Clovis Oncology, Inc.
Form 10-K
February 23, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2016.

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

For the transition period from to .

Commission file number: 001-35347

Clovis Oncology, Inc.

(Exact name of Registrant as specified in its charter)

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

(Address of principal executive offices) (Zip Code)

(303) 625-5000

(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the registrant’s common stock, par value $0.001 per share, held by non-affiliates of the registrant on June 30, 2016, the last business day of the registrant’s most recently completed second quarter, was $454,585,803 based on the closing price of the registrant’s common stock on the NASDAQ Global Market on that date of $13.72 per share.

The number of outstanding shares of the registrant’s common stock, par value $0.001 per share, as of February 16, 2017 was 44,626,493.

DOCUMENTS INCORPORATED BY REFERENCE

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

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PART I

This Annual Report filed on Form 10-K and the information incorporated herein by reference includes statements that are, or may be deemed, "forward-looking statements." In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereo comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Annual Report on Form 10-K and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, the market acceptance and commercial viability of our approved product, the development of our sales and marketing capabilities, the performance of our third party manufacturers, our ongoing and planned non-clinical studies and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, including our ability to confirm the clinical benefit of our approved product through confirmatory trials and other post-marketing requirements, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, expectations regarding sales of our products, our results of operations, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate, including our competition, 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®, the Clovis logo and Rubraca™ 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., together with its consolidated subsidiaries.

ITEM 1.BUSINESS

Overview

We are a biopharmaceutical company focused on acquiring, developing and commercializing innovative anti-cancer agents in the United States, Europe and additional international markets. We target our development programs for the treatment of specific subsets of cancer populations, and simultaneously develop, with partners, diagnostic tools intended to direct a compound in development to the population that is most likely to benefit from its use.

Our commercial product Rubraca™ (rucaparib) is the first and only oral, small molecule poly ADP-ribose polymerase, or PARP, inhibitor of PARP1, PARP2 and PARP3 approved in the United States by the Food and Drug Administration, or FDA, as monotherapy for the treatment of patients with deleterious BRCA (human genes associated with the repair of damaged DNA) mutation (germline and/or somatic) associated advanced ovarian cancer, who have been treated with two or more chemotherapies, and selected for therapy based on an FDA-approved companion diagnostic for Rubraca™.

The Marketing Authorization Application, or MAA, submission with the European Medicines Agency, or EMA, for a comparable ovarian cancer indication was accepted by the EMA during the fourth quarter of 2016. Additionally,

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rucaparib is being studied as a potential maintenance therapy for ovarian cancer patients in the ARIEL3 trial. Data from ARIEL3 is anticipated in mid-2017. Pending positive data from ARIEL3, we intend to follow up with a supplemental NDA for second-line maintenance therapy in women with ovarian cancer who have responded to platinum-based therapy. Rucaparib is also being developed in patients with mutant BRCA tumors and other DNA repair deficiencies beyond BRCA – commonly referred to as homologous recombination deficiencies, or HRD. Studies open for enrollment or under consideration include prostate, breast, pancreatic, gastroesophageal, bladder and lung cancers. We hold worldwide rights for rucaparib.

In addition, we have two other product candidates: lucitanib, an oral inhibitor of the tyrosine kinase activity of vascular endothelial growth factor receptors (VEGFR) 1-3, platelet-derived growth factor receptors (PDGFR) alpha and beta and fibroblast growth factor receptors (FGFR) 1-3, and rociletinib, an oral mutant-selective inhibitor of epidermal growth factor receptor ("EGFR"). While we have stopped enrollment in ongoing trials for each of these candidates, we continue to provide drug to patients whose clinicians recommend continuing therapy. We maintain certain development and commercialization rights for lucitanib and global development and commercialization rights for rociletinib.

Clovis was founded in 2009. We have built our organization to support innovative oncology drug development for the treatment of specific subsets of cancer populations. To implement our strategy, we have assembled an experienced team with core competencies in global clinical and non-clinical development, regulatory operations and commercialization in oncology, as well as conducting collaborative relationships with companies specializing in companion diagnostic development.

Our Product

On December 19, 2016, we announced that the U.S. Food and Drug Administration, or FDA, approved Rubraca (rucaparib) tablets as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer, who have been treated with two or more chemotherapies, and selected for therapy by an FDA-approved companion diagnostic for Rubraca. Continued approval for this indication may be contingent upon verification and description of clinical benefit in ARIEL3 and/or ARIEL4, our confirmatory trials. Our commercial and medical affairs organizations in the United States are in place and are supporting the commercial launch of Rubraca.

The Rubraca New Drug Application, or NDA, filing received priority review from the FDA and was reviewed and approved under the FDA's accelerated approval program. A priority review designation means the FDA's goal is to take action on an application within six months (rather than 10 months under a standard review) for a product intended to treat a serious condition and that, if approved, would provide a significant improvement in safety or effectiveness. Under the FDA's accelerated approval program, the FDA may approve an application for a product intended to treat a serious or life-threatening condition upon a determination that the product has an effect on a surrogate endpoint reasonably likely to predict clinical benefit, or a clinical endpoint that can be measured earlier than irreversible

morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit and taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. The NDA efficacy data set was based on results from subgroups of two multicenter, single-arm, open-label clinical trials, Study 1 (Study 10, NCT01482715) and Study 2 (ARIEL2 Parts 1 and 2, NCT01891344), in women with advanced BRCA-mutant ovarian cancer who had progressed after two or more prior chemotherapies. Objective response rate, or ORR, and duration of response, or DOR, were assessed by the investigator and independent radiology review, or IRR, according to Response Evaluation Criteria in Solid Tumors, or RECIST, version 1.1.

The MAA submission with the EMA for a comparable ovarian cancer indication was accepted by the EMA during the fourth quarter of 2016. We anticipate an opinion from the Committee for Medicinal Products for Human Use ("CHMP") in late 2017 and a favorable opinion could lead to a potential approval shortly thereafter. If approved in the EU, we intend to commercialize rucaparib on our own and we are building our commercial infrastructure in Europe.

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Efficacy results

ORR and DOR in the 106 patients with BRCA-mutant ovarian cancer who received two or more chemotherapies who were evaluable for efficacy in the pooled analysis of Study 1 and Study 2, were as follows:

Overall Response and Duration of Response in Patients with BRCA-mutant Ovarian Cancer Who Received Two or More Chemotherapies in Study 1 and Study 2

	Investigator-assessed N=106
ORR (95% CI)	54% (44, 64)
Complete Response	9%
Partial Response	45%
Median DOR in months (95% CI)	9.2 (6.6, 11.6)

Response assessment by IRR was 42% (95% confidence interval, or CI: 32, 52), with a median DOR of 6.7 months (95% CI: 5.5, 11.1). Investigator-assessed ORR was 66% (52/79; 95% CI: 54, 76) in platinum-sensitive patients, 25% (5/20; 95% CI: 9, 49) in platinum-resistant patients, 0% (0/7; 95% CI: 0, 41) in platinum-refractory patients, 53% (47/88; 95% CI: 43, 64) in patients with a germline BRCA mutation, 56% (10/18; 95% CI: 31, 79) in patients with a somatic BRCA mutation, 68% (28/41; 95% CI: 52, 82) in patients who received two prior chemotherapies and 65% (39/60; 95% CI: 52, 77) in patients who received two prior platinum-based chemotherapies. ORR was similar for patients with a BRCA1 gene mutation or BRCA2 gene mutation. With respect to the target lesion component of RECIST, the majority of patients experienced a decrease in the sum of the diameters of the target lesions.

Safety data

The overall safety evaluation of Rubraca 600 mg twice daily as monotherapy is based on data from 377 patients with ovarian cancer treated in two open-label, single arm trials. The most common adverse reactions (20% of patients; Grade 1-4) were nausea, asthenia/fatigue, vomiting, anemia, constipation, dysgeusia, decreased appetite, diarrhea, abdominal pain, thrombocytopenia and dyspnea. The most common laboratory abnormalities (35% of patients; Grade 1-4) were increase in creatinine, increase in aspartate aminotransferase, or AST, levels, increase in alanine aminotransferase levels, or ALT, decrease in hemoglobin, decrease in lymphocytes, increase in cholesterol, decrease in platelets and decrease in absolute neutrophil count. The most common Grade 3-4 adverse reaction was anemia, and the most common Grade 3-4 laboratory abnormality was a decrease in hemoglobin.

Myelodysplastic Syndrome/Acute Myeloid Leukemia, or MDS/AML, was reported in two of the 377 (0.5%) patients with ovarian cancer treated with Rubraca. Both of these patients had received prior treatment with platinum and other

DNA damaging agents. In addition, AML was reported in two (<1%) patients with ovarian cancer enrolled in ARIEL3, a blinded, randomized trial evaluating Rubraca versus placebo. One case of AML was fatal. Both patients had received prior treatment with platinum and other DNA damaging agents.

Companion Diagnostic

Clovis partnered with Foundation Medicine, Inc. to co-develop a companion diagnostic test, the FDA approved FoundationFocusTM CDx $_{BRCA}$, to select patients for Rubraca treatment. FoundationFocus CDx $_{BRCA}$ is a next-generation sequencing assay that assesses tumor BRCA mutations from tumor tissue samples from patients with ovarian cancer.

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Rucaparib Clinical Development

We are developing rucaparib for selected patient populations and collaborating with partners for companion diagnostic development. The following table summarizes the ongoing studies:

The ARIEL (Assessment of Rucaparib in Ovarian Cancer Trial) program is a novel, integrated translational-clinical program designed to accurately and prospectively identify ovarian cancer patients with tumor genotypes associated with benefit from rucaparib therapy. Rucaparib is also being developed in patients with mutant BRCA tumors and other DNA repair deficiencies beyond BRCA – commonly referred to HRD. Studies open for enrollment or under consideration include prostate, breast, pancreatic, gastroesophageal, bladder and lung cancers.

The ARIEL3 pivotal study (NCT01968213) is a randomized, double-blind study comparing the effects of rucaparib against placebo to evaluate whether rucaparib given as a maintenance therapy to platinum-sensitive patients can extend the period of time for which the disease is controlled after a positive outcome with platinum-based chemotherapy. Patients who have high-grade serous ovarian cancer and have had at least two prior lines of platinum based chemotherapies are randomized to receive either placebo or rucaparib and the primary endpoint of the study is progression free survival, or PFS. The primary efficacy analysis will evaluate, in a step-down process, BRCA-mutant patients, all patients with a HRD signature (including BRCA and non-BRCA), followed by all patients. Target enrollment in ARIEL3 was completed during the second quarter of 2016. Data from ARIEL3 are expected mid-2017. Pending positive data from ARIEL3, we intend to follow up with a supplemental NDA for second-line maintenance therapy in women with ovarian cancer who have responded to platinum-based therapy.

The ARIEL4 confirmatory study (NCT 02855944), which is open for enrollment, is a Phase 3 multicenter, randomized study of rucaparib versus chemotherapy in relapsed ovarian cancer patients with BRCA mutations (inclusive of germline and/or somatic) who have failed two prior lines of therapy. The primary endpoint of the study is PFS.

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During the second half of 2016, we initiated the TRITON (Trial of Rucaparib in Prostate Indications) program in prostate cancer, which includes two Clovis-sponsored potential registration studies which are currently open for enrollment:

- The TRITON2 study, a Phase 2 single-arm study in men with metastatic castrate-resistant prostate cancer, or mCRPC, enrolling patients with BRCA mutations and ataxia-telangiectasia mutations, or ATM, (both inclusive of germline and/or somatic) or other deleterious mutations in other homologous recombination repair genes and all patients will have progressed after receiving one line of taxane-based chemotherapy and one or two lines of androgen-receptor, or AR, targeted therapy in the castrate-resistant setting. The primary endpoints of the study are radiologic ORR in patients with measurable disease and protein-specific antigen response rate in patients who do not have measurable disease. TRITON2 initiated during the fourth quarter of 2016.
- The TRITON3 study, a Phase 3 comparative study in men with mCRPC enrolling BRCA mutant and ATM (both inclusive of germline and/or somatic) patients who have progressed on AR-targeted therapy and who have not yet received chemotherapy in the castrate-resistant setting. TRITON3 will compare rucaparib to physician's choice of AR-targeted therapy or chemotherapy in these patients. The planned primary endpoint of the study is radiologic PFS. TRITON3 initiated during the first quarter of 2017.

