

Cyclacel Pharmaceuticals, Inc.
Form 10-K
March 31, 2015
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K
(Mark One)

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

For the fiscal year ended December 31, 2014
OR

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

Commission file number 00-50626
CYCLACEL PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	91-1707622
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
200 Connell Drive Suite 1500 Berkeley Heights, New Jersey	07922
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (908) 517-7330

Securities registered under Section 12(b) of the Exchange Act:

Title of each class	Name of each exchange on which registered
Common Stock, \$0.001 par value	The NASDAQ Stock Market LLC
Preferred Stock, \$0.001 par value	The NASDAQ Stock Market LLC

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange 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 (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or

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information statements incorporated by reference in Part III of this Form 10-K or any amendments 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	Smaller reporting company

[Do not check if a 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 voting and non-voting common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate), as of June 30, 2014 (based upon the closing sale price of \$3.07 of such shares on The NASDAQ Global Market on June 30, 2014) was \$68,370,466.

As of March 27, 2015, there were 34,388,485 shares of the registrant’s common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of the Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the Registrant’s Proxy Statement for the Annual Meeting of Stockholders to be held on or about May 22, 2015.

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PART I

Item 1.

Business

The following Business Section contains forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain risks, uncertainties and other factors including the risk factors set forth in Part I, Item 1A of this Annual Report on Form 10-K. In this report, “Cyclacel,” the “Company,” “we,” “us,” and “our” refer to Cyclacel Pharmaceuticals, Inc.

General

Cyclacel is a pioneer company in the field of cell cycle biology with a vision to improve patient healthcare with orally available innovative medicines. Our goal is to develop and commercialize small molecule drugs that target the various phases of cell cycle control for the treatment of cancer and other serious diseases, particularly those of high unmet medical need.

Our strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a development pipeline of novel drug candidates. Substantially all efforts of the Company to date have been devoted to performing research and development, conducting clinical trials, developing and acquiring intellectual property, raising capital and recruiting and training personnel.

Drug Candidates

The cell cycle, the biological process by which cells progress and divide, lies at the heart of cancer. In normal cells, the cell cycle is controlled by a complex series of signaling pathways by which a cell grows, replicates its DNA and divides. This process also includes mechanisms to ensure errors are corrected, and if not, the cells commit suicide or apoptosis. In cancer, as a result of genetic mutations, this regulatory process malfunctions, resulting in uncontrolled cell proliferation.

We have generated several families of anticancer drugs that act on the cell cycle including sapacitabine, seliciclib and CYC065. We believe that these drug candidates are differentiated in that they are orally-available and interact with unique target profiles and mechanisms and have the potential to treat multiple cancer indications.

Our lead candidate, sapacitabine, is a novel, orally-available nucleoside analog. A number of nucleoside drugs, such as gemcitabine and cytarabine, also known as Ara-C, both generic drugs, are in wide use as conventional chemotherapies. Both sapacitabine and its major metabolite, CNDAC, have demonstrated potent anti-tumor activity in both blood and solid tumors in preclinical studies. In a liver metastatic mouse model, sapacitabine was shown to be superior to gemcitabine and fluorouracil, or 5-FU, two widely used nucleoside analogs, in delaying the onset and growth of liver metastasis. We hold the worldwide rights to commercialize sapacitabine, except for Japan, for which Daiichi Sankyo Co., Ltd., or Daiichi Sankyo, has a right of first negotiation.

The U.S. Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA, have designated sapacitabine as an orphan drug for the treatment of both Acute Myeloid Leukemia, or AML, and Myelodysplastic Syndromes, or MDS.

We are currently evaluating sapacitabine in a Phase 3 study being conducted under a Special Protocol Assessment, or SPA, with the FDA for the front-line treatment of AML in the elderly. We are also exploring sapacitabine in Phase 2 studies for MDS, non-small cell lung cancer, or NSCLC, and chronic lymphocytic leukemia, or CLL and in a Phase 1 study in solid tumors in combination with seliciclib, another of our drug candidates. Sapacitabine has been evaluated in approximately 1,000 patients to date.

In our second development program we are evaluating cyclin dependent kinase, or CDK, inhibitors. CDKs are involved in cancer cell growth, metastatic spread and DNA damage repair. Seliciclib, our lead CDK inhibitor, selectively inhibits a spectrum of enzyme targets — CDK2, CDK5, CDK7 and CDK9 — that are central to the process of cell division and cell cycle control. In breast and lung tumors overexpression of cyclin E is associated with poor prognosis and drug resistance. Resistant breast and lung tumor cell lines overexpressing cyclin E are resensitized to apoptotic cell killing by seliciclib. NSCLC cell

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lines with Ras-activating mutations, such as KRAS and NRAS, have been found to be sensitive to seliciclib-induced apoptosis. Seliciclib will also be evaluated in an investigator-initiated clinical study to treat rheumatoid arthritis, or RA, supported by an approximately \$1.5 million grant from the UK's Medical Research Council. Enabled by the clinical development experience in solid tumors, investigators believe that seliciclib's mechanism of action and oral administration route may be of benefit in treating patients with RA. To date, seliciclib has been evaluated in approximately 450 patients in several Phase 1 and 2 studies and has shown signs of anti-cancer activity. We have retained worldwide rights to commercialize seliciclib. Seliciclib has completed a Phase 2B randomized study in third-line NSCLC and is currently undergoing a study in solid tumors in combination with our own drug candidate, sapacitabine.

Our second generation CDK inhibitor, CYC065, is a highly selective inhibitor of CDKs targeting CDK2, CDK5 and CDK9 enzymes. CYC065 has increased anti-proliferative potency and improved pharmaceutical properties compared to seliciclib. Independent investigators have reported that CYC065 reverses resistance in breast cancer cells that have become resistant to trastuzumab. CYC065 has also shown activity against leukemia cells, including those with mixed lineage leukemia rearrangements, or MLLr. Investigational new drug, or IND, — enabling studies with CYC065 have been completed. These were supported by a \$1.9 million grant from the Biomedical Catalyst, a United Kingdom government program.

In addition to these development programs, in our polo-like kinase, or PLK, inhibitor program, we have discovered CYC140 and other potent and selective small molecule inhibitors of PLK1, a kinase active during cell division, targeting the mitotic phase of the cell cycle. PLK was discovered by Professor David Glover, our Chief Scientist. We have received a grant award of approximately \$3.7 million from the Biomedical Catalyst of the United Kingdom government to complete IND-directed preclinical development of CYC140.

We currently retain virtually all marketing rights worldwide to the compounds associated with our drug programs. To optimize our commercial return, we intend to enter into selected partnering arrangements.

Lead Development Programs

Our pipeline and expertise in cell cycle biology

Our core area of expertise is in cell cycle biology and we focus primarily on the development of orally-available anticancer agents that target the cell cycle with the aim of slowing the progression or shrinking the size of tumors, and enhancing the quality of life and improving survival rates of cancer patients.

We have retained rights to commercialize our clinical development candidates and our business strategy is to enter into selective partnership arrangements with these programs.

Oncology Development Programs

We have generated several families of anticancer drugs that act on the cell cycle, including nucleoside analogs, CDK inhibitors, PLK inhibitors and Aurora Kinase/vascular endothelial growth factor, or AK/VEGFR2, inhibitors. In our development programs, we have been an early adopter of biomarker analysis to help evaluate whether our drug candidates are having their intended effect through their assumed mechanisms at different doses and schedules. Biomarkers are proteins or other substances whose presence in the blood can serve as an indicator or marker of diseases. Biomarker data from early clinical trials may also enable us to design subsequent trials more efficiently and to monitor patient compliance with trial protocols. For example, we reported that sapacitabine efficacy is enhanced in tumor cells that are defective in homologous recombination DNA repair. In another example, we reported that sensitivity to our PLK1 inhibitor CYC140 correlated with the status of tumor suppressor protein p53, in a panel of esophageal cancer cell lines, which could be used as a predictive biomarker in clinical trials to identify responders. We believe that in the longer term biomarkers may allow the selection of patients more likely to respond to our drugs in clinical trials and increase the benefit to patients.

Although a number of pharmaceutical and biotechnology companies are currently attempting to develop nucleoside analogs, CDK inhibitors, PLK inhibitors and AK and/or VEGFR inhibitor drugs, we believe that our drug candidates, are differentiated in that they are orally-available and demonstrate unique target profiles and mechanisms. For example, we believe that our sapacitabine is the only orally-available nucleoside analog presently being tested in Phase 3 trials in previously untreated AML and in Phase 2 for high risk MDS.

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Research and Development Pipeline

The following table summarizes our currently active clinical and preclinical programs.

