,577 |

| | | | | | |
|---|---|---|---|---|---|
| Vested at December 31, 2012 | 496,022 | $ | 4.51 | 7.78 | $ 5,697,119 |

The aggregate intrinsic value in the tables above represents the pretax intrinsic value, based on our closing stock price of $16.00 as of December 31, 2012, 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.

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**CLOVIS ONCOLOGY, INC.**

**(A Development Stage Enterprise)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Weighted-average grant-date fair value per share | $ 15.00 | $ 8.62 | $ 2.10 |
| Intrinsic value of options exercised | $ 954,927 | $ 505,806 | $ 19,100 |
| Cash received from stock option exercises | $ 141,182 | $ 1,088,737 | $ 28,500 |

The 2009 Plan allows for the option holder to exercise stock option shares prior to the vesting of the option. The shares acquired from an early exercise are subject to repurchase if the option holder terminates employment or service with the Company. The number of unvested common shares at the point of termination will be repurchased by the Company at the stated exercise price of the option. The number of common shares which were exercised prior to vesting was 191,092 and 354,367 at December 31, 2012 and December 31, 2011, respectively. The number of early exercised shares expected to vest using estimated forfeiture rates over the remaining service period of the option term was 153,455 and 300,346 at December 31, 2012 and December 31, 2011, respectively.

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Risk-free interest rate(a) | 1.14% | 2.13% | 2.10% |
| Dividend yield | | | |
| Volatility(b) | 71% | 74% | 80% |
| Expected term (years)(c) | 6.3 | 6.0 | 5.6 |

(a) *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.
(b) *Volatility:* The expected volatility was estimated using peer data of companies in the biopharmaceutical industry with similar equity plans.
(c) *Expected life:* The expected life 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 nonvested options, adjusted for expected forfeitures, was $12.0 million at December 31, 2012. The unrecognized share-based compensation expense is expected to be recognized over the weighted-average remaining vesting period of 2.8 years at December 31, 2012.

**Common Stock Reserved for Issuance**

As of December 31, 2012, 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 | 795,346 | | 795,346 |
| 2011 Stock Incentive Plan | 803,698 | 1,669,894 | 2,473,592 |
| 2011 Employee Stock Purchase Plan | | 438,209 | 438,209 |

| | | | |
|---|---|---|---|
| | 1,599,044 | 2,108,103 | 3,707,147 |

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**CLOVIS ONCOLOGY, INC.**

**(A Development Stage Enterprise)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Employee Stock Purchase Plan**

In August 2011, our Board of Directors approved the Clovis Oncology, Inc. 2011 Employee Stock Purchase Plan, (the Purchase Plan ). Under the Purchase Plan, we are authorized to issue 189,656 shares of common stock to qualified employees. 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 will provide for consecutive 6-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 will be 85% of the lower of the fair market value of a share of common stock on the first trading date of each offering period or the fair market 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. The first offering period of the Purchase Plan commenced on July 1, 2012 and ended on December 31, 2012. We sold 12,817 shares to employees in 2012 at a purchase price of $13.60 per share. The total share-based compensation expense recorded as a result of the Purchase Plan was approximately $104,000 during the year ended December 31, 2012.

The fair value of purchase awards granted to our employees during the year ended December 31, 2012 was estimated using the Black-Scholes option pricing model using the weighted-average assumptions provided in the following table:

| | |
|---|---|
| Risk-free interest rate(a) | 0.15% |
| Dividend yield | |
| Volatility(b) | 72% |
| Expected term (years)(c) | 0.5 |

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

**9. Commitments**

The Company leases office space in Boulder, Colorado, San Francisco, California and Cambridge, U.K. under non-cancelable operating lease agreements. The lease agreements contain periodic rent increases that result in the Company recording deferred rent over the term of certain leases. Rental expense under these leases was approximately $849,000, $788,000 and $609,000 for the years ended December 31, 2012, 2011 and 2010, respectively, and $2.3 million from April 20, 2009 (inception) to December 31, 2012. Future minimum rental commitments, by fiscal year and in the aggregate, for the Company s operating leases are provided below (in thousands):

| | December 31, 2012 |
|---|---|
| 2013 | $ 994 |
| 2014 | 521 |
| 2015 | 298 |
| 2016 | |
| 2017 | |

| | |
|---|---|
| Total future minimum lease payments | $ 1,813 |

**10. License Agreements**

**CO-101**

In November 2009, the Company entered into a license agreement with Clavis Pharma ASA ( Clavis ) to develop and commercialize CO-101 in North America, Central America, South America and Europe. Under terms of the license agreement, the Company made an up-front payment to Clavis in the amount $15.0 million, which was comprised of $13.1 million for development costs incurred prior to the execution of the agreement that was recognized as acquired in-process research and development and $1.9 million for the prepayment of preclinical activities to be performed by Clavis. In November 2010, the license agreement was amended to expand the license territory to include Asia and other international markets. The Company made a payment of $10.0 million to Clavis for the territory expansion and recognized the payment as acquired in-process research and development. As part of the amended license agreement, Clavis also agreed to reimburse up to $3.0 million of the Company s research and development costs for certain CO-101 development activities subject to the Company incurring such costs, all of which was completed in 2011.