In addition to the ARIEL and TRITON programs in ovarian and prostate, respectively, we are supporting several clinical studies in ovarian, prostate and other indications:

- The Phase 2 investigator-initiated study, MITO-25, evaluating rucaparib and bevacizumab in combination as a first-line maintenance therapy for advanced ovarian cancer expected to initiate during the first quarter of 2017.
- The Phase 1B combination study sponsored by Genentech, of the cancer immunotherapy Tecentriq (atezolizumab; anti-PDL1) and rucaparib for the treatment of solid tumors and gynecological cancers, with a focus on ovarian cancer, which is expected to have the first patient initiated during the second quarter of 2017. The rationale for the combination is supported by non-clinical data that suggests greater activity in the combination of rucaparib and a PDL-1 inhibitor compared with either agent alone.
- The investigator-initiated RUBY Phase 2 study in women with breast cancer whose tumors have a somatic BRCA mutation or HRD signature other than a known germline BRCA mutation, which enrolled the first patient in the third quarter of 2016.
- The investigator-initiated PLATFORM Phase 2 study in gastroesophageal cancer in the first-line maintenance setting, which is expected to initiate during the first quarter of 2017.
- The investigator-initiated Phase 2 STRAT-STAMPEDE study in newly-diagnosed castrate-sensitive de novo metastatic prostate cancer patients whose tumors have a tBRCA mutation or are HRD positive, which is expected to initiate during the first half of 2017.
- The investigator-initiated RIO Phase 2 study in triple-negative or gBRCA breast cancer patients, which initiated during the third quarter of 2015.
- In February 2017, Clovis and Strata Oncology, Inc. ("Strata") announced an agreement to accelerate patient identification and enrollment for Clovis' ongoing TRITON clinical trial program. The Strata Trial, sponsored by Strata, is an observational study that provides next-generation sequencing at no cost to all advanced cancer patients at clinical sites that have agreed to participate in the Strata Trial, and match advanced prostate cancer patients with specified mutations to Clovis' TRITON2 and TRITON3 clinical trials for rucaparib. Strata has agreed not to provide similar matching services on behalf of any other Strata collaborator for any other mCRPC clinical trials for patients having the same specified mutations.

DNA damage and cancer therapy

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. 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 die undergoing a form of suicide termed apoptosis. A fundamental principle of cancer therapy is to damage cells profoundly with radiation or DNA-binding drugs, such as alkylating agents or platinums, to induce apoptosis and,

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subsequently, cancer cell death. Multiple DNA repair mechanisms active in the cell may reduce the activity of these anti-cancer therapies.

DNA repair

The PARP family comprises 17 structurally related proteins that have been identified on the basis of sequence similarity. PARP1, PARP2, and PARP3 play a central role in DNA repair. They are rapidly recruited to the sites of DNA damage and catalyze the recruitment of additional proteins that initiate the repair of damaged DNA. The breast cancer 1 (BRCA1) and breast cancer 2 (BRCA2) genes also have important roles in DNA repair pathways such as homologous recombination. Mutations in BRCA1 and BRCA2 are associated with an increased risk of ovarian, breast, prostate, and pancreatic cancers.

PARP inhibitors and synthetic lethality

Rucaparib is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, including PARP1, PARP2, and PARP3. PARP inhibitors have shown activity in BRCA1/2 mutant and homologous recombination (HR) repair deficient cancer cell lines through a mechanism known as synthetic lethality in which the loss of two genes/pathways is required for cell death. The inhibition/inactivation of repair pathways by administration of a PARP inhibitor in the context of an underlying genetic defect such as a BRCA mutation results in tumor cell death through accumulation of unrepaired DNA damage. In addition to catalytic inhibition of the enzymatic activity, PARP inhibitors may also function by “trapping” PARP enzymes at damaged DNA. Trapped PARP-DNA complexes may act as “poisons” to interfere with replication that would require BRCA dependent homologous recombination to be resolved.

Homologous recombination deficient tumors

Alterations in DNA repair genes other than BRCA1/2 have been observed in, and contribute to the hereditary risk of, ovarian, breast, prostate and pancreatic cancers. PARP inhibitors have shown evidence of nonclinical and clinical activity in tumors with alterations in non-BRCA HR genes. DNA repair deficiencies resulting from genetic and epigenetic alterations can result in a “BRCA-like” phenotype that may also render tumor cells sensitive to PARP inhibitors. One approach to identify patients with DNA repair deficiencies due to mechanisms other than a BRCA mutation is to assess loss of heterozygosity (LOH), or the loss of one normal copy of a gene, which arises from error-prone DNA repair pathways when HR is compromised. A next-generation sequencing (NGS) assay was developed in collaboration with Foundation Medicine to use as a companion diagnostic to assess genomic LOH in tumor samples, and this biomarker has the potential to expand the clinical utility of rucaparib in ovarian cancer and other indications.

Rociletinib - an Oral EGFR Mutant-Selective Inhibitor

Rociletinib is an oral mutant-selective inhibitor of epidermal growth factor receptor ("EGFR"). During the second quarter of 2016, we received a Complete Response Letter ("CRL") from the FDA for the rociletinib NDA, which was submitted during the third quarter of 2015. The FDA issues a CRL to indicate that their review of an application is complete and that the application is not ready for approval. In anticipation of receiving the CRL, we terminated enrollment in all ongoing sponsored clinical studies, although we continue to provide drug to patients whose clinicians recommend continuing rociletinib therapy. In addition, we withdrew our MAA for rociletinib on file with the EMA. We are continuing analyses of rociletinib data to determine whether certain populations of patients may represent an opportunity for a partner committed to investing in further clinical development. We hold global development and commercialization rights for rociletinib.

Lucitanib – a VEGFR, PDGFR and FGFR Inhibitor

Lucitanib is an oral inhibitor of the tyrosine kinase activity of vascular endothelial growth factor receptors (VEGFR) 1-3, platelet-derived growth factor receptors (PDGFR) alpha and beta and fibroblast growth factor receptors (FGFR) 1-3. Lucitanib was previously evaluated in breast and lung cancers. Development in those indications has ceased and we continue to provide drug to patients whose clinicians recommend continuing lucitanib therapy. Along with our development partner, Servier, we are continuing to evaluate what, if any, further development of lucitanib will be pursued. We hold development and commercialization rights in the U.S. and Japan and have sublicensed rights to Europe and rest of world markets, excluding China, to Servier.

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Competition

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

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

Rucaparib Competition

Lynparza™/olaparib (AstraZeneca) was approved in December 2014 in the US as monotherapy in patients with germline BRCA-mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy, and in the EU for use as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete response or partial response) to platinum-based chemotherapy.

There are a number of PARP inhibitors in clinical development including Tesaro’s niraparib, AbbVie’s veliparib and ABT-767, Pfizer’s talazoparib. BeiGene’s BGB-290, and Checkpoint Therapeutics’ CK-102. While most PARP inhibitor development focuses on ovarian cancer, breast cancer, and prostate cancer, additional efforts are aimed toward bladder, lung, and pancreatic cancers as well.

Outside of the PARP class, Avastin®/bevacizumab is approved in the US for recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer that is platinum-resistant in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, and was approved in December 2016 in the US for recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer that is platinum-sensitive in combination with carboplatin and paclitaxel or in combination with carboplatin and gemcitabine, followed by Avastin as a single agent. Other out of class agents approved for use in advanced ovarian cancer include chemotherapeutic agents (e.g. platinum-based doublets, platinum

monotherapy, non-platinum chemotherapy, etc.), Doxil® (Janssen), and Hycamtin® (Novartis) and there are additional out-of-class agents in clinical development that may pose a future competitive threat to rucaparib.

License Agreements

Pfizer Inc.

In June 2011, we entered into a license agreement with Pfizer Inc. to obtain the exclusive global rights to rucaparib. The exclusive rights are exclusive even as to Pfizer and include the right to grant sublicenses. Pursuant to the terms of the license agreement, we made a $7.0 million upfront payment to Pfizer. In April 2014, we initiated a pivotal registration study for rucaparib, which resulted in a $0.4 million milestone payment to Pfizer as required by the license agreement. In September 2016, we made a milestone payment of $0.5 million to Pfizer upon acceptance of the NDA for rucaparib by the FDA. The MAA submission with the EMA for a comparable ovarian cancer indication was accepted by the MAA during the fourth quarter of 2016, which resulted in a $0.5 million milestone payment to Pfizer as required by the license agreement. These payments were recognized as acquired in-process research and development expense.

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

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On December 19, 2016, the FDA approved Rubraca tablets as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer, who have been treated with two or more chemotherapies, and selected for therapy based on an FDA-approved companion diagnostic for Rubraca. The FDA approval resulted in a $0.75 million milestone payment to Pfizer as required by the license agreement. The FDA approval also resulted in the obligation to pay a $20.0 million milestone payment, for which we have exercised the option to defer payment by agreeing to pay $23.0 million within 18 months after the date of the FDA approval. These payments were recognized as intangible assets and amortized over the estimated remaining useful life of rucaparib.

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. We are required to make regulatory milestone payments to Pfizer of up to an additional $69.75 million in aggregate 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, and tiered royalty payments 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.

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.

AstraZeneca UK Limited

In April 2012, we 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, we made an upfront payment of $0.25 million upon execution of the agreement. During the second quarter of 2016, we made a milestone payment of $0.3 million to AstraZeneca upon the NDA submission for rucaparib. These payments were recognized as acquired in-process research and development expense. The FDA approval of rucaparib on December 19, 2016 resulted in a $0.35 million milestone payment to AstraZeneca as required by the license agreement. This payment was recognized as intangible assets and amortized over the estimated remaining useful life of rucaparib. AstraZeneca will also receive royalties on any net sales of rucaparib.

Advenchen Laboratories LLC

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

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

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Les Laboratoires Servier

In September 2012, EOS entered into a collaboration and license agreement with Servier, whereby EOS sublicensed to Servier exclusive rights to develop and commercialize lucitanib in all countries outside of the U.S., Japan and China. In exchange for these rights, EOS received an upfront payment of €45.0 million. We are entitled to receive additional payments on the achievement of specified development, regulatory and commercial milestones up to €100.0 million in the aggregate, €10.0 million of which was received in the first quarter of 2014. In addition, we are entitled to receive sales milestone payments if specified annual sales targets for lucitanib are met, each of which relates to annual sales targets of €250.0 million and above, which, in the aggregate, could amount to a total of €250.0 million. We are also entitled to receive royalties at percentage rates ranging from low-to-mid teens on sales of lucitanib by Servier.

We and Servier are developing lucitanib pursuant to a development plan agreed to between the parties. Servier is responsible for all of the development costs for lucitanib up to €80.0 million. Cumulative global development costs in excess of €80.0 million, if any, will be shared equally between us and Servier. During the second quarter of 2016, we and Servier agreed to discontinue the development of lucitanib for breast cancer and lung cancer and are continuing to evaluate what, if any, further development of lucitanib will be pursued. Based on current estimates, we expect to complete the committed on-going development activities in 2017 and expect full reimbursement of our development costs from Servier. Reimbursements are recorded as reduction to research and development expense on the Consolidated Statement of Operations.

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

Celgene Corporation

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

We made an upfront payment of $2.0 million upon execution of the license agreement, a $4.0 million milestone payment in the first quarter of 2012 upon the acceptance by the FDA of our Investigational New Drug ("IND") application for rociletinib and a $5.0 million milestone payment in the first quarter of 2014 upon the initiation of the Phase II study for rociletinib. In the third quarter of 2015, we made milestone payments totaling $12.0 million upon

acceptance of the NDA and MAA for rociletinib by the FDA and EMA, respectively. We recognized all payments prior to commercial approval as acquired in-process research and development expense.

We are obligated to pay royalties at percentage rates ranging from mid-single digits to low teens on the volume of annual net sales achieved. We are required to pay up to an additional aggregate of $98.0 million in development and regulatory milestone payments if certain clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, we are required to pay up to an aggregate of $120.0 million in sales milestone payments if certain annual sales targets are achieved.

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

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

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obligation to assign or license to Celgene any intellectual property rights or other rights we may have in rociletinib, including our regulatory filings, regulatory approvals, patents and trademarks for rociletinib.

Government Regulation

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

U.S. Government Regulation

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

- submission to the FDA of an IND which must become effective before human clinical trials may begin and must be updated annually;
- completion of extensive non-clinical laboratory tests and non-clinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice regulations;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of an NDA after completion of the agreed clinical trial program;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the active pharmaceutical ingredient ("API") and finished drug product are produced and tested to assess compliance with Current Good Manufacturing Practices ("cGMP") and/or sites involved in clinical studies to assess compliance with Good Clinical Practices ("GCP"); 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 GCP, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site's Institutional Review Board ("IRB") before the trials may be initiated, and the IRB must monitor the study until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

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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 2 clinical trials. The total number of participants included in Phase I clinical trials varies, but is generally in the range of 20 to 80.
- Phase II. Phase II includes controlled clinical trials conducted to preliminarily or further evaluate the effectiveness of the investigational drug for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the drug. Phase II clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population, usually involving no more than several hundred participants.
- Phase III. Phase III clinical trials are generally controlled clinical trials conducted in an expanded patient population generally at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug product and to provide an adequate basis for product approval. Phase III clinical trials usually involve several hundred to several thousand participants.

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

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

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

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

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

After the FDA evaluates the NDA and conducts inspections of clinical research facilities and/or manufacturing facilities where the drug product and/or its API will be produced, it may issue an approval letter or a Complete Response

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Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase III clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, non-clinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategies plan to mitigate risks, which could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase IV clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to determine the overall survival benefit of the drug.

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

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

Europe/Rest of World Government Regulation

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

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

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

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

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

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

Available Special Regulatory Procedures

Formal Meetings

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

The EMA also provides the opportunity for dialogue with us. This is usually done in the form of Scientific Advice, which is given by the Scientific Advice Working Party of 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 Special Protocol Assessment procedures are available. A SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement with the sponsor that the protocol design, clinical endpoints and statistical analyses are acceptable to support regulatory approval of the product candidate with respect to effectiveness in the indication studied. The FDA’s agreement to a SPA is binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining the safety or effectiveness of the product after clinical studies begin, or if the study

sponsor fails to follow the protocol that was agreed upon with the FDA. There is no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to a SPA.