Program	Indication	Development Status	Target	Cell Cycle Mechanism
Oncology				
Sapacitabine, CYC682	Elderly AML	Phase 3 registration study on-going Enrollment completed	DNA polymerase	G2 and S phase
Sapacitabine, CYC682	MDS	Phase 2 randomized trial on-going	DNA polymerase	G2 and S phase
Sapacitabine, CYC682	NSCLC	Phase 2 trial closed to accrual	DNA polymerase	G2 and S phase
Sapacitabine, CYC682	CLL	Phase 2 trial. Investigator-initiated study	DNA polymerase	G2 and S phase
Sapacitabine + Seliciclib	Cancer	Phase 1 trial on-going		
Seliciclib, CYC202, CDK inhibitor	NSCLC	Phase 2b randomized trial. Trial closed to accrual	CDK2, 5, 7, 9	G1/S checkpoint and others
Seliciclib, CYC202	NPC	Phase 2 randomized trial. Trial closed to accrual	CDK2, 5, 7, 9	G1/S checkpoint and others
CYC065 CDK inhibitor	Cancer	IND-directed development completed	CDK2, 5, 9	G1/S checkpoint and others
CYC140 PLK inhibitor	Cancer	Preclinical	PLK1	G2/M checkpoint
Other therapeutic areas				
Seliciclib, CYC202	Autoimmune & Inflammatory Diseases	Phase 2 trial. Investigator-initiated study	CDK	G1/S checkpoint and others

Market opportunity in hematology

Cancer remains a major life-threatening disease in the United States with approximately 3.2 million people afflicted by cancer and approximately 1.4 million new cases of cancer diagnosed every year.

AML is a cancer of the blood cells that progresses rapidly and if not treated, could be fatal in a few months. AML is generally a disease of older people and is uncommon before the age of 40. The average age of a patient with AML is about 67 years. According to the American Cancer Society approximately 44,000 cases of leukemia are diagnosed annually in the United States of which about 15,000 are classified as AML of which about half are elderly aged 70 years or older. Nearly 9,000 deaths are caused by this cancer each year in the United States. A review of The University of Texas MD Anderson Cancer Center's historical experience with front-line intensive induction chemotherapy for AML patients aged 70 years or older demonstrated that while 45% achieved a complete remission, median overall survival was only 4.6 months and was associated with a 4-week death rate of 26% and an 8-week death rate of 36%.

MDS is a family of clonal myeloid neoplasms, or malignancies of the blood, caused by the failure of blood cells in the bone marrow to develop into mature cells. Patients with MDS typically suffer from bone marrow failure and cytopenias, or reduced counts of platelets, red and white blood cells. The exact incidence and prevalence of MDS are unknown because it can go undiagnosed and a national survey canvassing both hospitals and office practitioners has not been completed. Some estimates place MDS incidence at 15,000 to 20,000 new cases each year in the US alone with some authors estimating incidence as

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high as 46,000. Literature suggests that there is a rising incidence of MDS as the age of the population increases with the majority of patients aged above 60 years. Patients currently receive hypomethylating agents as first-line treatment. There is no approved therapy for second-line treatment.

Sapacitabine

Sapacitabine, previously known as CYC682, is an orally-available nucleoside analog. Both sapacitabine and CNDAC, its major metabolite, have demonstrated potent anti-tumor activity in preclinical studies. Sapacitabine is an orally-available prodrug of CNDAC, which is a novel nucleoside analog, or a compound with a structure similar to a nucleoside. A prodrug is a compound that has a therapeutic effect after it is metabolized within the body. CNDAC has a significantly longer residence time in the blood when it is produced in the body through metabolism of sapacitabine than when it is given directly. Sapacitabine acts through a novel mechanism whereby the compound interferes with DNA synthesis through the incorporation of CNDAC into DNA during replication or repair, triggering a beta-elimination reaction and leading to the formation of SSBs, which can activate the G2 checkpoint transcription coupled nucleotide excision repair, or TC-NER. During subsequent rounds of replication, SSBs are converted to double-strand breaks, or DSBs; these can be repaired by the homologous recombination repair, or HRR, pathway, or, if unrepaired, result in cell death.

We are currently exploring sapacitabine in both hematological cancers and solid tumors. Approximately 1,000 patients have received sapacitabine in Phase 1, 2 and 3 studies.

Hematological Cancers

SEAMLESS, randomized Phase 3, pivotal trial of sapacitabine in elderly patients with AML

The SEAMLESS study is being conducted under an SPA agreement that Cyclacel reached with the FDA.

The study is chaired by Hagop M. Kantarjian, M.D., Chairman and Professor, Department of Leukemia, The University of Texas MD Anderson Cancer Center. SEAMLESS is a multicenter, randomized, Phase 3 study of sapacitabine as a front-line treatment in approximately 485 elderly patients aged 70 years or older with newly diagnosed AML who are not candidates for or have refused intensive induction chemotherapy. In SEAMLESS an investigational arm of oral sapacitabine administered in alternating cycles with intravenous decitabine is compared with a control arm of intravenous decitabine administered alone. The primary efficacy endpoint is overall survival. SEAMLESS completed enrollment in December 2014 with approximately 110 centers participating from the United States and Europe. Also in December 2014, the Data Safety Monitoring Board, or DSMB, conducted a planned interim analysis for futility after 247 events, or patient deaths, and the final safety review of 470 randomized patients. The DSMB found no safety concerns. However, the planned futility boundary has been crossed and the DSMB determined that, based on available interim data, it would be unlikely for the study to reach statistically significant improvement in survival. The DSMB saw no reasons why patients should discontinue treatment on their assigned arm and recommended that recruited patients stay on treatment.

The interim analysis for futility is primarily driven by the events within the first 6 months of patients entering into the trial. Of 247 events in SEAMLESS, 173 (70%) have occurred in the first 6 months. This means that the survival curves beyond 6 months are poorly estimated at this time. Furthermore, follow up of European patients is significantly shorter than that of U.S. patients as the study opened for European accrual in April 2014. It is important to have complete follow up of all patients to ensure that a potential treatment effect beyond 6 months is not missed.

We remain blinded and, in accordance with the DSMB's recommendations, will follow-up patients as per the study protocol until the prespecified 424 events have been observed. This is estimated to occur between the second half of 2015 and the first half of 2016. Depending on the final data, we may meet with regulatory authorities in Europe and the U.S. to discuss registration submissions for sapacitabine for the AML indication.

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Pilot/Lead-in study of sapacitabine in elderly patients with AML

Results from a single-arm, multicenter, Phase 1/2 clinical trial examining the safety and efficacy of oral sapacitabine administered sequentially with intravenous decitabine, the same regimen as in the investigational arm of SEAMLESS, were reported during a poster session at the 2012 American Society of Hematology, or ASH, Annual Meeting.

Forty-six patients were treated with alternating cycles of sapacitabine and decitabine. Median age was 77 years (range 70-90). Thirty-three patients (72%) were 75 years or older. Median overall survival was 238 days, or approximately 8 months. The number of patients still alive at 3 months was 38 (83%), at 6 months 30 (65%), at 12 months 16 (35%) and at 18 months 12 (26%). Sixteen patients (35%) survived 1 year or longer. Among 33 patients who were 75 years or older, median overall survival was 263 days, or approximately 9 months, and one-year survival was 36%. Nineteen patients (41%) responded with 10 complete responses (CRs), 4 partial responses (PRs) and 5 major hematological improvements (HIs). Median time to response was 2 cycles, i.e., one cycle of decitabine and one cycle of sapacitabine (range 1-10). Twenty-seven patients (59%) received 5 or more cycles of treatment. Two dose-limiting toxicities (DLT) were observed (lung infection/sepsis, typhlitis). Thirty-day mortality from all causes was 4%. Sixty-day mortality from all causes was 13% with one death from typhlitis considered to be possibly related to decitabine by investigator assessment.

Phase 2 randomized study of sapacitabine in patients with previously untreated or first relapse AML

SEAMLESS builds on promising one year survival observed in elderly patients with AML enrolled in a Phase 2 study of single agent sapacitabine. In December 2007, we initiated a multicenter, randomized Phase 2 clinical trial of oral sapacitabine in 60 elderly patients with AML aged 70 years or older who were previously untreated or in first relapse. The Phase 2 study, led by Dr. Kantarjian, had a primary endpoint of one year survival and randomized patients to one of three dosing schedules of sapacitabine. Secondary objectives were to assess complete remission, or CR, partial remission, or PR, duration of CR or CRp, or major hematological improvement and their corresponding durations, transfusion requirements, number of hospitalized days and safety. The study used a selection design with the objective of identifying a dosing schedule among three different arms, A. 200 mg twice daily for seven days every 3-4 weeks, B. 300 mg twice daily for seven days every 3-4 weeks, and C. 400 mg twice daily for three days per week for two weeks every 3-4 weeks, which would produce a better one year survival rate in the event that all three dosing schedules were active.