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**CLOVIS ONCOLOGY, INC.**

**(A Development Stage Enterprise)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

On November 12, 2012, the Company reported results from a pivotal study for CO-101 in metastatic pancreatic cancer. The study results failed to demonstrate a difference in overall survival between the two study arms, CO-101 versus gemcitabine. Based on the results of the study, the Company has terminated development of CO-101.

**CO-1686**

In May 2010, the Company entered into a worldwide license agreement with Avila Therapeutics, Inc. ( Avila ) to discover, develop and commercialize a covalent inhibitor of mutant forms of the epidermal growth factor receptor gene product. In March 2012, Avila was acquired by Celgene Corporation ( Celgene ). CO-1686 was identified as the lead inhibitor candidate developed under the license agreement. The Company is responsible for all preclinical, clinical, regulatory and other activities necessary to develop and commercialize CO-1686. The Company made an up-front payment of $2.0 million upon execution of the license agreement which was recognized as acquired in-process research and development expense. The Company is obligated to pay royalties on net sales of CO-1686, based on the volume of annual net sales achieved. Celgene has the option to increase royalty rates by electing to reimburse a portion of the development expenses incurred by the Company. This option must be exercised within a limited period of time after Celgene is notified of our intent to pursue regulatory approval of CO-1686 in the United States or European Union as a first line therapy.

In January 2012, the U.S. Food and Drug Administration (FDA) accepted our investigational new drug (IND) application to begin clinical investigation of CO-1686. Following the FDA s acceptance of the IND application, we made a milestone payment of $4.0 million to Avila as required by the license agreement and recognized the payment as acquired in-process research and development expense. The Company may be required to pay up to an additional aggregate of $115.0 million in development and regulatory milestone payments if certain clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, the Company may be required to pay up to an aggregate of $120.0 million in sales milestones if certain annual sales targets are achieved.

**Rucaparib**

In June 2011, the Company entered into a worldwide license agreement with Pfizer Inc. to acquire exclusive development and commercialization rights to Pfizer s drug candidate PF-01367338, also known as rucaparib. This drug candidate is a small molecule inhibitor of poly (ADP-ribose) polymerase, or PARP, which the Company is developing for the treatment of selected solid tumors. Pursuant to the terms of the license agreement, the Company made an up-front payment by issuing to Pfizer a $7.0 million convertible promissory note with a 5% annual interest rate, due in 2012. Upon completion of the Company s initial public offering in November 2011, the principal balance and all accrued and unpaid interest due on this note of $7.2 million was converted into 551,222 shares of common stock. The Company is responsible for all development and commercialization costs of rucaparib and, if approved, Pfizer will receive royalties on the net sales of the product. In addition, Pfizer is eligible to receive up to $259 million of further payments, in aggregate, if certain development, regulatory and sales milestones are achieved.

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 up-front payment of $250,000 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.

**Drug Discovery Collaboration Agreement**

In July 2012, the Company entered into a drug discovery collaboration agreement with Array BioPharma Inc. for the discovery of a novel KIT inhibitor targeting resistance mutations for the treatment of GIST, a gastrointestinal cancer. Under the terms of the agreement, the Company is responsible to fund all costs of the discovery program, as well as costs to develop and commercialize any clinical candidates discovered. If any clinical candidates are discovered and the Company seeks to pursue clinical development of such clinical candidates, the Company may be

required to pay Array up to an aggregate of $192.0 million in milestone payments if certain development and regulatory objectives and annual net sales targets are achieved.