Orphan Drug Designation

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

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

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

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

Pediatric Development

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

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

Authorization Procedures in the European Union

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

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

immune dysfunctions, and officially designated orphan medicines.

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

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

Breakthrough Therapy Designation in the United States

The U.S. Congress created the Breakthrough Therapy designation program as a result of the passage of the Food and Drug Administration Safety Act of 2012. FDA may grant Breakthrough Therapy status to a drug intended for the

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

Expedited Review and Approval in the United States

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

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

Accelerated Review in the European Union

Under the Centralized Procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be

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

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity

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and cost effectiveness of our products, in addition to the costs required to obtain FDA approvals. The development of a product dossier and a Budget Impact Model may be helpful in assisting the payors in evaluating cost effectiveness. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be established. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

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

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

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

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

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on

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

Advertising and Promotion

The FDA and other U.S. federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, the FDCA and the FDA's implementing regulations and standards. The FDA's review of marketing and promotional activities encompasses, but is not limited to, direct-to-consumer advertising, healthcare provider-directed advertising and promotion, sales representative communications to healthcare professionals, communications regarding unapproved or "off-label" uses, industry-sponsored scientific and educational activities and promotional activities involving the internet. A product cannot be commercially promoted before it is approved. After approval,

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product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. FDA regulations impose stringent restrictions on manufacturers' communications regarding off-label uses. Failure to comply with applicable FDA requirements and restrictions regarding unapproved uses of a drug or for other violations of its advertising and labeling laws and regulations, may result in adverse publicity and enforcement action by the FDA, the Department of Justice or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. A range of penalties are possible that could have a significant commercial consequences, including product seizures, injunctions, civil and/or criminal fines and agreements that materially restrict the manner in which a company promotes or distributes its products or regulatory letters, which may require corrective advertising or other corrective communications to healthcare professionals.

Other Healthcare Laws and Compliance Requirements

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

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

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

In addition to the laws described above, the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or the PPACA, also imposed new reporting requirements on drug manufacturers for payments made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1.0 million per year for “knowing failures”), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Applicable drug manufacturers are required to collect data for each calendar year and submit reports to CMS by March 31st of each subsequent calendar year. In addition, there are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us.

For those marketed products which are covered in the United States by the Medicaid programs, we have various obligations, including government price reporting and rebate requirements, which generally require products be offered at substantial rebates/discounts to Medicaid and certain purchasers (including “covered entities” purchasing under the 340B Drug Discount Program). We are also required to discount such products to authorized users of the Federal Supply Schedule of the General Services Administration, under which additional laws and requirements apply. These programs require submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as

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well as the entry into government procurement contracts governed by the Federal Acquisition Regulations, and the guidance governing such calculations is not always clear. Compliance with such requirements can require significant investment in personnel, systems and resources, but failure to properly calculate our prices, or offer required discounts or rebates could subject us to substantial penalties. One component of the rebate and discount calculations under the Medicaid and 340B programs, respectively, is the "additional rebate", a complex calculation which is based, in part, on the rate at which a branded drug price increases over time more than the rate of inflation (based on the CPI-U). This comparison is based on the baseline pricing data for the first full quarter of sales associated with a branded drug's NDA, and baseline data cannot generally be reset, even on transfer of the NDA to another manufacturer. This "additional rebate" calculation can, in some cases where price increase have been relatively high versus the first quarter of sales of the NDA, result in Medicaid rebates up to 100% of a drug's "average manufacturer price" and 340B prices of one penny. Subject to the control of Directive 89/105/EEC, pricing and reimbursement in the EU/EEA (European Economic Area) is governed by national rules and policy and may vary from Member State to Member State.

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

Regulation of Diagnostic Tests

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

PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, non-clinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA application typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation, or QSR, which requires

manufacturers to follow design, testing, control, documentation and other quality assurance procedures. FDA review of an initial PMA application is required by statute to take between six to ten months, although the process typically takes longer, and may require several years to complete. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

We and our third-party collaborators who are developing the companion diagnostics will work cooperatively to generate the data required for submission with the PMA application, and will remain in close contact with the Center for Devices and Radiological Health ("CDRH") at the FDA to ensure that any changes in requirements are incorporated into

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the development plans. We anticipate that meetings with the FDA with regard to our drug product candidates, as well as companion diagnostic product candidates, will include representatives from the Center for Drug Evaluation and Research and CDRH to ensure that the NDA and PMA submissions are coordinated to enable FDA to conduct a parallel review of both submissions. On July 14, 2011, the FDA issued its final guidance document addressing the development and approval process for "In Vitro Companion Diagnostic Devices." According to the guidance, for novel therapeutic products such as our product candidates, the PMA for a companion diagnostic device should be developed and approved or cleared contemporaneously with the therapeutic. We believe our programs for the development of our companion diagnostics are consistent with this guidance.

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

Patents and Proprietary Rights

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

In June 2011, we obtained an exclusive, worldwide license from Pfizer to develop and commercialize rucaparib. U.S. Patent 6,495,541, and its equivalent counterparts issued 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 Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") could be available to extend our patent exclusivity for rucaparib to the fourth quarter of 2023 in the United States. In Europe, we believe that patent term extension under a supplementary protection certificate could be available for an additional five years to at least 2025. In April 2012, we obtained an exclusive license from AstraZeneca under a family of patents and patent applications which will permit the development and commercialization of rucaparib for certain methods of treating patients with PARP inhibitors. Additionally, other

patents and patent applications are directed to methods of making, methods of using, dosing regimens, various salt and polymorphic forms and formulations and have expiration dates ranging from 2020 through potentially 2035, including the camsylate salt/polymorph patent family licensed from Pfizer, which expires in 2031 and a patent application directed to high dosage strength rucaparib tablets that, if issued, will expire in 2035. We are aware of a number of challenges of salt and polymorph patents, and while the ultimate results of patent challenges can be difficult to predict, we believe a number of factors, including a constellation of unexpected properties, support the novelty and non-obviousness of our rucaparib camsylate salt/polymorph composition of matter patent, would make a successful challenge of that patent more difficult.

We obtained rights to lucitanib by acquiring EOS in November 2013, along with its license agreements with Advenchen and Servier. In October 2008, EOS entered into an exclusive license agreement with Advenchen to develop and commercialize lucitanib on a global basis, excluding China. In September 2012, EOS entered into a collaboration and license agreement with Servier whereby EOS sublicensed to Servier exclusive rights to develop and commercialize lucitanib in all countries outside of the U.S., Japan and China. Composition of matter and method of use patent protection for lucitanib and a group of structurally-related compounds is issued in the U.S., Europe and Japan and is issued or pending in other jurisdictions. In the U.S., the composition of matter patent will expire in 2030, and in other jurisdictions, it expires in 2028. We believe that patent term extension could be available to extend our composition of

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matter patent up to five years beyond the scheduled expiration under the Hatch-Waxman Act. Additionally, patents or patent applications directed to methods of manufacturing lucitanib are issued or pending in the United States, Europe, Japan, and China.

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

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

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

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

The patent term of a patent that covers 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 Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The

length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other non-U.S. jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our pharmaceutical products receive FDA approval, we expect to apply for patent term extensions on patents covering those products.

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

In addition, we have sought and intend to continue seeking orphan drug status whenever it is available. If a product which has an orphan drug designation subsequently receives the first regulatory approval for the indication for which it

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has such designation, the product is entitled to orphan exclusivity, meaning that the applicable regulatory authority may not approve any other applications to market the same drug for the same indication, except in certain very limited circumstances, for a period of seven years in the United States and ten years in the European Union. Orphan drug designation does not prevent competitors from developing or marketing different drugs for an indication.

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

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

Manufacturing

We currently contract with third parties for the manufacture of our product candidates for non-clinical studies and clinical trials and intend to do so in the future. We currently have long-term agreements with third-party contract manufacturing organizations ("CMOs") for the production of the active ingredient and final product for rucaparib. 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.

We have developed the process for manufacturing rucaparib's active pharmaceutical ingredient ("API") to a degree sufficient to meet clinical demands and, as production capacity is increased as described below under "Lonza Agreement,", projected commercial requirements. Manufacturing of rucaparib API is being performed at a single CMO. The rucaparib drug product formulation and manufacturing process to produce that formulation have been developed to a degree sufficient to meet clinical demands and projected commercial requirements. A single third-party CMO capable of both formulation development and drug product manufacturing is currently producing rucaparib drug product. Our operating plan for the next 12 months includes a significant investment in inventory to meet the projected commercial requirements for Rubraca. We believe the single third-party CMO is capable of manufacturing

rucaparib's API to a degree sufficient to meet the projected market requirements.

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.

Lonza Agreement

On October 3, 2016, we entered into an agreement with Lonza Ltd ("Lonza") for the long-term manufacture and supply of the API for rucaparib.

Under this agreement, Lonza will be a non-exclusive manufacturer of the rucaparib API during the 10 year term of the agreement. Lonza will construct, in an existing Lonza facility, a production train that will be exclusively dedicated to the manufacture of the rucaparib API. The dedicated production train will provide manufacturing capacity to meet our currently anticipated needs for commercial supply of rucaparib API. We are obligated to make scheduled capital program fee payments towards capital equipment and other costs associated with the construction of the dedicated production train and, once the facility is operational, to pay a fixed facility fee each quarter for the duration of the term of the agreement.

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

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

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

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

Commercial Operations

We have established a commercial organization in the U.S., including sales, marketing, market access, and supply chain management, to support the commercialization of Rubraca. We believe the U.S. oncology market for Rubraca in its approved indication is addressable with a targeted sales and marketing organization, with capabilities that include the management of key accounts such as managed care organizations, group-purchasing organizations, oncology group networks and government accounts. We sell Rubraca through a limited distribution network consisting of select number of specialty pharmacies and distributors. Healthcare providers order Rubraca through these suppliers. We intend to continue promoting Rubraca ourselves in the U.S. for its current indication and any additional indications we may obtain in the future. We retain the rights to Rubraca in the rest of the world. The MAA submission with the EMA for a comparable ovarian cancer indication was completed and accepted during the fourth quarter of 2016. We may

elect in the future to utilize strategic partners, distributors or contract sales forces to assist in the commercialization of Rubraca.

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Customers

We are currently approved to sell Rubraca in the United States market. We distribute our product principally through a limited number of specialty distributor and specialty pharmacy providers, collectively, our customers. Our customers subsequently resell our products to patients and health care providers, at which time we recognize the associated revenue.

Our customers, which distribute our product, consist of three specialty distributors and four specialty pharmacy providers. Currently, we do not have a disproportionate concentration with any one of these customers and our sales volume, once increased, is expected to be evenly distributed throughout. Furthermore, we do not believe the loss of one of these customers would significantly impact the ability to distribute our product as we expect that sales volume would be absorbed evenly by the remaining customers.

Employees

As of February 16, 2017, we employed 278 full-time employees. None of our employees is represented by labor unions, and a very small number of international employees are covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Research and Development

We invested $251.1 million, $269.3 million and $137.7 million in research and development during the years ended December 31, 2016, 2015 and 2014, respectively.

About Clovis

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

Available Information

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

ITEM 1A. RISK FACTORS

Our business faces significant risks and uncertainties. Certain factors may have a material adverse effect on our business prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in or incorporated by reference into this Annual Report on Form 10-K and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

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Risks Related to Our Financial Position and Capital Requirements

We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future. We have generated only modest historical revenues, which makes it difficult to assess our future viability.

We are a biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have focused primarily on in-licensing and developing our product candidates. We are not profitable and have incurred losses in each year since our inception in April 2009. We have only a limited operating history upon which you can evaluate our business and prospects. There are many risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. Three of our product candidates, CO-101, CO-1686 (rociletinib) and CO-3810 (lucitanib), encountered development and/or regulatory setbacks after initial promising data, leading us to discontinue enrollment in ongoing clinical trials. We have received regulatory approval to market Rubraca in the U.S., but we do not yet know whether it will achieve market acceptance and be commercially successful. We have generated only modest revenues 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, 2016, 2015 and 2014, we had net losses of $349.1 million, $352.9 million and $160.0 million, respectively. As of December 31, 2016, we had an accumulated deficit of $1,131.0 million. We expect to continue to incur losses for the foreseeable future. As such, we are subject to all of the risks incident to the development of new biopharmaceutical products and related companion diagnostics, and we may encounter unforeseen expenses, difficulties, complications, regulatory scrutiny, delays and other unknown factors that may adversely affect our business. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if Rubraca or any of our product candidates, if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

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

Based on current estimates, we believe that our existing cash, cash equivalents and available-for-sale securities will allow us to fund our operating plan through at least the next 12 months. We do not have any material committed external source of funds or other support for our development efforts.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do in sufficient amounts, we expect to finance future cash needs through a combination of public or private equity offerings, collaborations, strategic alliances and other similar licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. Furthermore, it may be difficult for us to raise additional funds while we are subject to uncertainty related to litigation described under “Part I, Item 3-Legal Proceedings” in this report. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates, or our plans for acquisition or in-license of new product candidates. We may also seek collaborators for one or more of our current or future product candidates on terms that are less favorable than might otherwise be available. Any of these events could significantly harm our business, financial condition and prospects.