In November 2012, the results from the Phase 2 study were published in *The Lancet Oncology*, demonstrating the safety and efficacy of sapacitabine in this patient population. Between December 27, 2007 and April 21, 2009, a total of 105 patients were enrolled and treated in the Phase 2 study. Their median age was 77 years with a range of 70-91 years. The group was comprised of a randomized cohort of 60 patients and an expanded, non-randomly assigned cohort enrolling a further 45 patients. Of the 105 patients, 86 were previously untreated and 19 in first relapse.

Approximately 50% of patients had AML de novo and 50% had AML preceded by antecedent hematological disorder, or AHD, such as MDS or myeloproliferative disease, or treatment-related AML. All but one enrolled patients had intermediate or unfavorable cytogenetics. The randomized cohort of patients was assigned to one of three dosing schedules: 200 mg twice a day for 7 days (Arm A); 300 mg twice a day for 7 days (Arm B); and 400 mg twice a day for 3 days each week for 2 weeks (Arm C). All schedules were given in 28 day cycles. The 3-day dosing schedule in Arm C was selected for further clinical development in elderly patients with untreated AML. This decision was based on the schedule's overall efficacy profile, which included a one-year survival rate of 30%, median overall survival of 213 days and durable complete remissions, or CRs, in 25% of patients. The median overall survival of patients from all arms who achieved CR was 525 days (95% C.I. 192-798). The most common grade 3-4 adverse events regardless of causality were anemia, neutropenia, thrombocytopenia, febrile neutropenia and pneumonia. Seven deaths were thought to be probably or possibly related to sapacitabine treatment.

Randomized Phase 2 clinical trial in older patients with MDS as a second-line treatment

In September 2008, we advanced sapacitabine into an open-label, multi-center, randomized Phase 2 trial as a second-line treatment in patients aged 60 or older with intermediate-2 or high-risk MDS after treatment failure of front-line hypomethylating agents, such as azacitidine and/or decitabine. The Phase 2

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study randomized 63 patients aged 60 years or older with MDS of intermediate-2 (n=52) or high-risk (n=11) classification by the International Prognostic Scoring System, or IPSS, at study entry to receive sapacitabine every 4 weeks on one of 3 dosing schedules: 200 mg twice daily for 7 days (Arm G), 300 mg once daily for 7 days (Arm H), or 100 mg once daily for 5 days per week for 2 weeks (Arm I). The primary efficacy endpoint of the study is one-year survival with the objective of identifying a dosing schedule that produces a better one-year survival rate in the event that all three dosing schedules are active. All patients in the study progressed after receiving azacitidine, decitabine, or both agents. Secondary objectives are to assess the number of patients who have achieved CR or CRp, PR, hematological improvement and their corresponding durations, transfusion requirements, number of hospitalization days and safety.

In December 2013 at the 2013 ASH Meeting and Exposition, we announced primary endpoint data from the ongoing, open-label, multicenter, randomized Phase 2 trial of oral sapacitabine capsules in older patients with myelodysplastic syndromes after treatment failure of front-line hypomethylating agents, such as azacitidine and/or decitabine. The median overall survival for each arm was approximately 9.7 months for Arm G, 9.7 months for Arm H, and 7.6 months for Arm I. The median overall survival for all three arms was approximately 8.6 months. One-year survival was 38% for Arm G, 24% for Arm H, and 33% for Arm I. Nine patients had responded (2 CRs, 2 CRp, and 5 major HIs): 19% for Arm G, 10% for Arm H and 14% for Arm I and the time to response was one to four cycles. Median number of cycles was three with a range of one to over 23 and 30 patients received four or more cycles.

Additionally, 23 patients achieved stable disease lasting longer than 16 weeks. The 30 day mortality from all causes was 5% in each of the three arms and ten patients, or approximately 16%, were still alive.

Median survival after treatment failure of front-line hypomethylating agents, such as azacitidine and/or decitabine, for patients with intermediate-2 or high-risk disease per IPSS, is reported in the literature to range between 5.6 and 4.3 months. Patients with high-risk IPSS scores also have a high probability of experiencing transformation of their MDS into AML, an aggressive form of blood cancer with typically poor survival.

Solid Tumors

Phase 2 clinical trial in patients with NSCLC

We are also evaluating sapacitabine in a Phase 2, single arm, multicenter, clinical trial in patients with NSCLC who have had at least one prior chemotherapy. This study builds on the observation of prolonged stable disease of four months or longer experienced by heavily pretreated NSCLC patients enrolled in two Phase 1 studies of sapacitabine. The multicenter Phase 2 trial is led by Philip D. Bonomi, M.D., at Rush University Medical Center, Chicago. The primary objective of the study is to evaluate the rate of response and stable disease in patients with previously treated NSCLC. Secondary objectives are to assess progression-free survival, duration of response, duration of stable disease, one year survival, overall survival and safety.

Sixty-two patients have been treated with two dosing schedules, either twice daily or once a day. In the twice daily schedule 15 patients were treated with escalating doses. The recommended Phase 2 dose was reached at 75 mg twice daily for 5 days per week for 2 weeks every 3 weeks. Among 12 patients treated at this recommended Phase 2 dose, 4 achieved stable disease. All 4 responders had at least 2 prior therapies and have been discontinued from the study.

Responders received an average of 7 treatment cycles.

In the once daily schedule 45 patients were treated with escalating doses. The recommended Phase 2 dose was reached at 250 mg once daily dosing level for 5 days per week for 2 weeks every 3 weeks. Among 25 patients treated with daily doses ranging from 100 mg to 175 mg, two patients achieved PR and 10 stable disease. The two PR responders had 3 or 4 prior therapies, respectively, and one remains on study. Among the 10 stable disease responders, 9 had at least 2 prior therapies and 2 remain on study. Responders received an average of 10 treatment cycles. The study is closed to accrual.

Phase 1 clinical trial of sapacitabine and seliciclib in patients with advanced cancers

In an ongoing Phase 1, single-arm, dose escalation study, sapacitabine and seliciclib are administered sequentially in patients with incurable advanced solid tumors unresponsive to conventional treatment or for which no effective therapy exists. Sapacitabine is dosed twice daily for 7 days (Day 1-7) and seliciclib twice

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daily for 3 days (Day 8-11) for three week cycles. At least 3 patients were enrolled at each escalating dose level. The first tumor imaging study is conducted after 2 cycles of treatment and every 3 cycles thereafter. The primary objective of the study is to determine the maximum tolerated dose, or MTD, and recommended Phase 2 dosing schedule of sapacitabine and seliciclib administered sequentially. The secondary objective is to evaluate the antitumor activity of sequential treatment and to explore the pharmacodynamic effect of this treatment in skin and peripheral blood mononuclear cells. At the 2013 American Society of Cancer Research Annual Meeting we reported that of 38 patients with incurable solid tumors and adequate organ function enrolled in the Phase 1 study, 16 were found to be BRCA mutation carriers. Four patients with BRCA-deficient pancreatic, breast or ovarian cancers had confirmed partial responses to the drug regimen. Based on available follow-up to date, three patients are experiencing durable partial responses, with the longest lasting more than 78 weeks. Researchers observed stable disease of 12 weeks or more in eight additional patients, including two patients with ovarian and breast cancers who carried BRCA mutations and whose stable disease lasted 64 and 21 weeks, respectively. Sapacitabine was administered twice daily for seven days followed by seliciclib twice daily for three days. The maximum tolerated doses were 50 mg sapacitabine twice daily and 1,200 mg seliciclib twice daily. Dose-limiting toxicities included reversible transaminase elevations and neutropenia. Adverse events were mild to moderate in intensity. Results of skin biopsies after treatment showed a 2.3-fold increase in DNA damage induced by sapacitabine, as measured by gamma-H2AX immunohistochemistry. Additional DNA damage occurred after treatment with seliciclib with a 0.58-fold further increase in gamma-H2AX staining.

BRCA1 and BRCA2, or breast cancer susceptibility genes, are tumor suppressor genes that help ensure the stability of DNA, the cell's genetic material, and help prevent uncontrolled cell growth. Genetic testing for BRCA-status is routinely available. BRCA mutation has been linked to predisposition to breast and ovarian cancer. According to the US National Cancer Institute, during her life time a woman has a 60% chance of developing breast cancer and 15-40% chance of developing ovarian cancer if she inherits a harmful BRCA mutation. These risks are 5 times and over 10 times more likely than for women without the mutation, respectively.

Orphan Designation

European Union

During May 2008, we received designation from the EMA for sapacitabine as an orphan medicine in two separate indications: AML and MDS. The EMA's Committee for Orphan Medicinal Products, or COMP, adopted a positive opinion on our application to designate sapacitabine as an orphan medicinal product for the indications of AML and MDS. The objective of European orphan medicines legislation is to stimulate research and development of medicinal products for rare diseases by providing incentives to industry. An orphan designation in the European Union confers a range of benefits to sponsor companies including market exclusivity for a period of 10 years, EMA scientific advice on protocol development, direct access to the centralized procedure for review of marketing authorizations, EMA fee reductions and eligibility for grant support from European agencies.