**11. 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, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, convertible preferred stock and stock options are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

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**CLOVIS ONCOLOGY, INC.**

**(A Development Stage Enterprise)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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, | | | Cumulative from April 20, 2009 (Inception) to December 31, |
|---|---|---|---|---|
| | 2012 | 2011 | 2010 | 2012 |
| Common shares under option | 826 | 935 | 422 | 826 |
| Convertible preferred stock | | | 7,245 | |
| Total potential dilutive shares | 826 | 935 | 7,667 | 826 |

**12. Income Taxes**

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Federal income tax (benefit) at statutory rate | (34.0)% | (34.0)% | (34.0)% |
| State income tax benefit, net of federal benefit | (3.8) | (3.6) | (3.6) |
| Tax credits | (12.5) | (13.4) | (12.9) |
| Other | 1.5 | (2.7) | 0.3 |
| Change in valuation allowance | 48.8 | 53.7 | 50.2 |
| Effective income tax rate | % | % | % |

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**CLOVIS ONCOLOGY, INC.**

**(A Development Stage Enterprise)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

| | December 31, | |
|---|---|---|
| | 2012 | 2011 |
| Deferred tax assets: | | |
| Net operating loss carryforward | $ 53,860 | $ 26,129 |
| Tax credit carryforwards | 31,999 | 18,167 |
| Product acquisition costs | 4,417 | 11,169 |
| Share-based compensation expense | 1,286 | 322 |
| Accrued liabilities and other | 123 | 79 |
| Total deferred tax assets | 91,685 | 55,866 |
| Valuation allowance | (91,448) | (55,342) |
| Deferred tax assets, net of valuation allowance | 237 | 524 |
| Deferred tax liabilities: | | |
| Prepaid expenses | (142) | (435) |
| Depreciation | (95) | (89) |
| Total deferred tax liabilities | (237) | (524) |
| Net deferred tax assets | $ | $ |

The realization of deferred tax assets is dependent upon future earnings, the timing and amount of these future earnings 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 $36.1 million and $29.8 million during the years ended December 31, 2012 and 2011, respectively, due primarily to an increase in net operating loss carryforwards and tax credit carryforwards.

At December 31, 2012, the Company had approximately $136.1 million, $211.7 million and $0.5 million of U.S. federal, state and foreign net operating loss carryforwards, respectively. The U.S. net operating losses will expire from 2029 to 2032 if not utilized. Included in the U.S. net operating loss is approximately $0.7 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 $32.0 million that will expire from 2029 through 2032 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 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. The Company s federal and state income taxes for the period from inception to December 31, 2012 remain open to an audit.

Tax positions must initially be 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 as 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, 2012.

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

During 2010, the Company was awarded $489,000 under the Qualifying Therapeutic Discovery Project Program (section 48D of the internal revenue code), which the Company elected to receive in the form of a grant. This award has been reflected as other income in the consolidated statement of operations for the year ended December 31, 2010.

**13. Employee Benefit Plan**

In 2010, the Company established 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 $295,000, $181,000 and $104,000 for the years ended December 31, 2012, 2011 and 2010, respectively, and $580,000 from April 20, 2009 (inception) to December 31, 2012. 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 $76,000, $64,000 and $41,000 for the year ended December 31, 2012, 2011 and 2010, respectively, and $181,000 from April 20, 2009 (inception) to December 31, 2012.

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**CLOVIS ONCOLOGY, INC.**

**(A Development Stage Enterprise)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**14. Subsequent Events**

The Company has evaluated subsequent events after the balance sheet date of December 31, 2012 and up to the date the Company filed this Annual Report.

**15. Quarterly Information (Unaudited)**

The results of operations on a quarterly basis for the years ended December 31, 2012 and 2011 were as follows:

| | (In thousands, except per share data) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **March 31, 2012** | **June 30, 2012(2)** | **Sept. 30, 2012** | **Dec. 31, 2012** | **March 31, 2011** | **June 30, 2011** | **Sept. 30, 2011** | **Dec. 31, 2011(1)** |
| Revenues | $ | $ | $ | $ | $ | $ | $ | $ |
| Expenses: | | | | | | | | |
| Research and development | 12,562 | 12,590 | 15,458 | 18,284 | 7,041 | 9,679 | 11,566 | 12,440 |
| General and administrative | 2,425 | 2,680 | 2,762 | 2,771 | 1,405 | 1,705 | 1,714 | 2,036 |
| Acquired in-process research and development | 4,000 | 250 | | | | 7,000 | | |
| Operating loss | (18,987) | (15,520) | (18,220) | (21,055) | (8,446) | (18,384) | (13,280) | (14,476) |
| Other income (expense), net | (4) | (172) | (48) | (4) | 118 | (115) | (555) | (405) |
| Loss before income taxes | (18,991) | (15,692) | (18,268) | (21,059) | (8,328) | (18,499) | (13,835) | (14,881) |
| Income taxes | (8) | 35 | | | | | | (27) |
| Net loss | $ (18,999) | $ (15,657) | $ (18,268) | $ (21,059) | $ (8,328) | $ (18,499) | $ (13,835) | $ (14,908) |
| Net loss per share: basic and diluted | $ (0.86) | $ (0.61) | $ (0.71) | $ (0.81) | $ (6.64) | $ (14.32) | $ (10.73) | $ (1.30) |
| Weighted average shares: basic and diluted | 22,041 | 25,744 | 25,906 | 25,948 | 1,254 | 1,292 | 1,289 | 11,498 |

(1) In November 2011, the Company completed its initial public offering, which resulted in net proceeds of $129.4 million from the issuance of 10,700,000 shares of common stock. In connection with the initial public offering, all of the outstanding shares of the Company s convertible preferred stock and convertible promissory notes payable and related accrued interest were converted into 10,002,311 shares of common stock.