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

In September 2014, we completed a private placement of $287.5 million aggregate principal amount of 2.5% convertible senior notes due 2021 (the “Notes”), resulting in net proceeds to the Company of $278.3 million after deducting offering expenses. The Notes are governed by the terms of the indenture between the Company, as issuer, and

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The Bank of New York Mellon Trust Company, N.A., as trustee. Interest is payable on the Notes semi-annually, and the Notes mature on September 15, 2021, unless redeemed, repurchased or converted prior to that date. In addition, if, as defined by the terms of the indenture, a fundamental change occurs, holders of the Notes may require us to repurchase for cash all or any portion of their Notes at a purchase price equal to 100% of the principal amount of the Notes to be repurchased plus accrued and unpaid interest, if any, to, but excluding, the fundamental change repurchase date. As of December 31, 2016, all $287.5 million principal amount of the Notes remained outstanding.

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

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

We and certain of our officers were named as defendants in four separate purported class action lawsuits initiated in 2015, all of which have since been consolidated in the District of Colorado, that generally allege that we and certain of our officers violated federal securities laws by making allegedly false and misleading statements regarding the progress toward FDA approval and the potential for market success of rociletinib. Moreover, in January 2016, we and certain of our officers, directors, investors and underwriters were named as defendants in a purported class action lawsuit that alleges that the defendants violated the Securities Act because the offering documents for our July 2015 follow-on offering contained allegedly false and misleading statements regarding the progress toward FDA approval and the potential for market success of rociletinib. Additionally, in November 2016, we and certain of our officers, directors and underwriters were named as defendants in an individual lawsuit that alleges that the defendants violated the Securities Act because the offering documents for our July 2015 follow-on offering contained allegedly false and misleading statements regarding the efficacy of rociletinib, its safety profile, and its prospects for market success. This action also asserts Colorado state law claims and common law claims based on allegedly false and misleading statements regarding rociletinib’s progress toward FDA approval.

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

payments that are not covered by, or exceed the limits of, our available directors' and officers' liability insurance, which could have a material adverse effect on our operating results or financial condition.

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

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Risks Related to Our Business and Industry

We are highly dependent on the commercial success of Rubraca in the U.S.; Rubraca may not achieve market acceptance and may not be commercially successful and we may not attain profitability and positive cash flow from operations.

On December 19, 2016, the FDA granted approval for Rubraca as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer, who have been treated with two or more chemotherapies, and selected for therapy based on an FDA approved companion diagnostic for Rubraca. Rubraca is commercially available. The degree of market acceptance and the commercial success of Rubraca will depend on a number of factors, including:

- the effectiveness of our sales and marketing strategy and operations
- maintaining compliance with all regulatory requirements applicable to Rubraca and our commercial activities, including the post-marketing requirements and post-marketing commitments required by the FDA to verify Rubraca's clinical benefit or safety by completing certain confirmatory trials, pharmacology studies and additional diagnostic development
- the acceptance of Rubraca by patients and the medical community and the availability, perceived advantages and relative cost, safety and efficacy of alternative and competing products and therapies
- the continued acceptable safety profile of Rubraca and the occurrence of any unexpected side effects, adverse reactions or misuse, or any unfavorable publicity in these areas
- the ability of our third-party manufacturers to manufacture commercial supplies of Rubraca, to remain in good standing with regulatory agencies, and to develop, validate and maintain commercially viable manufacturing processes that are, to the extent required, compliant with current good manufacturing practice, or cGMP, regulations
- the availability of coverage and adequate reimbursement from managed care plans, private health insurers and other third party payors and the willingness and ability of patients to pay for Rubraca
- the development or commercialization of competing products or therapies
- marketing and distribution support for Rubraca, including the degree to which the approved labeling supports promotional initiatives for commercial success
- the actual market size for Rubraca, which may be different than expected
- our ability to enforce our intellectual property rights in and to Rubraca
- our ability to avoid third party patent interference or patent infringement claims and
- our ability to obtain regulatory approvals to commercialize Rubraca in markets outside of the U.S.

As many of these factors are beyond our control, we cannot assure you that we will ever be able to generate meaningful revenue through the sale of Rubraca. In addition, we may experience significant fluctuations in sales of Rubraca from period to period. We currently do not have any other product candidates in active development. Any inability on our part to successfully commercialize Rubraca in the United States and any foreign territories where it may be approved, or any significant delay in such approvals, could have a material adverse impact on our ability to execute upon our business strategy and, ultimately, to generate sufficient revenues from Rubraca to reach or maintain profitability or sustain our anticipated levels of operations.

Rubraca may cause undesirable side effects or have other properties that could limit its commercial potential.

If we or others identify previously unknown side effects or if known side effects are more frequent or severe than in the past, then:

· sales of Rubraca may decline
· regulatory approvals for Rubraca may be restricted or withdrawn

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- we may decide to, or be required to, send product warning letters or field alerts to physicians, pharmacists and hospitals
- additional nonclinical or clinical studies, changes in labeling or changes to manufacturing processes, specifications and/or facilities may be required
- government investigations or lawsuits, including class action suits, may be brought against us and
- our reputation may suffer.

Any of the above occurrences would harm or prevent sales of Rubraca, increase our expenses and impair our ability to successfully commercialize Rubraca. As Rubraca is commercially available, it may be used in a wider population and in a less rigorously controlled environment than in clinical studies. As a result, regulatory authorities, healthcare practitioners, third-party payors or patients may perceive or conclude that the use of Rubraca is associated with previously unknown serious adverse effects, undermining our commercialization efforts.

If our sales, marketing and distribution capabilities for Rubraca or our product candidates for which we obtain marketing appro

Prior to the launch of Rubraca, we had not commercialized any drug products as a company. To achieve commercial success for Rubraca and any product candidate that may be approved by the FDA or comparable foreign regulatory authorities, we must continue to expand our sales, marketing, managerial and other nontechnical capabilities or make arrangements with third parties to perform these services. We will be competing with companies that currently have extensive, well-funded, and more experienced sales and marketing operations. We may be unable to compete successfully against these more established companies.

We have recently built a field organization and other capabilities for the sales, marketing and distribution of Rubraca in the United States, and there are significant risks involved with building and managing a sales organization. Factors that may inhibit our efforts to effectively commercialize Rubraca on our own include:

- our inability to recruit, train, retain and incentivize adequate numbers of qualified and effective sales and marketing personnel
- the inability of sales personnel to generate sufficient sales leads and to obtain access to physicians or persuade adequate numbers of physicians to use or prescribe Rubraca
- our inability to effectively manage a geographically dispersed sales and marketing team.

If we are unable to maintain effective sales, marketing and distribution capabilities for Rubraca in the United States or if
we are unable to establish and maintain sales, marketing and distribution capabilities for Rubraca outside of the United States, i
independently or with third parties, we may not be able to generate product revenue or may not become profitable. If the cost of establishing and maintaining a sales and marketing
organization exceeds the cost-effectiveness of doing so, we may not become profitable.

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

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We cannot give any assurance that that rucaparib will receive regulatory approval outside the United States or that the rucaparib development program in other lines of therapies and indications will be successful or that our other product candidates will receive regulatory approval.

To date, we have invested a significant portion of our efforts and financial resources in the acquisition and development of our product candidates. Our business depends entirely on the successful development and commercialization of our product candidates.

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

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

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

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

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

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

· obtaining regulatory approval to commence a trial;

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

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

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may impose a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for rucaparib in other indications and lines of therapy or for our other 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 only obtained regulatory approval for Rubraca in the United States for a specific indication, and it is possible that Rubraca may not obtain regulatory approval outside the United States or for broader indications and lines of therapy or other tumor types or that any of our other existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Indeed, in anticipation of the issuance of a Complete Response Letter by the FDA with respect to the rociletinib NDA, we decided to discontinue ongoing development of rociletinib.

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

· the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;

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

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

Even if we receive regulatory approval for 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 and when approved, could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

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

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA and comparable foreign authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and

· injunctions or the imposition of civil or criminal penalties.

All of the foregoing limitations, obligations, and requirements also apply to Rubraca, for which we have received regulatory approval in the United States for certain limited indications.

We may seek approval from U.S. and foreign regulatory authorities for one or more product candidates on a conditional basis with full approval conditioned upon fulfilling the requirements of regulators. For example, we received accelerated approval from the FDA for rucaparib and are seeking conditional marketing authorization from the E.U. for rucaparib. Each of these approval pathways has certain conditions to approval, some of which may be post-approval,

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such as the conduct of a post-approval, or confirmatory, trial using due diligence. For example, continued approval of Rubraca by the FDA may be contingent upon verification and description of clinical benefit in ARIEL3 and/or ARIEL4, our confirmatory trials. If we are unable to fulfill the requirements of regulators that are conditions of a product's accelerated or conditional approval, if the confirmatory trial shows unfavorable results or increased or additional undesirable side effects, or if regulators re-evaluate the data or risk-benefit profile of our product candidate, the availability of accelerated or conditional approval may be withdrawn or our conditional approval may not result in full approval or may be revoked or not renewed. Alternatively, we may be required to change a product candidate's labeled indications or even withdraw the product, if approved, from the market.

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

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

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

Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related AEs could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if 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.

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

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

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

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

Servier is responsible for all of the global development costs for lucitanib up to €80.0 million. Cumulative global development costs in excess of €80.0 million, if any, will be shared equally between us and Servier. During the second quarter of 2016, we and Servier agreed to discontinue the development of lucitanib for breast cancer and lung cancer and are continuing to evaluate what, if any, further development of lucitanib will be pursued. Based on current estimates, we expect to complete the committed on-going development activities in 2017 and expect full

reimbursement of our development costs from Servier. However, we have limited control over the costs Servier may incur with respect to its development activities for the compound, and therefore our obligation to share additional costs could be triggered sooner than planned.

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

- Servier may not comply with applicable regulatory requirements with respect to developing or commercializing lucitanib, which could adversely affect future development or sales of lucitanib in Servier's licensed territory and elsewhere;
- If Servier does not agree to include within the global development plan new studies that we propose to conduct for lucitanib, we may be responsible for all costs associated with carrying out such activities;
- We and Servier could disagree as to current or future development plans for lucitanib, and Servier may delay clinical trials or stop a clinical trial for which it is the sponsor;
- There may be disputes between us and Servier, including disagreements regarding the collaboration and license agreement, that may result in (1) the delay of or failure to achieve regulatory and commercial objectives that

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would result in milestone or royalty payments, (2) the delay or termination of any future development or commercialization of lucitanib, and/or (3) costly litigation or arbitration that diverts our management's attention and resources;

- Business combinations or significant changes in Servier's business strategy may adversely affect Servier's ability or willingness to perform its obligations under our collaboration and license agreement; and
- The royalties we are eligible to receive from Servier may be reduced or eliminated based upon Servier's and our ability to maintain or defend our intellectual property rights and the presence of generic competitors in Servier's licensed territory.

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

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

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

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

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

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

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

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

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

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

We expect to continue to depend on third-party contract manufacturers for the foreseeable future. While we have long-term agreements with Lonza for the manufacture of API for Rubraca and with the manufacturer of the finished drug product, we have not entered into agreements with any alternate suppliers. We currently obtain our supplies of finished drug product through individual purchase orders.

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 other 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;

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

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

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

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

In late 2014, Lynparza™ (olaparib) was approved in the U.S. as monotherapy in patients with germline BRCA mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy and in the EU for the maintenance treatment of BRCA mutated platinum-sensitive relapsed serous ovarian cancer. There are a number of other PARP inhibitors in clinical development including Tesaro Inc.’s’s niraparib, AbbVie’s (veliparib) and ABT-767, Pfizer’s talazoparib, BeiGene’s BGB-290, and Checkpoint Therapeutics’ CK-102.

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

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

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our

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

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

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

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

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates. Even if we obtain coverage for our product candidates, third-party payors may not establish adequate reimbursement amounts, which may reduce the demand for, or the price of, our products. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

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

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may

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adversely affect the demand for any drug products for which we may obtain regulatory approval, as well as our ability to set satisfactory prices for our products, to generate revenues, and to achieve and maintain profitability.

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

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

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

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

As of February 16, 2017, we employed 278 full-time employees. As our development plans and strategies develop, we expect to expand our employee base for managerial, operational, financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy.

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

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may at any time be insufficient to counteract more lucrative offers from other companies. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize product candidates will be limited.

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

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

Our relationships with healthcare professionals, investigators, consultants, customers (actual and potential) and third-party payors are and will continue to be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, transparency and disclosure (or “sunshine”) laws, government price reporting, 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.

Our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may affect, among other things, our current activities with clinical study investigators and research subjects, as well as proposed and future sales, marketing, disease awareness, and patient assistance 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, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, including any kickback, bribe, or certain rebate, directly or indirectly, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment will be made, in whole or in part, under a

federal healthcare program, such as the Medicare and Medicaid programs;

- a person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or special intent to violate the law in order to have committed a violation; in addition, 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 federal False Claims Act;
- federal false claims and civil monetary penalty laws, including the False Claims Act, which impose criminal and civil penalties, including through civil "qui tam" or "whistleblower" actions, against individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from federal programs, such as Medicare and Medicaid, that are false or fraudulent, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the Health Insurance Portability and Accountability Act of 1996, or HIPAA which imposes criminal and civil liability for, among other things, willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, which also imposes certain requirements on certain covered healthcare providers,

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health plans, and healthcare clearinghouses, as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, with respect to safeguarding the privacy, security and transmission of individually identifiable health information

- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers
- federal government price reporting laws, which require drug manufacturers to calculate and report complex pricing metrics to government agencies, including CMS, where such reported prices may be used in the calculation of reimbursement and/or discounts on marketed products. Participation in these programs and compliance with the applicable requirements may result in potentially significant discounts on products subject to reimbursement under federal healthcare programs and increased infrastructure costs, and may potentially limit a drug manufacturer's ability to offer certain marketplace discounts and
- analogous state laws and regulations, such as state anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payer, including commercial insurers state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities 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.