United States

In June 2010, we announced that the FDA granted orphan drug designation to our sapacitabine product candidate for the treatment of both AML and MDS. An orphan designation in the United States confers a range of benefits to sponsor companies, including market exclusivity for a period of seven years from the date of drug approval, the opportunity to apply for grant funding from the United States government to defray costs of clinical trial expenses, tax credits for clinical research expenses and a potential waiver of the FDA's application user fee. Orphan status is granted by the FDA to promote the development of new drug therapies for the treatment of diseases that affect fewer than 200,000 individuals in the United States.

Seliciclib

Although our current clinical development priorities are focused on sapacitabine only, our second drug candidate, seliciclib, is a novel, orally-available, CDK inhibitor. The compound selectively inhibits a spectrum of enzyme targets, CDK2, -7 and -9 that are central to the process of cell division and cell cycle

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control. The target profile of seliciclib is differentiated from the published target profile of other CDK inhibitors. Its selectivity is differentiated by recent publications by independent investigators which showed that seliciclib (i) is more active against NSCLC cells with K-Ras or N-Ras mutations than those with wild type Ras and (ii) overcomes resistance to letrozole in breast cancer cells caused by a particular form of cyclin E in complex with CDK2. Preclinical studies have shown that the drug works by inducing cell apoptosis, or cell suicide, in multiple phases of the cell cycle. To date, seliciclib has been evaluated in approximately 450 patients in several Phase 1 and 2 studies and has shown signs of anti-cancer activity. Seliciclib will also be evaluated in an investigator-initiated clinical study to treat rheumatoid arthritis, or RA, supported by an approximately \$1.5 million grant from the UK's Medical Research Council. Seliciclib may work for RA by targeting proliferating fibroblasts, a different type of approach than conventional RA therapies. We have retained worldwide rights to commercialize seliciclib.

Phase 2 clinical trial in patients with NSCLC

Four Phase 2 trials have been conducted in cancer patients to evaluate the tolerability and antitumor activities of seliciclib alone or in combination with standard chemotherapies used in the treatment of advanced NSCLC and also breast cancer. Interim data from two Phase 2 open-label studies of a total of 52 patients with NSCLC, suggests that seliciclib treatment neither aggravated the known toxicities of standard first and second-line chemotherapies nor appeared to cause unexpected toxicities, although these trials were not designed to provide statistically significant comparison.

In December 2010, we announced topline results from APPRAISE, our Phase 2b, randomized discontinuation, double-blinded, placebo-controlled, study of oral seliciclib capsules as a third line or later treatment in patients with NSCLC. APPRAISE was led by Chandra P. Belani, M.D. at Milton S. Hershey Medical Center, Penn State University. Topline results, after unblinding the treatment assignment among randomized patients, showed that there was no difference between the seliciclib and placebo arms in terms of progression free survival, or PFS (48 versus 53 days respectively). However, an increase in median overall survival, or OS, was observed favoring the seliciclib arm over the placebo arm (388 versus 218 days respectively). A total of 187 patients from 21 centers in the United States were entered in the study after having progressed on at least two prior therapeutic regimens for their NSCLC. Of these, 53 (28%) were randomized, 27 on seliciclib and 26 on placebo. Forty-five out of 53 randomized patients (85%) received 3 or more prior therapies and 45 out of 53 randomized patients (85%) previously received at least one EGFR inhibitor drug, with 22 on seliciclib and 23 on placebo. Fourteen patients were crossed-over to the seliciclib arm after their cancer progressed while they were receiving placebo. Study data demonstrated seliciclib to be safe at the administered dose.

Published preclinical work indicated that K-Ras mutational status, cyclin D1 and cyclin E1 protein levels correlated strongly with tumor sensitivity to seliciclib. In order to explore this possible molecular rationale for the difference in OS, we retrospectively collected and analyzed available biopsy samples from APPRAISE patients who granted informed consent. As only 30 patient samples were available from 152 consenting APPRAISE patients, results of the retrospective analysis were insufficient to allow meaningful correlation. A new prospectively designed study is required to test the hypothesis that these biomarkers can predict therapeutic effect of seliciclib in patients with advanced stage NSCLC.

Phase 2 clinical trials in patients with NPC

In November 2007, we commenced a Phase 2 multicenter, international, study of oral seliciclib as a single agent in patients with nasopharyngeal cancer, or NPC. The primary objective is to evaluate 6-month progression free survival, or PFS, of two dosing schedules of seliciclib in approximately 75 patients with previously treated NPC. Secondary objectives are OS, response rate, response duration, safety and tolerability. The first part of the study is designed to confirm safety and tolerability of 400 mg twice a day for four days per week or 800 mg once a day for four days per week of seliciclib. It is open to approximately 12 to 24 patients with advanced solid tumors as well as patients with NPC. The second part of the study, which is dependent on clinical data from the lead-in phase and available resources to fund the study, is designed to detect major differences between the two dosing schedules of seliciclib and a placebo group in terms of 6-month PFS in approximately 51 patients.

In May 2009, at the American Society of Clinical Oncology, or ASCO, annual meeting, we reported interim data from the lead-in portion of the Phase 2 study which demonstrated that oral seliciclib could be

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safely administered in two dosing schedules which were well tolerated and met the criteria for proceeding to the randomized stage of the study. Seliciclib treatment resulted in prolonged stable disease in 70% of previously-treated NPC patients, including 3 with stable disease lasting longer than 8 months, suggesting seliciclib inhibits tumor growth in NPC. The data support further clinical development of oral seliciclib in NPC.

CYC065

CYC065 is a highly-selective, orally-available, 2nd generation inhibitor of CDK2, -5 and -9. These CDK enzymes play pivotal roles in cancer cell growth, metastatic spread and DNA damage repair. Pharmacological inhibition of CDK2 and CDK9 has been shown to have potent anticancer effects in certain tumor types resistant to established treatments. CYC065 causes apoptotic cell death of cancer cells at sub-micromolar concentrations. Antitumor efficacy has been achieved in vivo with once a day oral dosing at well tolerated doses. Translational biology supports the development of CYC065 as a stratified medicine for solid tumors as well as orphan diseases including adult and pediatric leukemias. Published preclinical studies show that CYC065 has the potential for development in AML, multiple myeloma, chronic lymphocytic leukemia and drug-resistant breast cancer.

CYC065 is mechanistically similar to Cyclacel's first generation CDK inhibitor, seliciclib, but with significantly improved potency in vitro and in vivo. CYC065 causes proportionally greater CDK9 inhibition, leading to improved efficacy in hematological malignancies and more prolonged down regulation of MCL-1, a biomarker of cell survival. CYC065 has improved metabolic stability and improved efficacy and dose potency compared with seliciclib.

CYC065's physicochemical properties enable dosing by oral or intravenous routes. In September 2014, at the 2014 Society of Hematologic Oncology, or SOHO, meeting, we presented preclinical data demonstrating the therapeutic potential of CYC065 to treat acute leukemias and, in particular, those with rearrangements in the mixed lineage leukemia, or MLL, gene. The data showed that in vitro all human AML, acute lymphocytic leukemia, or ALL, and MLLr cell lines tested were sensitive to CYC065 and that the drug inhibited MLL-driven gene expression. Potent anticancer activity of CYC065 was demonstrated in vivo in AML xenograft models resulting in over 90% inhibition of tumor growth. We received a grant award of approximately \$1.9 million from the Biomedical Catalyst of the United Kingdom government to support the IND-directed preclinical development of CYC065 which was completed in 2014.

PLK inhibitors

In our PLK inhibitor program we have discovered potent and selective small molecule inhibitors of PLK1, a kinase active during cell division, targeting the mitotic phase of the cell cycle. At the 2012 Annual Meeting of the American Association of Cancer Research, or AACR, we reported that one of these compounds, CYC140, was selected for further preclinical development. In a panel of esophageal cancer cell lines, sensitivity to CYC140 correlated with p53 status. Esophageal cell lines lacking functional p53 showed the greatest sensitivity to CYC140. Short drug exposure times demonstrated differential sensitivity between cancerous esophageal cells versus control, outlining the potential broad therapeutic index for CYC140 in treating esophageal cancers, and in particular those with non-functional p53. Status of p53 could be used as a predictive biomarker in clinical trials to identify responders. PLK was discovered by Professor David Glover, our Chief Scientist. We have received a grant award of approximately \$3.7 million from the Biomedical Catalyst of the United Kingdom government to complete IND-directed preclinical development of CYC140.

Aurora kinase inhibitors

Aurora kinases, or AK, are a family of serine/threonine protein kinases discovered by Professor David Glover, our Chief Scientist, which are only expressed in actively dividing cells and are crucial for the process of cell division, or mitosis. These proteins, which have been found to be over-expressed in many types of cancer, have generated significant scientific and commercial interest as cancer drug targets. VEGFR2 is a receptor protein that plays a key regulatory role in the angiogenesis pathway, or blood vessel formation. VEGFR is targeted by recently approved drugs such as bevacizumab and sorafenib indicated for the treatment of several solid cancers, such as breast, colorectal, kidney, liver and lung.