(2) In April 2012, the Company sold 3,750,000 shares of its common stock in a public offering at $20.00 per share. The net offering proceeds realized after deducting offering expenses and underwriters discounts and commissions was $70.0 million.

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**INDEX TO EXHIBITS**

| Exhibit Number | Exhibit Description |
|---|---|
| 3.1(5) | Amended and Restated Certificate of Incorporation of Clovis Oncology, Inc. |
| 3.2(5) | Amended and Restated Bylaws of Clovis Oncology, Inc. |
| 4.1(3) | Form of Common Stock Certificate of Clovis Oncology, Inc. |
| 4.2(1) | Clovis Oncology Inc. Investor Rights Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and certain investors named therein. |
| 10.1*(1) | Amended and Restated License Agreement, dated as of November 10, 2010, by and between Clovis Oncology, Inc. and Clavis Pharma ASA. |
| 10.2*(4) | Amended and Restated Strategic License Agreement, dated as of June 16, 2011, by and between Clovis Oncology, Inc. and Avila Therapeutics, Inc. |
| 10.3*(4) | License Agreement, dated as of June 2, 2011, by and between Clovis Oncology, Inc. and Pfizer Inc. |
| 10.4+(1) | Clovis Oncology, Inc. 2009 Equity Incentive Plan. |
| 10.5+(4) | Clovis Oncology, Inc. 2011 Equity Incentive Plan. |
| 10.6+(1) | Form of Clovis Oncology, Inc. 2009 Equity Incentive Plan Stock Option Agreement. |
| 10.7+(4) | Form of Clovis Oncology, Inc. 2011 Equity Incentive Plan Stock Option Agreement. |
| 10.8+(3) | Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Patrick J. Mahaffy. |
| 10.9+(3) | Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Erle T. Mast. |
| 10.10+(3) | Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Gillian C. Ivers-Read. |
| 10.11+(3) | Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Andrew R. Allen. |
| 10.12+(1) | Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and John C. Reed. |
| 10.13+(1) | Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Paul Klingenstein. |
| 10.14+(1) | Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and James C. Blair. |
| 10.15+(1) | Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Edward J. McKinley. |
| 10.16+(1) | Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Thorlef Spickschen. |
| 10.17+(1) | Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and M. James Barrett. |
| 10.18+(1) | Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Brian G. Atwood. |
| 10.19+(1) | Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Patrick J. Mahaffy. |
| 10.20+(1) | Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Erle T. Mast. |
| 10.21+(1) | Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Gillian C. Ivers-Read. |
| 10.22+(1) | Indemnification Agreement, dated as of May 13, 2009, between Clovis Oncology, Inc. and Andrew R. Allen. |
| 10.23+(1) | Restricted Stock Purchase Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Patrick J. Mahaffy. |
| 10.24+(1) | Restricted Stock Purchase Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Erle T. Mast. |
| 10.25+(1) | Restricted Stock Purchase Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Gillian C. Ivers-Read. |
| 10.26+(1) | Restricted Stock Purchase Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Andrew R. Allen. |
| 10.27*(4) | Companion Diagnostics Agreement, dated as of April 19, 2011, by and between Clovis Oncology, Inc. and Roche Molecular Systems, Inc. |

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| Exhibit Number | Exhibit Description |
|---|---|
| 10.28*(4) | Master Service Agreement, dated as of March 23, 2010, by and between Clovis Oncology, Inc. and Ventana Medical Systems, Inc., together with the related Individual Project Agreement, dated as of March 25, 2010. |
| 10.29+(4) | Clovis Oncology, Inc. 2011 Employee Stock Purchase Plan. |
| 10.30+(4) | Clovis Oncology, Inc. 2011 Cash Bonus Plan. |
| 10.31+(6) | Employment Agreement, dated as of March 22, 2012, by and between Clovis Oncology, Inc. and Steven L. Hoerter. |
| 10.32+(6) | Indemnification Agreement, dated as of March 22, 2012, by and between Clovis Oncology, Inc. and Steven L. Hoerter. |
| 21.1(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 Amendment No. 1 to the Registrant s Registration Statement on Form S-1 (File No. 333-175080) on August 5, 2011.
(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.
+ 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.