In addition, the research and development of our product candidates outside the United States, and any sales of our products or product candidates once commercialized outside the United States will also likely subject us to foreign equivalents the healthcare laws mentioned above, among other foreign laws.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs, including investments in infrastructure and additional resources. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities, including our consulting agreements and other relationships with physicians, could be subject to challenge under one or more of such laws. Governmental and enforcement authorities may conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. 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, without limitation, civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

We face an inherent risk of product liability. 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

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under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

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

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

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

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

further development of our product candidates could be delayed.

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Risks Related to Our Intellectual Property

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

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

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

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

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

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

Third parties may assert that we are employing their proprietary technology without authorization. There are or may be third-party patents with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications, which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of

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

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

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

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

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

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

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

We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim

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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, including by failing to use commercially reasonable efforts to develop or commercialize the product candidate, our licensing partners may have the right to terminate the license in whole or in part. Generally, the loss of any one of our 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; and
- the patents of others may have an adverse effect on our business.

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

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

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

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

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

The trading price of our common stock has been, and may continue to be, volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. During the 12-month period ended December 31, 2016, the price of our common stock on the NASDAQ Global Select Market ranged from $11.57 per share to $46.97 per share. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this report, these factors include:

- adverse results of regulatory actions or decisions;
- our failure to successfully commercialize our product candidates, if approved;
- actual or anticipated adverse results or delays in our clinical trials;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approvals;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- inability to obtain adequate product supply for any approved drug product or inability to do so at acceptable prices;
- our dependence on third parties, including CMOS and CROs, as well as our partners that provide us with companion diagnostic products;
- additions or departures of key scientific or management personnel;
- failure to meet or exceed any financial guidance or expectations regarding development milestones that we may provide to the public;
- actual or anticipated variations in quarterly operating results;

- failure to meet or exceed the estimates and projections of the investment community;
- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- introduction of new products offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- issuances of debt or equity securities;

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- significant lawsuits, including patent or stockholder litigation;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- ineffectiveness of our internal controls;
- general political and economic conditions;
- effects of natural or man-made catastrophic events; and
- other events or factors, many of which are beyond our control.

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

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

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

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

Certain members of management and their affiliates own a significant percentage of our stock and will be able to exert significant influence over matters subject to stockholder approval.

Our executive officers, directors and their respective affiliates known to us beneficially owned approximately 14.8% of our voting stock as of February 21, 2017. These stockholders may have the ability to significantly influence the outcome of all matters submitted to our stockholders for approval. The interests of our executive officers, directors, and their affiliates might not coincide with the interests of the other holders of our capital stock which 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.

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

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

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

Pursuant to our equity incentive plan(s), our compensation committee (or its designee) is authorized to grant equity-based incentive awards to our employees, directors and consultants. As of December 31, 2016, the number of shares of our common stock available for future grant under our 2011 Stock Incentive Plan (“2011 Plan”) is 2,006,352. 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 and restricted stock unit, or RSU, grants and issuances of common stock under our 2011 Plan may have an adverse effect on the market price of our common stock. In addition, a substantial number of shares of our common stock are reserved for issuance upon conversion of the Notes.

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

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

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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

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

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

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

We may not be able to raise the funds necessary to repurchase the Notes upon a fundamental change, and our future debt may contain limitations on our ability to repurchase the Notes.

If we undergo a fundamental change, as defined in the indenture, prior to the maturity date of the Notes, holders may require us to repurchase for cash all or any portion of the Notes at a fundamental change repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. We may not have or be able to borrow the funds required to repurchase the Notes on the fundamental change repurchase date. In addition, our ability to repurchase the Notes may otherwise be limited by law, regulatory authority or agreements governing our future indebtedness. Our failure to repurchase the Notes at a time when the repurchase is required by the indenture would constitute a default under the indenture. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes when required.

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

We may incur substantial additional debt in the future, subject to the restrictions contained in any debt instruments that we enter into in the future, some of which may be secured debt. We are not restricted under the terms of the indenture governing the Notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture governing the Notes that could have the effect of diminishing our ability to make payments on the Notes when due. Our ability to refinance the Notes or future indebtedness will depend on the capital markets and our financial condition at such time. In addition, agreements that govern any future indebtedness that we may incur may contain financial and other restrictive covenants that will limit our ability to engage in activities that may be in our long-term best interests. Our failure to comply with those covenants could result in an event of default that, if not cured or waived, could result in the acceleration of some or all of our debt.

ITEM 1B.UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2.PROPERTIES

Our principal offices are located at four leased facilities, a 29,177 square foot facility in Boulder, Colorado used primarily for corporate functions, a 24,877 square foot facility in San Francisco, California used for clinical development

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operations and research laboratory space, a 4,411 square foot facility in Cambridge, United Kingdom used for our European regulatory and clinical operations and a 416 square foot facility in Milan, Italy used for clinical operations. These leases expire in January 2023, December 2021, May 2017 and March 2017, respectively. We believe that our existing facilities are sufficient for our needs for the foreseeable future.

ITEM 3.LEGAL PROCEEDINGS

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

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

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

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

On February 2, 2016, the Arkin Plaintiffs filed a motion to transfer the Moran Complaint to the District of Colorado (the "Motion to Transfer"). Also on February 2, 2016, the defendants filed a statement in the Northern District of California supporting the consolidation of all actions in a single court, the District of Colorado. On February 3, 2016,

the Northern District of California court denied without prejudice the lead plaintiff motions filed in that court pending a decision on the Motion to Transfer.

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

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

On April 1, 2016, the Arkin Plaintiffs and the defendants filed a stipulated motion to set the schedule for the filing of a consolidated complaint in the Medina, Kimbro and Rocco actions (the "Consolidated Complaint") and the responses thereto, including the defendants' motion to dismiss the Consolidated Complaint (the "Motion to Dismiss"), and to stay discovery and related proceedings until the District of Colorado issues a decision on the Motion to Dismiss. The stipulated motion was entered by the District of Colorado on April 4, 2016.

Subject to further agreed-upon extensions by the parties, the Arkin Plaintiffs filed a Consolidated Complaint on May 6, 2016. The Consolidated Complaint names as defendants the Company and certain of its current and former officers

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

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

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

On February 9, 2017, Judge Raymond P. Moore of the District of Colorado issued an Opinion and Order granting in part and denying in part the Clovis Defendants' Motion to Dismiss. The Clovis Defendants' Motion to Dismiss was granted with prejudice with respect to named defendant Gillian Ivers-Read and granted with respect to certain statements determined by the Court to be nonactionable statements of opinion or optimism. The Clovis Defendants' Motion to Dismiss was otherwise denied. Next, the Court granted in part and denied in part the Underwriter Defendants' Motion to Dismiss. The Underwriter Defendants' Motion to Dismiss was granted without prejudice with respect to Plaintiffs' claim under Section 12(a) of the Securities Act and granted insofar as the Court determined that certain statements challenged under Section 11 of the Securities Act are nonactionable statements of opinion or optimism. The Opinion and Order provided that Plaintiffs shall have until February 23, 2017 to file an amended pleading directed solely as to their Section 12(a) claim against the Underwriter Defendants. The Underwriters Defendants' Motion to dismiss was otherwise denied. Finally, the court granted the Venture Capital Defendants' Motion to Dismiss with prejudice.

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

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

contained allegedly false and misleading statements regarding the progress toward FDA approval and the potential for market success of rociletinib. The Electrical Workers Complaint seeks unspecified damages.

On February 25, 2016, the defendants removed the case to the United States District Court for the Northern District of California and thereafter moved to transfer the case to the District of Colorado ("Motion to Transfer"). On March 2, 2016, the plaintiff filed a motion to remand the case to San Mateo County Superior Court ("Motion to Remand"). Following briefing on the Motion to Transfer and the Motion to Remand, the Northern District of California held a hearing on April 18, 2016 concerning the Motion to Remand, at the conclusion of which the court granted to the Motion to Remand. On May 5, 2016, the Northern District of California issued a written decision and order granting the Motion to Remand the case to the Superior Court, County of San Mateo and denying the Motion to Transfer as moot.

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

On June 30, 2016, the Electrical Workers Plaintiffs filed an amended Complaint (the "Amended Complaint"). The Amended Complaint names as defendants the Company and certain of its current and former officers and directors,

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certain underwriters for the July 2015 Offering and certain Company venture capital investors. The Amended Complaint purports to assert claims under the Securities Act based upon alleged misstatements in Clovis' offering documents for the July 2015 Offering. The Amended Complaint includes new allegations about the Company's rociletinib disclosures. The Amended Complaint seeks unspecified damages.

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

The Company intends to vigorously defend against the allegations contained in the Electrical Workers Amended Complaint, but there can be no assurance that the defense will be successful.

On November 10, 2016, Antipodean Domestic Partners ("Antipodean") filed a complaint (the "Antipodean Complaint") against Clovis and certain of its officers, directors and underwriters in New York Supreme Court, County of New York. The Antipodean Complaint alleges that the defendants violated certain sections of the Securities Act by making allegedly false statements to Antipodean and in the Offering Materials for the Secondary Offering relating to the efficacy of rociletinib, its safety profile, and its prospects for market success. In addition to the Securities Act claims, the Antipodean Complaint also asserts Colorado state law claims, and common law claims. Both the state law and common law claims are based on the allegedly false and misleading statements regarding rociletinib's progress toward FDA approval. The Antipodean Complaint seeks compensatory, recessionary, and punitive damages.

On December 15, 2016, the Antipodean Plaintiffs filed an amended complaint ("the Amended Complaint") asserting substantially the same claims against the same defendants. The Amended Complaint purports to correct certain details in the original Complaint.

On January 21, 2017, the parties entered into a stipulation extending the defendants' time to respond to the Antipodean Amended Complaint until March 29, 2017, subject to the terms and conditions stated therein. Pursuant to the January 21, 2017 stipulation, the defendants filed a motion to stay the Antipodean action pending resolution of the Medina, Kimbro, Moran, and Rocco actions in the District of Colorado ("Motion to Stay") on January 31, 2017. The Motion to Stay has a scheduled return date of March 24, 2017.

The Company intends to vigorously defend against the allegations contained in the Antipodean Amended Complaint, but there can be no assurance that the defense will be successful.

We received a letter dated May 31, 2016 from an alleged owner of our common stock, which purports to set forth a demand for inspection of certain of our books and records pursuant to 8 Del. C. § 220 (the "Macalinao Demand Letter"). The Macalinao Demand Letter was purportedly made for the purposes of investigating alleged misconduct at the Company relating to rociletinib. On June 24, 2016, we submitted a response to the Macalinao Demand Letter. We believe that the allegations in the Macalinao Demand Letter are unfounded and that the Macalinao Demand Letter fails to establish an entitlement to any of the requested documents, but there can be no assurance about the likelihood of an adverse outcome. In January 2017, the Company produced certain books and records in response to the Macalinao Demand Letter.

We received a letter dated December 15, 2016 from a second alleged owner of our common stock, which purports to set forth a demand for inspection of the Company's books and records pursuant to 8 Del. C. § 220 (the "McKenry Demand Letter"). The McKenry Demand Letter was purportedly made for the purposes of investigating alleged misconduct at the Company relating to rociletinib. In addition, citing unnamed sources, the McKenry Demand Letter alleges that the Company engaged in patient eligibility, record management and verification, and informed consent violations in connection with the TIGER-X study at multiple testing sites, and that the FDA is purportedly investigating the Company's conduct. On January 4, 2017, we submitted a response to the McKenry Demand Letter. The Company believes that the allegations in the McKenry Demand Letter are unfounded and that the McKenry Demand Letter fails to establish an entitlement to any of the requested documents, but there can be no assurance about the likelihood of an

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adverse outcome. In February 2017, the Company produced certain books and records in response to the McKenry Demand Letter.

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

ITEM 4.MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information and Holders

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

	HIGH	LOW
Balance, December 31, 2016		
First Quarter	$ 34.75	$ 16.78
Second Quarter	$ 20.90	$ 11.57
Third Quarter	$ 40.29	$ 13.43
Fourth Quarter	$ 46.97	$ 25.50
Balance, December 31, 2015		
First Quarter	$ 83.46	$ 54.88
Second Quarter	$ 102.28	$ 68.40
Third Quarter	$ 116.75	$ 65.00
Fourth Quarter	$ 109.18	$ 24.50

On February 19, 2017, there were approximately 27 holders of record of our common stock. The holders of record number does not include a substantially greater number of holders whose shares are held of record in nominee or street name accounts through banks, brokers and/or other financial institutions.