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At the Annual Meeting of the AACR 2012 we reported that collaborators tested the activity of CYC3, our novel Aurora Kinase A specific inhibitor, in pancreatic cancer cell lines. The collaborators reported that CYC3 suppresses pancreatic cancer cell growth, inducing mitotic arrest and apoptosis. CYC3 was also shown to act synergistically against pancreatic cancer cell lines in combination with paclitaxel at a 10-fold lower dose resulting in comparable anti-proliferative activity to standard paclitaxel dosing. As myelosuppression is associated with paclitaxel administration, the CYC3/low-dose paclitaxel combination was compared with high-dose paclitaxel in an in vitro granulocyte and macrophage assay in which the CYC3/low-dose paclitaxel combination displayed less myelotoxicity. The collaborators reported that the combination merits further investigation and has the potential for improved therapeutic index in vivo. In June 2007, we initiated and completed a multicenter Phase 1 pharmacologic clinical trial of CYC116, an orally-available inhibitor of Aurora kinase A and B and VEGFR2, in patients with advanced solid tumors. We have retained worldwide rights to commercialize CYC116 and our other Aurora kinase inhibitors.

Non-oncology Programs

Cell Cycle Inhibitors in Autoimmune & Inflammatory Diseases

Preclinical results from several independent investigators suggest that cell cycle inhibitors such as seliciclib and its backup molecules arrest the progress of the cell cycle and may have therapeutic benefit in the treatment of patients with autoimmune and inflammatory diseases as well as in diseases characterized by uncontrolled cell proliferation. Published data indicate potential benefit in glomerulonephritis, graft-versus-host disease, idiopathic pulmonary fibrosis, lupus nephritis, polycystic kidney disease and rheumatoid arthritis.

Business Strategy

Our operating plan is to focus on the clinical development of sapacitabine, specifically in hematology and the on-going SEAMLESS trial, with selective investment in the advancement of other clinical studies or our other drug candidates. We currently anticipate that our cash and cash equivalents of approximately \$24.2 million at December 31, 2014 are sufficient beyond the data read-out of the SEAMLESS Phase 3 trial but not sufficient to complete development of other indications or product candidates or to commercialize any of the Company's product candidates.

Focus on the cell cycle and cancer

Our core area of expertise is in cell cycle biology and our scientists include recognized leaders in this field. In addition, our senior management has extensive experience in research, preclinical and clinical development and sales and marketing. The novel, mechanism-targeted cell cycle drugs we are developing are designed to be highly selective in comparison to conventional chemotherapies, potentially inducing death in cancer cells while sparing most normal cells which may give rise to fewer side-effects.

Thus, we believe that we are well placed to exploit the significant opportunities that this area offers for new drug discovery and development. In this regard, we believe that our sapacitabine is the only orally-available nucleoside analog presently being tested in a Phase 3 trial in previously untreated AML.

Develop anticancer drug candidates in all phases of the cell cycle and multiple compounds for particular cell cycle targets

Targeting a broad development program focused on multiple phases of the cell cycle allows us to minimize risk while maximizing the potential for success and also to develop products that are complementary to one another.

Enter into partnering arrangements selectively, while developing our own sales and marketing capability

We currently retain virtually all marketing rights to the compounds associated with our current clinical-stage drug programs. To optimize our commercial return, we intend to enter into selected partnering arrangements, and to leverage our sales and marketing capability by retaining co-promotion rights as

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appropriate. Historically, we have planned to develop compounds through the Phase 2 proof-of-efficacy stage before seeking a partner. We may enter into partnering arrangements earlier than Phase 2 proof-of-concept trials where appropriate or in connection with drug programs outside our core competency in oncology.

Patents, Proprietary Technology and Collaborations

We consider intellectual property rights to be vital and use a variety of methods to secure, protect and evaluate these rights. These include:

- Ownership and enforcement of patent rights;
- Patent applications covering our own inventions in fields that we consider important to our business strategy;
- License agreements with third parties granting us rights to patents in fields that are important to our business strategy;
- Invention assignment agreements with our employees and consultants;
- Non-compete agreements with our key employees and consultants;
- Confidentiality agreements with our employees, consultants, and others having access to our proprietary information;
- Standard policies for the maintenance of laboratory notebooks to establish priority of our inventions;
- Freedom to use studies from patent counsel;
- Material transfer agreements; and
- Trademark protection.

We give priority to obtaining substance of matter claims in the United States, the EPO, Japan and other important markets if such protection is available. We prefer substance of matter claims because they give us rights to the compounds themselves, and not merely a particular use. In addition to substance of matter claims, we seek coverage for solid state forms, polymorphic and crystalline forms, medical uses, combination therapies, specific regimens, pharmaceutical forms of our compounds and synthetic routes where available and appropriate. Claims covering combination therapies, specific regimens and pharmaceutical forms can be valuable because the therapeutic effect of pharmaceuticals used in the anticancer field is often enhanced when individual therapeutics are used in particular combinations or dosed in a certain way. The availability of protection in these areas can, however, vary from jurisdiction to jurisdiction and combination claims are particularly difficult to obtain for many inventions.

We own 19 patents granted in the United States, 10 granted by the EPO and 40 granted in other countries worldwide. In addition, we have a license to 36 patents granted worldwide.

We own 10 patent applications pending in the United States, 10 before the EPO and over 28 pending patent applications in other countries.

No assurances can be given that patents will be issued with respect to the pending applications, nor that the claims will provide equivalent coverage in all jurisdictions. In addition to the pending patent applications referred to above that we own, there are 10 pending patent applications worldwide to which we have a license or an option to take a license. Since publications in the scientific or patent literature often lag behind actual discoveries, we are not certain of being first to make the inventions covered by each of our pending patent applications or the first to file those patent applications. Generally, patent applications in the United States are maintained in secrecy for a period of 18 months or more, which increases the uncertainty we face. Moreover, the patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. As a result, we cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. To date, there has been no consistent policy regarding the

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breadth of claims allowed in biotechnology patents. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire, or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent and the commercial opportunity of the product.

If patents are issued to others containing valid claims that cover our compounds or their manufacture or use or screening assays related thereto, we may be required to obtain licenses to these patents or to develop or obtain alternative technology. We are aware of several published patent applications, and understand that others may exist, that could support claims that, if granted and held valid, would cover various aspects of our developmental programs, including in some cases particular uses of our lead drug candidates, sapacitabine, seliciclib or other therapeutic candidates, or gene sequences, substances, processes and techniques that we use in the course of our research and development and manufacturing operations.

In addition, we understand that other applications and patents exist relating to uses of sapacitabine and seliciclib that are not part of our current clinical programs for those compounds. Although we intend to continue to monitor the pending applications, it is not possible to predict whether these claims will ultimately be allowed or if they were allowed what their breadth would be. In addition, we may need to commence litigation to enforce any patents issued to us or to determine the scope and validity of third-party proprietary rights. Litigation would create substantial costs. In one case we have opposed a European patent relating to human aurora kinase and the patent has been finally revoked (no appeal was filed). We are also aware of a corresponding United States patent containing method of treatment claims for specific cancers using aurora kinase modulators which, if held valid, could potentially restrict the use of our aurora kinase inhibitors once clinical trials are completed. We are aware that other patents exist that claim substances, processes and techniques, which, if held valid, could potentially restrict the scope of our research, development or manufacturing operations. If competitors prepare and file patent applications in the United States that claim technology that we also claim, we may have to participate in interference proceedings in the United States Patent and Trademark Office to determine which invention has priority. These proceedings could result in substantial costs, even if the eventual outcome is favorable to us. An adverse outcome in litigation could subject us to significant liabilities to third parties and require us to seek licenses of the disputed rights from third parties or to cease using the technology, even a therapeutic product, if such licenses are unavailable or too expensive.

Licenses

Several of our programs are based on technology licensed from others. Our breach of an existing license or failure to obtain a license to technology required to develop, test and commercialize our products may seriously harm our business.

Sapacitabine

On September 10, 2003, we entered into a license agreement with Daiichi Sankyo Co., Ltd. of Japan or Daiichi Sankyo with respect to patents and patent applications covering the sapacitabine compound. Daiichi Sankyo filed patent applications claiming sapacitabine and certain crystalline forms of sapacitabine and methods for its preparation and use which encompass our chosen commercial development form as well as related know-how and materials. The issued patents for the sapacitabine compound cover the United States, EPO, Japan and 19 other countries. These patents expired in the United States in 2014 and expired elsewhere in 2012. The issued patents for the crystalline forms cover the United States, EPO, Japan and thirteen other countries, with patents pending in one further country. These patents expire in 2022. It may be possible to extend the term of a patent in the United States, Europe or Japan for up to five years to the extent it covers the sapacitabine compound or its crystalline form upon regulatory approval of that compound in the United States, Europe or Japan, but there is no assurance that we will be able to obtain any such extension.

Separately, we own an issued United States patent with granted claims to a specified method of administration of sapacitabine, adding to the existing composition of matter patents and supporting market exclusivity out to 2030. We also own patents issued in the United States or in Europe which claim

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methods of use of sapacitabine with hypomethylating agents, including decitabine, which is being tested as one of the arms of the SEAMLESS Phase 3 trial and with other anticancer drugs such as HDAC inhibitors with other anticancer drugs including HDAC inhibitors. The license grants us the exclusive right to exploit and sublicense the sapacitabine compound and any other products covered by the patents and patent applications owned by Daiichi Sankyo. The license originally was subject to certain third party rights related to certain countries but the license has been extended and is now worldwide. The license agreement also grants us nonexclusive, sublicensed rights to CNDAC, both a precursor compound and initial metabolite of sapacitabine.

We are under an obligation to use reasonable endeavors to develop a product and obtain regulatory approval to sell a product and we agreed to pay Daiichi Sankyo an up-front fee, reimbursement for Daiichi Sankyo's enumerated expenses, milestone payments and royalties on a country-by-country basis. Under this agreement, \$1.6 million was paid in April 2011, and further aggregate milestone payments totaling approximately \$10.0 million could be payable subject to achievement of specific contractual milestones and our decision to continue with these projects. The up-front fee and certain past reimbursements have been paid. Royalties are payable in each country for the term of patent protection in the country or for ten years following the first commercial sale of licensed products in the country, whichever is later. Royalties are payable on net sales. Net sales are defined as the gross amount invoiced by us or our affiliates or licensees, less discounts, credits, taxes, shipping and bad debt losses. The agreement extends from its commencement date to the date on which no further amounts are owed under it. If we wish to appoint a third-party to develop or commercialize a sapacitabine-based product in Japan, within certain limitations, Daiichi Sankyo must be notified and given a right of first refusal to develop and/or commercialize in Japan. Effective July 11, 2011, the license was amended to irrevocably waive a termination right Daiichi Sankyo possessed under a provision of the agreement that required the Company to obtain regulatory approval to sell sapacitabine in at least one country by September 2011, and releases the Company from all claims and liability of any kind arising under such provision. The amendment further provides that the royalty fee due from us to Daiichi Sankyo on future net sales of sapacitabine be increased by a percentage between 1.25% and 1.50%, depending on the level of net sales of sapacitabine realized. In general, however, the license may be terminated by us for technical, scientific, efficacy, safety, or commercial reasons on six months' notice, or twelve months if after a launch of a sapacitabine-based product, or by either party for material default.

Seliciclib

We have entered into an agreement with Centre National de Recherche Scientifique, or CNRS, and Institut Curie that grants us worldwide rights under the patents jointly owned by CNRS, Institut Curie and the Czech Institute of Experimental Botany covering the seliciclib compound. The effective date of the agreement is February 1, 2002. The license grants exclusive rights in the fields of auto-immune diseases, cardiovascular diseases, dermatological diseases, infectious diseases, inflammatory diseases, and proliferative diseases, including cancer. Non-acute chronic diseases of the central nervous system, neurological diseases and diseases of the peripheral nervous system are specifically excluded. The license runs for the term of the patents in each country, or for ten years from the first commercial sale in each country, whichever is later. We paid an up-front fee and yearly payments and milestone payments until the patents covering the seliciclib compound, particular uses of the compound, and particular uses and derivatives of the compound were published as granted in either the United States or by EPO which occurred in 2001 and 2003, respectively. Milestones are also payable on the first commercialization of a product that consists of a new chemical entity that is covered by one of the licensed patents.

We will be obligated to pay royalties based on our net sales of products covered by the patents. Royalties are payable on a country-by-country basis for the term of patent protection in each country or ten years from the first commercial sale of royalty-bearing products in that country, whichever is later. Royalties are payable on net sales. Net sales are defined as the gross amount invoiced by us or by our affiliates for the products, less normal trade discounts, credits for returned products, taxes and shipping charges. There is one royalty rate for products that are covered by valid licensed patent claims and a second, lower royalty rate for all other products that require a license under the licensed patents.

We must also pay a portion of sublicensing revenues. Although the license permits us to grant sublicenses, we cannot assign the license without the consent of the CNRS and Institut Curie, which may not be unreasonably withheld.

Under the

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agreement, assignment is defined to include many transactions of the type that we might wish to pursue, such as a merger or an acquisition by another company, as well as certain takeovers. This restriction may prevent us from pursuing attractive business opportunities. Moreover, the occurrence of a majority takeover or a similar transaction that we may be unable to control could cause a default under the license agreement, which could lead to its termination.

We have also purchased from the Czech Institute of Experimental Botany patents and patent applications covering the use of seliciclib and related compounds. The issued patents are in the United States, Australia and South Korea. Under the purchase agreement, we will pay royalties to the Czech Institute upon sales of products covered by those patents, but only if there are no royalties paid by us to CNRS for those sales under the license agreement with CNRS and Institut Curie covering seliciclib that is described above.

Patents covering the seliciclib compound are owned jointly by the Czech Institute of Experimental Botany and CNRS. The patents have been issued in the United States, in Japan and Canada by the EPO and expire in 2016. It may be possible to extend the term of a patent in the United States, Europe or Japan for up to five years to the extent it covers the seliciclib compound upon regulatory approval of that compound in the United States or Europe, but there is no assurance that we will be able to obtain any such extension. Under agreements between CNRS and the Czech Institute of Experimental Botany, CNRS has the exclusive right to enter into license agreements covering the patents. The agreement reserves to both CNRS and the Czech Institute of Experimental Botany certain rights, including the right to patent improvements and to use the patents for internal research purposes.

Manufacturing

We have no in-house manufacturing capabilities and have no current plans to establish manufacturing facilities for significant clinical or commercial production. We have no direct experience in manufacturing commercial quantities of any of our products, and we currently lack the resources or capability to manufacture any of our products on a clinical or commercial scale. As a result, we are dependent on corporate partners, licensees or other third parties for the manufacturing of clinical and commercial scale quantities of all of our products. We believe that this strategy will enable us to direct operational and financial resources to the development of our product candidates rather than diverting resources to establishing a manufacturing infrastructure.

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture, marketing and distribution of drugs. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our drug candidates and commercialized drugs.

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act and implementing regulations. The process required by the FDA before our drug candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies, all performed in accordance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND application which must become effective before clinical trials may begin;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the drug candidate for each proposed indication;
- submission of a New Drug Application, or NDA, to the FDA;
-

satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product is produced to assess compliance with current good manufacturing practice GMP, or cGMP, regulations;

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- FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug; and
- regulation of commercial marketing and sale of drugs.

This testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our drug candidates will be granted on a timely basis, if at all. Preclinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals. The results of preclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND application to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Our submission of an IND, or those of our collaborators, may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the clinical trial until completed. The FDA, the IRB or the clinical trial sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP, or Good Clinical Practices, regulations and regulations for informed consent.

Clinical Trials
For purposes of an NDA submission and approval, clinical trials are typically conducted in the following three sequential phases, which may overlap:

- Phase 1: The clinical trials are initially conducted in a limited population to test the drug candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients. Phase 1 clinical trials can be designed to evaluate the impact of the drug candidate in combination with currently approved drugs.

- Phase 2: These clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the drug candidate for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trial.

- Phase 3: These clinical trials are commonly referred to as pivotal clinical trials. If the Phase 2 clinical trials demonstrate that a dose range of the drug candidate is effective and has an acceptable safety profile, Phase 3 clinical trials are then undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites.

In some cases, the FDA may condition approval of an NDA for a drug candidate on the sponsor's agreement to conduct additional clinical trials to further assess the drug's safety and effectiveness after NDA approval.

New Drug Application

The results of drug candidate development, preclinical testing and clinical trials are submitted to the FDA as part of an NDA. The NDA also must contain extensive manufacturing information. Once the submission has been accepted for filing, by law the FDA has 180 days to review the application and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the NDA

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 generally follows such recommendations. The FDA may

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deny approval of an NDA if the applicable regulatory criteria are not satisfied, or it may require additional clinical data or an additional pivotal Phase 3 clinical trial. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators do. Once issued, the FDA may withdraw a drug approval if ongoing regulatory requirements are not met or if safety problems occur after the drug reaches the market. In addition, the FDA may require further testing, including Phase 4 clinical trials, and surveillance programs to monitor the effect of approved drugs which have been commercialized. The FDA has the power to prevent or limit further marketing of a drug based on the results of these post-marketing programs. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to a drug, including changes in indications, labeling or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require us to develop additional data or conduct additional preclinical studies and clinical trials.