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, 2016

			Number of securities remaining available for issuance under equity					
Common stock issued for services	—	—	13,111,904	13,111	—	—	314,889	—
Common stock issued in payment of shareholder loans	—	—	1,500,000	1,500	—	—	6,000	—
Common stock issued in payment of accounts payable	—	—	4,500,000	4,500	—	—	86,400	—

View Systems, Inc. and Subsidiaries
Consolidated Statements of Stockholders' Deficit
(Unaudited)
For the Years Ended December 31, 2013 and 2012
(Continued

	Shares	Amount	Common Stock Shares	Amount	Issuable	Stock Settlement in Process Note 13	Additional Paid-in Capital	Accumulated (Deficit)
Preferred stock issued for services	500,000	500	—	—	—	—	224,500	—
Stock compensation	—	—	—	—	—	—	450,000	—
Stock settlement	—	—	—	—	—	124,578	(58,888)	—
Common stock issuable (23,371,111 shares)	—	—	—	—	538,720	—	—	—
Net loss for the period ended December 31, 2013	—	—	—	—	—	—	—	(2,008,101)
Balance, December 31, 2013	3,489,647	$3,490	222,399,749	$222,399	$538,720	$—	$25,550,331	$(27,611,046)

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View Systems, Inc. and Subsidiaries
Consolidated Statements of Cash Flows

	For the Years Ended December 31,	
	2013	2012
Cash flows from operating activities:		
Net loss	$(2,008,101)	$(888,022)
Adjustments to reconcile net loss to net cash used in operations:		
Depreciation	12,597	14,976
Common stock issued/issuable in payment of services	585,438	479,396
Preferred stock issued in payment of services	225,000	44,297
Stock option expense	450,000	—
Bad debt	7,848	
(Gain) loss from renegotiated debt	(43,561)	(41,010)
Interest expense paid with stock	16,133	15,000
Change in operating assets and liabilities:		
(Increase) decrease in cash from:		
Accounts receivable	(12,597)	36,547
Inventories	117,956	19,284
Prepaid expenses	—	29,100
Increase (decrease) in cash from:		
Accounts payable and accrued expenses	(188,953)	211,811
Deferred compensation	96,088	(47,411)
Payroll taxes accrued and withheld	14,623	18,490
Accrued interest	36,960	27,045
Deferred revenue	(94,001)	(182,102)
Net cash used in operating activities	(784,570)	(262,599)
Cash flows from investing activities:		
Additions to fixed assets	(6,839)	—
Cash flows from financing activities:		
Proceeds from sales of common stock	518,000	322,500
Proceeds from issuable common stock	217,500	—
Proceeds/payments from stockholders loans	31,806	49,006
Principal payments on notes payable	(30,000)	(30,767)
Net cash provided by financing activities	737,306	340,739
(Decrease) increase in cash	(54,103)	78,140
Cash at beginning of period	107,181	29,041
Cash at end of period	$53,078	$107,181

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View Systems, Inc. and Subsidiaries
Consolidated Statements of Cash Flows (Continued)

	For the Years Ended December 31,	
	2013	2012
Cash paid for:		
Interest	$910	$680
Income Taxes	$—	$—
Non-Cash Investing and Financing Activities:		
Notes payable paid down with common stock issuable	$111,000	$—
Accrued interest paid with issuable common stock	$48,720	$60,000
Loans from stockholders paid with common stock	$17,500	$15,000
Accounts payable and accrued expense paid with common stock	$90,900	$137,001
Accounts payable paid with issuable stock	$—	$10,104
Stock settlement payable	$124,578	$—
Issuance of common stock issuable	$267,000	$—
Notes payable paid by shareholder	$35,075	$—
Common stock issued for prepayment of services	$20,000	$285,000
Preferred stock issued for prepayment of services	$—	$118,125
Deferred compensation paid with common stock	$—	$43,338

VIEW SYSTEMS, INC.

NOTES TO FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2013 AND 2012

1. NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Operations

View Systems, Inc. (the “Company”) designs, develops and sells computer software and hardware used in conjunction with surveillance capabilities. The technology utilizes the compression and decompression of digital inputs. In March 2002, the Company acquired Milestone Technology, Inc., which has developed a concealed weapons detection portal. In July 2009, the Company acquired FibreXpress, Inc., which is a company that specializes in developing and selling equipment and components for the fiber optic and communication cable industries.

Basis of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Milestone Technology, Inc. and FibreXpress, Inc. All significant intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

Management uses estimates and assumptions in preparing financial statements in accordance with accounting principles generally accepted in the United States of America. Those estimates and assumptions affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities, and the reported revenues and

expenses. Actual results could differ from the estimates that were used.

Accounts Receivable

Accounts receivable consists of amounts due from customers. Management periodically reviews the open accounts and makes a determination as to the ultimate collectability of each account. Once it is determined that collection is in doubt the account is written off as a bad debt. In order to provide for accounts that may become uncollectible in the future, the Company has established an allowance for doubtful accounts. The balance of the allowance for doubtful accounts is based on management's judgment and the Company's prior experience with managing accounts receivable.

The Company recognized bad debt expense of $7,848 and $0 for the years ended December 31, 2013 and 2012, respectively. Management's determination is that the remaining balance is collectible and therefore no allowance for possible uncollectible accounts receivable has been recorded for the years ended December 31, 2013 and 2012, respectively.

Revenue Recognition

The Company has three main products, namely the concealed weapons detection system, the visual first responder system and the Viewmaxx digital video system. In all cases revenue is considered earned when the product is shipped to the customer, installed (if necessary) and accepted by the customer as a completed sale. The concealed weapons detection system and the digital video system each require installation and training. The customer can engage us for installation and training, which is a revenue source separate and apart from the sale of the product. In those cases revenue is recognized at the completion of the installation and training and acceptance by the customer. However, the customer can also self-install or can engage another firm to provide installation and training. Each product has an unconditional 30 day warranty, during which time the product can be returned for a complete refund. Customers can purchase extended warranties, which provide for replacement or repair of the unit beyond the period provided by the unconditional warranty. Warranties can be purchased for various periods but generally they are for one year period that begins after any other warranties expire. The revenue from warranties is recognized on a straight line bases over the period covered by the warranty. Prior to the issuance of financial statements management reviews any returns subsequent to the end of the accounting period which are from sales recognized during the accounting period, and makes appropriate adjustments as necessary. Product prices are fixed or determinable and products are only shipped when collectability is reasonably assured.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined by the last-in-first-out method (LIFO). As of December 31, 2013 and 2012 the Company’s inventory consisted of a number of assembled units as well as unassembled parts of the product.

Property and Equipment

Property and equipment is recorded at cost and depreciated over their useful lives, using the straight-line and accelerated depreciation methods. Upon sale or retirement, the cost and related accumulated depreciation are eliminated from the respective accounts, and the resulting gain or loss is included in the results of operations. The useful lives of property and equipment for purposes of computing depreciation are as follows:

Equipment	5-7 years
Software tools	3 years

Repairs and maintenance charges which do not increase the useful lives of assets are charged to operations as incurred. Depreciation expense for the periods ended December 31, 2013 and 2012 amounted to $12,597 and $14,976,

respectively.

Income Taxes

Income taxes are recorded under the assets and liabilities method whereby deferred tax assets and liabilities are recognized for the future tax consequences, measured by enacted tax rates, attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss carry forwards. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period the rate change becomes effective. Valuation allowances are recorded for deferred tax assets when it is more likely than not that such deferred tax assets will not be realized.

The Company files income tax returns in the U.S. federal jurisdictions, and in various state jurisdictions. The Company is no longer subject to U.S. federal, state and local examinations by tax authorities for years prior to 2010. The company policy is to recognize interest related to unrecognized tax benefits as income tax expense. The Company believes that it has appropriate support for the income tax positions it takes and expects to take on its tax returns, and that its accruals for tax liabilities are adequate for all open years based on an assessment of many factors including past experience and interpretations of tax law applied to the facts of each matter.

Research and Development

Research and development costs are expensed as incurred.

Advertising

Advertising costs are charged to operations as incurred. Advertising costs for the periods ended December 31, 2013 and 2012 were $11,497 and $10,808, respectively.

Nonmonetary Transactions

Nonmonetary transactions are accounted for in accordance with ASC 845 “ Nonmonetary Transactions” which requires the transfer or distribution of a nonmonetary asset or liability to be based generally, on the fair value of the asset or liability that is received or surrendered, whichever is more clearly evident.

Financial Instruments

For most financial instruments, including cash, accounts receivable, accounts payable and accruals, management believes that the carrying amount approximates fair value, as the majority of these instruments are short-term in nature.

Stock-Based Compensation

We account for share-based compensation at fair value. Share-based compensation cost for stock options granted to employees, board members and service providers is determined at the grant date using an option pricing model that uses level 3 unobservable inputs. 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.

Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss available to common stockholder by the weighted average number of common shares outstanding. Diluted net loss per common share is computed by dividing net loss available to common stockholders by the weighted average number of common shares and dilutive potential common share equivalents then outstanding. Potential common shares consist of shares issuable upon the exercise of stock options and warrants in addition to shares that may be issued in the event that convertible debt is exchanged for shares of common stock. The calculation of the net loss per share available to common stockholders for the periods ended December 31, 2013 and 2012 does not include potential shares of common stock equivalents, as their impact would be antidilutive. The following reconciles amounts reported in the financial statements:

	Net Loss (Numerator)	Shares (Denominator)	Per-share Amount
Year ended December 31, 2013	$(2,008,101)	$194,843,005	$ (0.01)
Year ended December 31, 2012	$(888,022)	$157,505,608	$ (0.01)

2. GOING CONCERN

The Company has incurred and continues to incur, losses from operations. For the years ended December 31, 2013 and 2012, the Company incurred net losses of $2,008,101 and $888,022, respectively. In addition, certain notes payable have come due and the note holders are demanding payment.

Management is very actively working to cure these situations. It has implemented major plans to for the future growth and development of the Company. Management is in the process of renegotiating more favorable repayment terms on the notes payable and the Company anticipates that these negotiations will result in extended payment plans. In addition, during 2013 and 2012, the Company implemented marketing and information strategies to increase public awareness of its products and thereby sales. It has established new international markets which it believes will be the source for sales growth in the very near future. It also was able to reduce the per-unit cost of manufacturing its products. Additionally, the Company has increased the efficiency of its processes and focused its development efforts on products that appear to have greater sales potential.

Historically, the Company has financed its operations primarily through private financing. It is management's intention to finance operations during the remainder of 2014 primarily through increased sales although there will still be a need for additional equity financing. In addition, management is actively seeking out mergers and acquisitions which would be beneficial to the future growth of the Company. There can be no assurance, however, that this financing will be successful and the Company may be required to further reduce expenses and scale back operations.

As previously noted the Company is currently in default on a $50,000 loan from a stockholder.

The consolidated financial statements presented above and the accompanying Notes have been prepared on a going concern basis, which contemplates the realization of assets and discharge of liabilities in the normal course of business for the foreseeable future, and does not include any adjustments to reflect possible future effects on the recoverability and classification of assets, or the amounts and classification of liabilities that may result from the outcome of any extraordinary regulatory action, which would affect our ability to continue as a going concern.

Due to the conditions and events discussed above, there is substantial doubt about the Company's ability to continue as a going concern.

3. NEW ACCOUNTING PRONOUNCEMENTS

The Financial Accounting Standards Board ("FASB") periodically issues new accounting standards in a continuing effort to improve standards of financial accounting and reporting. The Company has reviewed the recently issued pronouncements and concluded that there are no new accounting standards are applicable to the Company.

4. NOTES PAYABLE

Notes payable as of December 31, 2013 and December 31, 2012 consists of the following:

	2013	2012
Stockholder An unsecured loan from a stockholder which is payable on demand with interest at 12%. The note was dated November 1, 2007 and the note matures and the principal is payable upon the demand of the lender. The note was paid in full during 2013 primarily through the issuance of common stock issuable.	$—	$116,000
Investor An unsecured loan from an investor, payable in monthly installments of $5,000 commencing July 1, 2013 until paid in full. The loan bears no interest and is the amount due as a result of a settlement of the stock settlement payable mentioned below.	45,000	—
Lafayette Community Bank A term loan secured by a stockholder, payable in monthly installments of $2,587 commencing in December 25, 2009 but refinanced in May 2011. The loan is due in full on May 18, 2016 and interest accrues monthly at 7.5% per annum.	72,596	97,185
Stockholder Demand loan payable with interest at 5% per month dated September 18, 2009. The loan is secured by the Company's accounts receivable. The note was payable in full on December 17, 2009 so this debt is currently in default.	50,000	50,000
Chase Equipment loan to finance the purchases of a truck, payable monthly in installments of $533, which include interest at 5.34% per annum.	4,618	10,104
TOTAL	172,214	273,289
Less current portion	126,116	197,058
Non-current portion	$46,098	$76,231

Principal payments for the next five years:

2014	$126,116
2015	28,555
2016	17,543
Thereafter	—

TOTAL	$172,214

5. INCOME TAXES

For income tax purposes the Company has net operating loss carry forwards of approximately $20 million as of December 31, 2013 that may be used to offset future taxable income. In the instance of future corporate acquisitions, the net operating losses may be used to offset the future taxable income of a qualifying subsidiary corporation which meets IRS regulations governing such situations. The losses have accumulated since 1998 and they will start to expire in 2018. IRS regulations also provide that significant changes in ownership (greater than 50%) could result in the expiration of some of the net operating loss carry forwards. As of the date of this report the Company has not made an analysis of the changes in ownership to determine of any of these losses have expired.