Fast Track Designation

The FDA's fast track program is intended to facilitate the development and to expedite the review of drugs that are intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug candidate may request the FDA to designate the drug candidate for a specific indication as a fast track drug concurrent with or after the filing of the IND for the drug candidate. The FDA must determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

If fast track designation is obtained, the FDA may initiate review of sections of an NDA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees.

However, the time period specified in the Prescription Drug User Fees Act, which governs the time period goals the FDA has committed to reviewing an application, does not begin until the complete application is submitted.

Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

In some cases, a fast track designated drug candidate may also qualify for one or more of the following programs:

- Priority Review. Under FDA policies, a drug candidate is eligible for priority review, or review within a six-month time frame from the time a complete NDA is accepted for filing, if the drug candidate provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. We cannot suggest or in any way guarantee that any of our drug candidates will receive a priority review designation, or if a priority designation is received, that review or approval will be faster than conventional FDA procedures, or that the FDA will ultimately grant drug approval.

- Accelerated Approval. Under the FDA's accelerated approval regulations, the FDA is authorized to approve drug candidates that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses, and that provide meaningful therapeutic benefit to patients over existing treatments based upon either a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than patient survival. In clinical trials, surrogate endpoints are alternative measurements of the symptoms of a disease or condition that are substituted for measurements of observable clinical symptoms. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to validate the surrogate endpoint or confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to validate a surrogate endpoint or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to

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prior review by the FDA. In rare instances the FDA may grant accelerated approval of an NDA based on Phase 2 data and require confirmatory Phase 3 studies to be conducted after approval and/or as a condition of maintaining approval. We can give no assurance that any of our drugs will be reviewed under such procedures.

When appropriate, we and our collaborators may attempt to seek fast track designation or accelerated approval for our drug candidates. We cannot predict whether any of our drug candidates will obtain a fast track or accelerated approval designation, or the ultimate impact, if any, of the fast track or the accelerated approval process on the timing or likelihood of FDA approval of any of our drug candidates.

Satisfaction of FDA regulations and requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Typically, if a drug candidate is intended to treat a chronic disease, as is the case with some of our drug candidates, safety and efficacy data must be gathered over an extended period of time. Government regulation may delay or prevent marketing of drug candidates for a considerable period of time and impose costly procedures upon our activities. The FDA or any other regulatory agency may not grant approvals for new indications for our drug candidates on a timely basis, if at all. Even if a drug candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a drug may result in restrictions on the drug or even complete withdrawal of the drug from the market. Delays in obtaining, or failures to obtain, regulatory approvals for any of our drug candidates would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future United States or foreign governmental action.

Special Protocol Assessment

If a Phase 2 clinical trial is the subject of discussion at an end-of-Phase 2 meeting with the FDA, a sponsor may be able to request a Special Protocol Assessment, or SPA, the purpose of which is to reach agreement with the FDA on the design of the Phase 3 clinical trial protocol design and analysis that will form the primary basis of an efficacy claim. If such an agreement is reached, it will be documented and made part of the administrative record, and it will be binding on the FDA and may not be changed unless the sponsor fails to follow the agreed-upon protocol, data supporting the request are found to be false or incomplete, or the FDA determines that a substantial scientific issue essential to determining the safety or effectiveness of the drug was identified after the testing began. Even if an SPA is agreed to, approval of the NDA is not guaranteed because a final determination that an agreed-upon protocol satisfies a specific objective, such as the demonstration of efficacy, or supports an approval decision, will be based on a complete review of all the data in the NDA.

Other regulatory requirements

Any products manufactured or distributed by us or our collaborators pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences associated with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a product from distribution, or withdraw approval of that product.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. A company can make only those

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claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

Competition

The biotechnology and biopharmaceutical industries are rapidly changing and highly competitive. We are seeking to develop and market drug candidates that will compete with other products and therapies that currently exist or are being developed. Other companies are actively seeking to develop products that have disease targets similar to those we are pursuing. We face competition from many different sources, including commercial, pharmaceutical and biotechnology companies, academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing and drug development resources than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we may develop. In addition, competitors compete in the areas of recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses.

A large number of drug candidates are in development for the treatment of leukemia and lymphomas, MDS, breast, lung, and nasopharyngeal cancer. Several pharmaceutical and biotechnology companies have nucleoside analogs or other products on the market or in clinical trials which may be competitive to sapacitabine in both hematology and oncology indications. These include Ambit, Astra-Zeneca, Baxter, Boehringer Ingelheim, Celator, Celgene, Eisai, Lilly, GlaxoSmithKline, Hospira, Johnson & Johnson, Onconova, Otsuka, Sanofi, Sunesis and Teva. Several pharmaceutical and biotechnology companies have CDK inhibitors in clinical trials including Bayer, Lilly, Merck, Nerviano Medical Sciences, Novartis, Otsuka, Pfizer, Piramal, Sanofi, Tolero and Tragara. Several companies are pursuing discovery and research activities in each of the other areas that are the subject of our research and drug development programs. We believe that Amgen, AstraZeneca, Entremed, Merck, Nerviano Medical Sciences, Otsuka, Pfizer, Rigel, Sunesis and Takeda-Millennium have commenced clinical trials of Aurora kinase inhibitors for hemato-oncology indications. We believe that Boehringer Ingelheim, GlaxoSmithKline, Merck, Nerviano Medical Sciences, Takeda-Millennium and Tekmira have commenced clinical trials with PLK inhibitor candidates for hemato-oncology indications.

Legal Proceedings

From time to time, we may be involved in routine litigation incidental to the conduct of our business.

Employees

As of March 27, 2015, we had 18 full-time employees. Our employees are not represented by any collective bargaining agreements, and management considers relations with our employees to be good.

Corporate information

Our corporate headquarters are located at 200 Connell Drive, Suite 1500, Berkeley Heights, New Jersey 07922, and our telephone number is 908-517-7330. This is also where our medical and regulatory functions are located. Our research facility is located in Dundee, Scotland, which is also the center of our translational work and development programs.

Available information

We file reports, proxy statements and other information with the Securities and Exchange Commission, or the SEC. Copies of our reports, proxy statements and other information may be inspected and copied at

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the public reference facilities maintained by the SEC at SEC Headquarters, Public Reference Room, 100 F Street, N.E., Washington D.C. 20549. The public may obtain information on the operation of the SEC's Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy statements and other information regarding Cyclacel. The address of the SEC website is <http://www.sec.gov>.

We will also provide copies of our current reports on Form 8-K, annual reports on Form 10-K, quarterly reports on Form 10-Q and proxy statements, and all amendments to those reports at no charge through our website at www.cyclacel.com as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. We have not incorporated by reference in this Annual Report on Form 10-K the information on, or accessible through, our website. Copies are also available, without charge, from Cyclacel Pharmaceuticals, Inc., 200 Connell Drive, Suite 1500, Berkeley Heights, NJ 07922.

Item 1A.

Risk Factors

In analyzing our company, you should consider carefully the following risk factors, together with all of the other information included in this Annual Report on Form 10-K. Factors that could cause or contribute to differences in our actual results include those discussed in the following subsection, as well as those discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this Annual Report on Form 10-K. Each of the following risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our company. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Associated with Development and Commercialization of Our Drug Candidates

Clinical trial designs that were discussed with the authorities prior to their commencement may subsequently be considered insufficient for approval at the time of application for regulatory approval. Thus, our SPA regarding our SEAMLESS trial does not guarantee marketing approval or approval of our sapacitabine oral capsules for the treatment of AML.

On September 13, 2010, and as amended on October 11, 2011, we reached agreement with the FDA regarding an SPA on the design of a pivotal Phase 3 trial for our sapacitabine oral capsules as a front-line treatment in elderly patients aged 70 years or older with newly diagnosed AML, who are not candidates for intensive induction chemotherapy, or the SEAMLESS trial. An SPA is an agreement between a sponsor of an NDA and the FDA on the design of the Phase 3 clinical trial protocol design and analysis that will form the primary basis of an efficacy claim, and if reached will be binding on the FDA. In the absence of a subsequent agreement between the FDA and the sponsor to modify the SPA, it is not binding if the sponsor fails to follow the agreed upon protocol, data supporting the request are found to be false or incomplete, or the FDA determines that a substantial scientific issue essential to product efficacy or safety was identified. An SPA, however, neither guarantees approval nor provides any assurance that a marketing application would be approved by the FDA. There are companies that have been granted SPAs but have ultimately failed to obtain final approval to market their drugs. In January 2011, we opened enrollment in the lead-in portion of the SEAMLESS trial and in October 2011, we opened enrollment in the randomized portion of the trial.