The components of the net deferred tax asset as of December 31, 2013 are as follows:

Effect of net operating loss carry forward	$10,986,000
Less evaluation allowance	(10,986,000)
Net deferred tax asset	$—

The components of income tax expense (benefit) are as follows:

	Year ended December 31 2013	December 31 2012
Net loss per financial statements which approximates net loss per income tax returns	$(2,008,101)	$(88,022)
Income tax expense (benefit) applying prevailing Federal and state income tax rates	(843,400)	(373,000)
Less valuation allowance	843,400	373,000
Net income tax expense	$—	$—

Net income tax benefit is not recognized at this time because there is no reasonable expectation that the benefit will be realized in the future.

The Company has adopted accounting rules that prescribe when to recognize and how to measure the financial statement effects, if any, of income tax positions taken or expected on its income tax returns. These new rules require

management to evaluate the likelihood that, upon examination by relevant taxing jurisdictions, those income tax positions would be sustained.

Based on that evaluation, if it were more than fifty percent (50%) probable that a material amount of income tax would be imposed at the entity level upon examination by the relevant taxing authorities, a liability would be recognized in the accompanying balance sheet along with any interest and penalties that would result from that assessment. Should any such penalties and interest be incurred, the Company’s policy would be to recognize them as operating expenses.

Due to continuous losses from operations the Company has assigned a full valuation allowance against its deferred tax assets.

6. CONVERTIBLE PREFERRED STOCK

In July 2005 the Company issued 7,171,725 shares of Series A Preferred Stock in payment of services. The issuance had been previously authorized by the Board of Directors. Each share of Series A Preferred Stock has a liquidation preference, in the event of liquidation of the corporation, of $0.001 per share before any payment or distribution is made to the holders of common stock.

During 2008 the Board of Directors approved a reverse split of the stock in which one new share of preferred stock was issued in exchange for each 80 shares of stock outstanding. Accordingly, the total issued of preferred stock was adjusted from 7,171,725 shares to 89,647 shares. The par value and the total authorized shares did not change.

Effective in 2010 the initial issuance of preferred of Series A Preferred can be converted into common stock in the ratio of 15:1. During 2011 the Board of Directors authorized the issuance of an additional 1,400,000 shares of Series A Preferred Stock in payment of a loan from a shareholder in the amount of $64,000 and also in payment of services in the amount of $34,000. These additional shares can be converted to common stock in 2013. Each share is entitled to fifteen votes and shall be entitled to vote on any matters brought to a vote on the common stock shareholder.

During 2012 the Board of Directors authorized the issuance of an additional 1,500,000 shares of Series A Preferred Stock in payment of deferred compensation and current compensation in the amount of $161,463.

During 2013 the Board of Directors authorized the issuance of an additional 500,000 shares of Series A Preferred Stock in payment of professional services in the amount of $225,000.

7. OPERATING LEASE

The Company leases 3,600 sq. ft. of office and warehouse space at 1550 Caton Center Drive, Suites D and E, Baltimore, Maryland, under a non-cancellable operating lease which expires in December 2014. The original base rent was $3,077 per month with a 3% annual rent escalator clause.The current monthly rent is $3,464. Rent expense, which includes the Caton Center property as well as some other short-term leases, was $44,652and $45,941 for the periods ended December 31, 2013 and 2012, respectively.

8. STOCK BASED COMPENSATION

During the periods ended December 31, 2012 and 2011 the Company granted restricted stock to independent contractors and consultants for payment of services.

On April 2, 2010 the Company adopted its 2010 Equity Incentive Plan. Reserved for equity issuances under the Equity Incentive Plan are 50,000,000 shares of our common stock. During 2011 14,116,433 shares of common stock were issued under the provisions of the 2010 Equity Incentive Plan for which $92,065 of expenses were recognized.

On June 1, 2010 the Company adopted its 2010 Service Provider Stock Compensation Plan. Reserved for equity issuances under the Service Provider Stock Compensation Plan are 50,000,000 shares of our common stock. No equity issuances were made during the reporting period from the 2010 Service Provider Stock Compensation Plan.

During 2013 and 2012, the Company issued the following compensatory shares outside of its existing Stock Option and Restricted Share Plans at the discretion of the Board of Directors:

For the year ended December 31, 2013 13,111,904 shares of common stock were issued in payment of expenses and prepaid expenses amounting to $328,000.

For the year ended December 31, 2012 14,250,000 shares of common stock were issued in payment of expenses and prepaid expenses amounting to $285,000.

For the year ended December 31, 2012 1, 500,000 shares of preferred stock were issued in payment of expenses and liabilities amounting to $161,463.

In addition, 4,500,000 shares of common stock were issued during 2013 in payment of accounts payable of $90,900 and another 1,500,000 shares of common stock were issued in payment of notes payable of $7,500.

In addition, shares of common stock were issued in 2012 in payment of accounts payable amounting to $28,500, in payment of accrued compensation of $108,501, in payment of notes payable of $15,000 and accrued interest of $75,000.

Independent contractors and consultants' expense was based on the estimated value of services rendered or the value of the common stock issued, if more reliably determined.

Stock Options and Warrants

On April 2, 2010, the Company adopted its 2010 Equity Incentive Plan, which authorized, among other forms of incentives, the issuance of stock options. Reserved for equity issuances under the 2010 Equity Incentive Plan are 50,000,000 shares of our common stock. No equity issuances have been made from the 2010 Equity Incentive Plan. Stock options, which may be tax qualified and non-qualified, are exercisable for a period of up to ten years at prices at or above market prices as established on the date of the grant.

Stock Options

Certain nonqualified stock options were issued during the year ended December 31, 2013 to a member of the board of directors as compensation for services performed.

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at January 1, 2013	—	$ —	—	$ —
Granted	15,000,000	$ 0.03	4.14	$ —
Exercised	—	$ —	—	$ —
Forfeited	(5,000,000)	$ —	—	$ —
Outstanding at December 31, 2013	10,000,000	$ 0.03	4.14	$ —
Exercisable at December 31, 2013	10,000,000	$ 0.03	4.14	$ —

The Company uses the Black-Scholes option pricing model to calculate the fair value of options. Significant assumptions used in this model include:

	Year ended December 31 2013		December 31 2012
Annual Dividend	—		NA
Expected Life (in years)	5		NA
Risk Free Interest Rate	0.78	%	NA
Expected Volatility	325.25	%	NA

The 10,000,000 options granted for the year ended December 31, 2013 had a weighted average grant date fair value of $0.03.

9. RELATED PARTY TRANSACTIONS

During the periods reflected on this report certain shareholders made cash advances to the Company to help with short-term working capital needs. The net proceeds from stockholders with unstructured payment plans amounted to $31,806 and 49,006 for the years ended December 31, 2013 and 2012, respectively. The total balance due on unstructured loans from shareholders amounted to $251,054 and $199,173 at December 31, 2013 and 2012, respectively. Loans from stockholders made with repayment terms are described in Note 4 above.

During the year ended December 31, 2013 a Board member provided professional services to the Company for which he was paid $25,000 in cash and awarded 7,113,333 shares of common stock with a value of $173,500. Of the total shares 1,680,000 were issued subsequent to December 31, 2013 and are reflected on the financial statements as issuable common stock.

During the year ended December 31, 2012 the Company's Chief Executive Officer was issued 1,000,000 shares of convertible preferred stock as a payment for compensation accrued during 2012 and 2011 in the amount of $43,338. He was also issued 1,839,000 shares of common stockas a payment for compensation accrued during 2011 and 2012 in the amount of $108,501. In addition, in December 2012 the Board of Directors authorized the issuance of 8,000,000 shares of common stock to the Chief Executive Officer as payment for compensation accrued during 2011 and 2012 in the amount of $160,000. These shares were issued subsequent to December 31, 2012 and are reflected on the financial statements as issuable common stock.

10. STOCK SETTLEMENT IN PROCESS

During 2006 the Company negotiated a loan from an individual in the amount of $100,000. Under the terms of the loan it was to be repaid in full within one year together with interest at the rate of 15% per annum. The Company was unable to pay the loan when due and under the threat of litigation the note holder was given 3,500,000 shares of common stock. The stock was issued on January 28, 2010. At that time the principal, accrued interest and legal fees amounted to $163,366. Under the terms of a court ordered stipulation agreement if the note holder was unable to liquidate the stock in full payment of the stipulated amount then the Company would be obligated to issue more stock to him to make up for the shortage.As a part of the agreement the note holder is required to account for proceeds realized from the sales of stock. The note holder has yet to report any stock sales so this settlement is considered to be in process.

During the year ended December 31, 2011 $38,788 was levied against the Company's bank accounts as a result of a legal action brought to force collection of the balance. The note holder's contention was that stock sales had fallen well short of the balance due and thus he was due to be paid. While the Company had a complaint that they had not been provided with any information regarding sales of stock management was unable to stave off the forced levy. As a result of the levy the debt balance as of December 31, 2011 was reduced to $124,578.

Subsequent to June 30, 2013 the note holder reported that he had sold all of the 3,500,000 shares of the common stock noted above. After giving effect to those proceeds, and the note holder and the Company agreed to settle the remaining debt for $75,000. As a result, the Company has agreed to make monthly payments of $5,000, commencing in July 2013, until the debt is paid in full. The agreement provides that there is no interest due on this debt. As of December 31, 2013 the balance due on this agreement was $45,000.

11. ISSUABLE COMMON STOCK

During 2013 the Board of Directors authorized the issuance of 23,371,111 shares of common stock that were not issued until after December 31, 2013. These authorizations were 11,911,111 shares for $217,500 of cash, 6,660,000 shares of common stock in payment of services amounting to $121,500, 1,400,000 shares of common stock in payment of accounts payable of $30,000 and 3,400,000 shares in payment of notes payable and accrued interest of $169,720.

During December 2012 the Board of Directors authorized the issuance of 12,000,000 shares of common stock in payment of services in the amount of $267,000. The certificates were issued subsequent to December 31, 2012.

12. JOINT VENTURE PROFIT SHARING

During 2011 the Company entered into an agreement with CRA, Inc. regarding a sale of 60 scanners to a municipal school system. Under the terms of the deal CRA, Inc. purchased all of the materials and paid substantially all of the cost, View Systems, Inc. assembled the products, shipped the scanners for installation and billed the school system. The terms of the agreement provide that each party is to share equally in the profits. As of December 31, 2012 the Company has estimated that it owed CRA $63,561 which is CRA's share on the profit is reflected on the financial statements as a component of cost of sales. However, since the project was not completed as of December 31, 2012 the ultimate calculation of profit could be made until the job is considered completed. During 2013 the parties agreed to settle the debt for $20,000 which was paid in full prior to December 31, 2013.

13. CONCENTRATIONS

During the years ended December 31, 2013 and 2012 the Company received 47% and 22% of its product sales revenue for a single state municipal agency. The contract with this agency was completed during 2013.

14. SUBSEQUENT EVENT

On March 10, 2014 the Company filed a Form S-1 with the SEC the purpose of which is to allow the Company to sell up to 100,000,000 shares of common stock directly to the public at a stated price of $0.04 per share. The funds raised by this offering will be used to reduce debt and provide working capital. The Form S-1 is pending approval by the SEC which will take at least 30 days from the date filed.

15. CHANGE TO PRIOR FINANCIAL STATEMENT

During 2013 it was noticed that the par value of preferred stock had been incorrectly reported as $0.01 per share while the correct par value was $0.001 per share. Accordingly, an adjustment was made to decrease the total par value of preferred stock issued and increase additional paid in capital in the amount of $26,907. The adjustment is reflected in beginning balances of preferred stock and additional paid-in-capital as of December 31, 2011. This adjustment had no effect on previously reported results of operations and also had no effect on the carrying value or historical costs of any assets or liabilities.

[Back Cover]

PROSPECTUS

A Total of 106,000,000, Shares of Common Stock Offered for Sale

100,000,000 Shares Offered at $0.04 Per Share by the Company

6,000,000 Shares Offered at Market Price by a Selling Shareholder

DEALER PROSPECTUS DELIVERY OBLIGATION

Until _____, 2014, all dealers that effect transactions in these securities, whether or not participating in the offering, may be required to deliver a prospectus. This is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to its unsold allotments or subscriptions.

PART II – INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 13.

OTHER EXPENSES OF DISTRIBUTION

The following table sets forth the costs and expenses, other than underwriting discounts and commission, paid or to be paid by the registrant in connection with the sale of the Shares of Common Stock being registered hereby. All amounts shown, except the Securities and Exchange Commission registration fee, are estimates.

Expense	**Amount**
	*
Registration Fee	$73
Cost of printing	$8,000 *
Legal fees & expenses	$18,000 *
Accounting fees & expenses	$1,000 *
Edgar Filing preparation & fees	$1,000 *
Transfer Agent fees	$0
Miscellaneous	$1,927 *
Total	$30,000

* Estimated subject to change

ITEM 14

INDEMNIFICATION OF DIRECTORS AND OFFICERS

Article VI of our Articles of Incorporation, as amended and restated, provides for mandatory indemnification of our officers and directors, except where such person has been adjudicated liable by reason of his negligence or willful misconduct toward the Company or such other Company in the performance of his duties as such officer or director.

Article V of our Bylaws provides for indemnification of our officers and directors. Our Bylaws provide as follows in pertinent part:

5.1 Indemnification of Directors. Unless otherwise provided in the articles of incorporation, the corporation shall indemnify any individual made a party to a proceeding because the individual is or was a director of the corporation, against liability incurred in the proceeding, but only if such indemnification is both (i) determined permissible and (ii) authorized, as such are defined in subsection (a) of this Section 5.1.

5.1.1 Determination of Authorization. The corporation shall not indemnify a director under this Section unless:

(a) a determination has been made in accordance with the procedures set forth in the Statutes that the director met the standard of conduct set forth in subsection (b) below, and

(b) payment has been authorized in accordance with the procedures set forth in the Statutes based on a conclusion that the expenses are reasonable, the corporation has the financial ability to make the payment, and the financial resources of the corporation should be devoted to this use rather than some other use by the corporation.

5.1.2 Standard of Conduct. The individual shall demonstrate that:

(a) he or she conducted himself in good faith; and

(b) he or she reasonably believed:

(i) in the case of conduct in his official capacity with the corporation, that his conduct was in its best interests;

(ii) in all other cases, that his conduct was at least not opposed to its best interests; and

(iii) in the case of any criminal proceeding, he or she had no reasonable cause to believe his conduct was unlawful.

5.1.3 Indemnification in Derivative Actions Limited. Indemnification permitted under this Section in connection with a proceeding by or in the right of the corporation is limited to reasonable expenses incurred in connection with the proceeding.

5.1.4 Limitation on Indemnification. The corporation shall not indemnify a director under this Section of Article 5:

(a) in connection with a proceeding by or in the right of the corporation in which the director was adjudged liable to the corporation; or

(b) in connection with any other proceeding charging improper personal benefit to the director, whether or not involving action in his or her official capacity, in which he or she was adjudged liable on the basis that personal benefit was improperly received by the director.

5.2 Advance of Expenses for Directors. If a determination is made following the procedures of the Statutes, that the director has met the following requirements, and if an authorization of payment is made following the procedures and standards set forth in the Statutes, then unless otherwise provided in the articles of incorporation, the corporation shall pay for or reimburse the reasonable expenses incurred by a director who is a party to a proceeding in advance of final disposition of the proceeding, if:

(a) the director furnishes the corporation a written affirmation of his good faith belief that he has met the standard of conduct described in this section;

(b) the director furnishes the corporation a written undertaking, executed personally or on his behalf, to repay the advance if it is ultimately determined that he did not meet the standard of conduct;

(c) a determination is made that the facts then known to those making the determination would not preclude indemnification under this Section or the Statutes.

5.3 Indemnification of Officers, Agents and Employees Who Are Not Directors. Unless otherwise provided in the articles of incorporation, the board of directors may indemnify and advance expenses to any officer, employee, or agent of the corporation, who is not a director of the corporation, to the same extent as to a director, or to any greater extent consistent with public policy, as determined by the general or specific actions of the board of directors.

5.4 Insurance. By action of the board of directors, notwithstanding any interest of the directors in such action, the corporation may purchase and maintain insurance on behalf of a person who is or was a director, officer, employee, fiduciary or agent of the corporation, against any liability asserted against or incurred by such person in that capacity or arising from such person's status as a director, officer, employee, fiduciary, or agent, whether or not the corporation would have the power to indemnify such person under the applicable provisions of the Statutes.

These provisions may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. Furthermore, a stockholder’s investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. We believe that these provisions, the insurance, and the indemnity agreements are necessary to attract and retain talented and experienced directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted for directors, officers or employees pursuant to the foregoing provisions, the Registrant has been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

ITEM 15

RECENT SALES OF UNREGISTERED SECURITIES

During fiscal year ended December 31, 2013 and to current date, we issued an aggregate of 39,241,778 shares of unregistered common stock and 1,400,000 Series A preferred shares as follows.

Common Stock -2013

During fiscal year ended December 31, 2013, we issued an aggregate 13,111,904 shares of our restricted common stock at a per share price of ranging from approximately $0.0200 to $0.0560 approximately sixteen vendors relating to expenses incurred in the amount of $328,000. The expenses were primarily related to professional services rendered. The 13,111,904 shares were issued in a private transaction to sixteen United States residents in reliance on Rule 506 of Regulation D promulgated under the Securities Act. The shares of common stock have not been registered under the Securities Act or under any state securities laws and may not be offered or sold without registration with the United States Securities and Exchange Commission or an applicable exemption from the registration requirements. The vendors acknowledged that the securities to be issued have not been registered under the Securities Act, that they understood the economic risk of an investment in the securities, and that they had the opportunity to ask questions of and receive answers from our management concerning any and all matters related to acquisition of the securities.

During fiscal year ended December 31, 2013, we issued an aggregate 4,500,000 shares of our restricted common stock at a per share price of approximately $0.02 to two creditors relating to accounts payable of $90.900. The 4,500,000 shares were issued in a private transaction to two United States residents in reliance on Rule 506 of Regulation D promulgated under the Securities Act. The shares of common stock have not been registered under the Securities Act or under any state securities laws and may not be offered or sold without registration with the United States Securities and Exchange Commission or an applicable exemption from the registration requirements. The creditors acknowledged that the securities to be issued have not been registered under the Securities Act, that they understood the economic risk of an investment in the securities, and that they had the opportunity to ask questions of and receive answers from our management concerning any and all matters related to acquisition of the securities.

During fiscal year ended December 31, 2013, we issued an aggregate 2,,000,000 shares of our restricted common stock at a per share price of approximately $0.005 relating to accounts payable and to one note holder relating to principal of $7,500 due and owing. The 2,000,000 shares were issued in a private transaction to one United States resident in reliance on Rule 506 of Regulation D promulgated under the Securities Act. The shares of common stock have not been registered under the Securities Act or under any state securities laws and may not be offered or sold without registration with the United States Securities and Exchange Commission or an applicable exemption from the registration requirements. The note holders acknowledged that the securities to be issued have not been registered under the Securities Act, that he understood the economic risk of an investment in the securities, and that he had the opportunity to ask questions of and receive answers from our management concerning any and all matters related to acquisition of the securities

Common Stock - Issued in 2014

During fiscal year ended December 31, 2013, we authorized the issuance of an aggregate 23,371,111 shares of our restricted common stock (which were issued subsequent to December 31, 2013) as follows: (i) 11,911,111 shares at a per share price of approximately $0.018 to investors resulting in gross proceeds of $217,500; (ii) 6,660,000 shares of common stock at a per share price of $0.018 to consultants in payment of services rendered in the aggregate amount of $121,500; (iii) 1,400,000 shares of common stock at a per share price of $0.021 in payment of services of $30,000; and (iv) 3,400,000 shares of common stock at a per share price of $0.049 to creditors in payment of notes payable and accrued interest of $169,720. The shares of common stock have not been registered under the Securities Act or under any state securities laws and may not be offered or sold without registration with the United States Securities and Exchange Commission or an applicable exemption from the registration requirements. The consultants acknowledged that the securities to be issued have not been registered under the Securities Act, that they understood the economic risk of an investment in the securities, and that they had the opportunity to ask questions of and receive answers from our management concerning any and all matters related to acquisition of the securities.

Preferred Stock - 2013

During fiscal year ended December 31, 2013, we authorized the issuance of an aggregate 500,000 shares of our Series A preferred stock at a per share price of approximately $0.45 to a consultant relating to professional services rendered in the amount of $225,000. The 500,000 shares were issued in a private transaction to one United States resident in reliance on Rule 506 of Regulation D promulgated under the Securities Act. The shares of Series A preferred stock have not been registered under the Securities Act or under any state securities laws and may not be offered or sold without registration with the United States Securities and Exchange Commission or an applicable exemption from the registration requirements. The consultant acknowledged that the securities to be issued have not been registered under the Securities Act, that he understood the economic risk of an investment in the securities, and that he had the opportunity to ask questions of and receive answers from our management concerning any and all matters related to acquisition of the securities.

During fiscal year ended December 31, 2013, we authorized the issuance of an aggregate 1,000,000 shares of our Series A preferred stock at a per share price of approximately $0.43 to one of the members of our Board of Directors as payment for compensation. The 1,000,000 shares were issued in a private transaction to one United States resident in reliance on Rule 506 of Regulation D promulgated under the Securities Act. The shares of Series A preferred stock have not been registered under the Securities Act or under any state securities laws and may not be offered or sold without registration with the United States Securities and Exchange Commission or an applicable exemption from the registration requirements.

ITEM 16

EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following exhibits are filed as part of this registration statement unless otherwise indicated:

3.1	Amended and Restated Articles of Incorporation (Incorporated by reference to exhibit 3(i).1 to Form 10-Q filed May 14, 2010)
3.2	Bylaws (Incorporated by reference to exhibit 3.2 for Form 10-QSB, filed November 14, 2003)
4.2	Subscription Agreement between View Systems, Inc. and Starr Consulting, Inc., Active Stealth, LLC, and KCS Referral Service LLC, dated December 23, 2005 (Incorporated by reference to exhibit 4.1 of Form 8-K, filed January 6, 2006)
5.1	Opinion re Legality incorporated by reference to Exhibit 5.1 of Amendment No. 3 to Registration Statement filed on July 16, 2014
10.1	View Systems, Inc. 2010 Equity Incentive Plan (Incorporated by reference to exhibit 10.1 to Form 10-Q filed May 14, 2010)
10.2	View Systems, Inc. 2010 Service Provider Stock Compensation Plan (Incorporated by reference to exhibit 10.4 to Form 10-Q filed August 19, 2010)
10.3	Employment agreement between View Systems and Gunther Than, dated December 1, 2009 (Incorporated by reference to exhibit 10.1 to Form 8-K, filed January 11, 2010)
10.4	Subcontractor Agreement dated March 9, 2009 between MasTec North America, Inc. and View Systems, Inc. (Incorporated by reference to exhibit 10.3 for Form 10-Q, Amendment No. 1, for the period ended March 31, 2009)
10.3	Purchase Agreement, dated June 1, 2012 (Incorporated by reference to exhibit 10.1 to Form 8-K, filed July 3, 2012)
10.4	Amendment to Purchase Agreement, dated June 28, 2012 (Incorporated by reference to exhibit 10.2 to Form 8-K, filed July 3, 2012)
10.5	Agreement to Accept View Systems Inc. Common Stock in Payment of Note Payable dated September 21, 2013 between View Systems Inc. and William W. Smith incorporated by reference to Exhibit 10.5 of Amendment No. 3 to Registration Statement filed on July 16, 2014
10.6	Subscription Agreement dated March 22, 2013 between View Systems Inc. and Reid Miles incorporated by reference to Exhibit 10.6 of Amendment No. 3 to Registration Statement filed on July 16, 2014

10.7	Agreement dated March 21, 2012 between View Systems, Inc. and Jerry W. Miller incorporated by reference to Exhibit 10.7 of Amendment No. 3 to Registration Statement filed on July 16, 2014.
21.1	List of Subsidiaries*
23.1	Consent of Stegman and Company incorporated by reference to Exhibit 23.1 of Amendment No. 3 to Registration Statement filed on July 16, 2014
31.1	Rule 13a-15(e)/15d-15(e) Certification by the Chief Executive Officer and Chief Financial Officer *
32.1	Certification by the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 *

ITEM 17.

UNDERTAKINGS

Registrant hereby undertakes:

• To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement to: (i) include any prospectus required by Section 10(a) (3) of the Securities Act; (ii) reflect in the Prospectus any facts or events which, individually or in the aggregate, represent a fundamental change in the information in the Registration Statement; and (iii) include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in the Registration Statement;

• That, for the purpose of determining liability under the Securities Act, each such post-effective amendment shall be deemed to be a new Registration Statement of the securities offered, and the offering of the securities at that time shall be deemed to be the initial bona fide offering thereof;

• To file a post-effective amendment to remove from registration any of the securities that remain unsold at the end of the offering;

• To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering;

• That, for the purpose of determining liability under the Securities Act to any purchaser:

• Pursuant to Rule 430B:

• That each prospectus filed by the Registrant pursuant to Rule 424(b)(3)shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

• Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date;

• that in a primary offering of securities by the Registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the Registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

• Any preliminary prospectus or prospectus of the Registrant relating to the offering required to be filed pursuant to Rule 424;

• Any free writing prospectus relating to the offering prepared by or on behalf of the Registrant or used or referred to by the Registrant;

• The portion of any other free writing prospectus relating to the offering containing material information about the Registrant or its securities provided by or on behalf of the Registrant; and

• Any other communication that is an offer in the offering made by the Registrant to the purchaser.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Baltimore, State of Maryland, on July 25, 2014.

View Systems, Inc.

By: */s/ Gunther Than*
Gunther Than
Chief Executive Officer and Chief Financial Officer

(Principal executive officer, principal financial officer, and principal accounting officer)

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Baltimore, State of Maryland, on August 11, 2014.

Name	**Title**	**Date**
/s/ Gunther Than Gunther Than	Director, Chief Executive Officer and Treasurer	August 11, 2014
/s/ Michael L. Bagnoli Michael L. Bagnoli	Director and Secretary	August 11, 2014
*/s/ Martin J. Maass*en Martin J. Maassen	Director	August 11, 2014
/s/ Reid Miles Reid Miles	Director	August 11, 2014

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