In addition, the FDA may revise previous guidance or decide to ignore previous guidance at any time during the course of clinical activities or after the completion of clinical trials. The FDA may raise issues relating to, among other things, safety, study conduct, bias, deviation from the protocol, statistical power, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision. The FDA may also seek the guidance of an outside advisory committee prior to making its final decision. Even with successful clinical safety and efficacy data, including such data from a clinical trial conducted pursuant to an SPA, we may be required to conduct additional, expensive clinical trials to obtain regulatory approval.

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Clinical trials are expensive, time consuming, subject to delay and may be required to continue beyond our available funding and we cannot be certain that we will be able to raise sufficient funds to complete the development and commercialize any of our product candidates currently in clinical development, should they succeed.

Clinical trials are expensive, complex, can take many years to conduct and may have uncertain outcomes. We estimate that clinical trials of our most advanced drug candidates may be required to continue beyond our available funding and may take several more years to complete. The designs used in some of our trials have not been used widely by other pharmaceutical companies. Failure can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future drug candidates, including but not limited to:

- delays in securing clinical investigators or trial sites for our clinical trials;

- delays in obtaining IRB and regulatory approvals to commence a clinical trial;

- slower than anticipated rates of patient recruitment and enrollment, or not reaching the targeted number of patients because of competition for patients from other trials, or if there is limited or no availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third party payors for the use of agents used in our clinical trials, such as decitabine in SEAMLESS, or other reasons;

- negative or inconclusive results from clinical trials, such as the recommendations of the DSMB, of our Phase 3 SEAMLESS study of sapacitabine oral capsules in AML. For example, in December 2014, the DSMB determined that the planned futility boundary had been crossed in the SEAMLESS trial and determined that based on available interim data, it would be unlikely for the study to reach statistically significant improvement in survival;

- unforeseen safety issues;

- uncertain dosing issues that may or may not be related to suboptimal pharmacokinetic and pharmacodynamics behaviors;

- approval and introduction of new therapies or changes in standards of practice or regulatory guidance that render our clinical trial endpoints or the targeting of our proposed indications obsolete;

- inability to monitor patients adequately during or after treatment or problems with investigator or patient compliance with the trial protocols;

- inability to replicate in large controlled studies safety and efficacy data obtained from a limited number of patients in uncontrolled trials;

- inability or unwillingness of medical investigators to follow our clinical protocols; and

-

unavailability of clinical trial supplies.

If we suffer any significant delays, setbacks or negative results in, or termination of, our clinical trials, we may be unable to continue development of our drug candidates or generate revenue and our development costs could increase significantly. Adverse events have been observed in our clinical trials and may force us to stop development of our product candidates or prevent regulatory approval of our product candidates.

Adverse or inconclusive results from our clinical trials may substantially delay, or halt entirely, any further development of our drug candidates. Many companies have failed to demonstrate the safety or effectiveness of drug candidates in later stage clinical trials notwithstanding favorable results in early stage clinical trials. Previously unforeseen and unacceptable side effects could interrupt, delay or halt clinical trials of our drug candidates and could result in the FDA or other regulatory authorities denying approval of our drug candidates. We will need to demonstrate safety and efficacy for specific indications of use, and monitor safety and compliance with clinical trial protocols throughout the development process. To date, long-term safety and efficacy has not been demonstrated in clinical trials for any of our drug candidates.

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Toxicity and serious adverse events as defined in trial protocols have been noted in preclinical and clinical trials involving certain of our drug candidates. For example, neutropenia and gastro-intestinal toxicity were observed in patients receiving sapacitabine and elevations of liver enzymes and decrease in potassium levels have been observed in patients receiving seliciclib.

In addition, we may pursue clinical trials for sapacitabine and seliciclib in more than one indication. There is a risk that severe toxicity observed in a trial for one indication could result in the delay or suspension of all trials involving the same drug candidate. Even if we believe the data collected from clinical trials of our drug candidates are promising with respect to safety and efficacy, such data may not be deemed sufficient by regulatory authorities to warrant product approval. Clinical data can be interpreted in different ways. Regulatory officials could interpret such data in different ways than we do which could delay, limit or prevent regulatory approval. The FDA, other regulatory authorities or we may suspend or terminate clinical trials at any time. Any failure or significant delay in completing clinical trials for our drug candidates, or in receiving regulatory approval for the commercialization of our drug candidates, may severely harm our business and reputation.

We are making use of biomarkers, which are not scientifically validated, and our reliance on biomarker data may thus lead us to direct our resources inefficiently.

We are making use of biomarkers in an effort to facilitate our drug development and to optimize our clinical trials. Biomarkers are proteins or other substances whose presence in the blood can serve as an indicator of specific cell processes. We believe that these biological markers serve a useful purpose in helping us to evaluate whether our drug candidates are having their intended effects through their assumed mechanisms, and thus enable us to identify more promising drug candidates at an early stage and to direct our resources efficiently. We also believe that biomarkers may eventually allow us to improve patient selection in connection with clinical trials and monitor patient compliance with trial protocols.

For most purposes, however, biomarkers have not been scientifically validated. If our understanding and use of biomarkers is inaccurate or flawed, or if our reliance on them is otherwise misplaced, then we will not only fail to realize any benefits from using biomarkers, but may also be led to invest time and financial resources inefficiently in attempting to develop inappropriate drug candidates. Moreover, although the FDA has issued for comment a draft guidance document on the potential use of biomarker data in clinical development, such data are not currently accepted by the FDA or other regulatory agencies in the United States, the European Union or elsewhere in applications for regulatory approval of drug candidates and there is no guarantee that such data will ever be accepted by the relevant authorities in this connection. Our biomarker data should not be interpreted as evidence of efficacy. Due to our reliance on contract research organizations or other third parties to conduct clinical trials, we may be unable to directly control the timing, conduct and expense of our clinical trials.

We do not have the ability to independently conduct clinical trials required to obtain regulatory approvals for our drug candidates. We must rely on third parties, such as contract research organizations, data management companies, contract clinical research associates, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials. In addition, we rely on third parties to assist with our preclinical development of drug candidates. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates.

If we fail to enter into and maintain successful strategic alliances for our drug candidates, we may have to reduce or delay our drug candidate development or increase our expenditures.

An important element of our strategy for developing, manufacturing and commercializing our drug candidates is entering into strategic alliances with pharmaceutical companies or other industry participants to advance our programs and enable us to maintain our financial and operational capacity.

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We face significant competition in seeking appropriate alliances. We may not be able to negotiate alliances on acceptable terms, if at all. In addition, these alliances may be unsuccessful. If we fail to create and maintain suitable alliances, we may have to limit the size or scope of, or delay, one or more of our drug development or research programs. If we elect to fund drug development or research programs on our own, we will have to increase our expenditures and will need to obtain additional funding, which may be unavailable or available only on unfavorable terms.

To the extent we are able to enter into collaborative arrangements or strategic alliances, we will be exposed to risks related to those collaborations and alliances.

Although we are not currently party to any collaboration arrangement or strategic alliance that is material to our business, in the future we expect to be dependent upon collaborative arrangements or strategic alliances to complete the development and commercialization of some of our drug candidates particularly after the Phase 2 stage of clinical testing. These arrangements may place the development of our drug candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

Dependence on collaborative arrangements or strategic alliances will subject us to a number of risks, including the risk that:

- we may not be able to control the amount and timing of resources that our collaborators may devote to the drug candidates;
- our collaborators may experience financial difficulties;
- we may be required to relinquish important rights such a marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete our obligations under any arrangement;
- a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our drug candidates.

We have no manufacturing capacity and will rely on third party manufacturers for the late stage development and commercialization of any drugs or devices we may develop or sell.

We do not currently operate manufacturing facilities for clinical or commercial production of our drug candidates under development. We currently lack the resources or the capacity to manufacture any of our products on a clinical or commercial scale. We anticipate future reliance on a limited number of third party manufacturers until we are able, or decide to, expand our operations to include manufacturing capacities. If the FDA or other regulatory agencies approve any of our drug candidates for commercial sale, or if we significantly expand our clinical trials, we will need to manufacture them in larger quantities and will be required to secure alternative third-party suppliers to our current suppliers. To date, our drug candidates have been manufactured in small quantities for preclinical testing and clinical trials and we may not be able to successfully increase the manufacturing capacity, whether in collaboration with our current or future third-party manufacturers or on our own, for any of our drug candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA and other regulatory bodies must review and approve. If we are unable to successfully increase the manufacturing capacity

for a drug candidate whether for late stage clinical trials or for commercial sale or are unable to secure alternative third-party suppliers to our current suppliers, the drug development, regulatory approval or commercial launch of any related drugs may be delayed or blocked or there may be a shortage in supply. Even if any third party manufacturer makes improvements in the manufacturing process for our drug candidates, we may not own, or may have to share, the intellectual property rights to such innovation. Any performance failure on the part of manufacturers could delay late stage clinical development or regulatory approval of our drug, the commercialization of our drugs or our ability to sell our commercial products, producing additional losses and depriving us of potential product revenues.

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As we evolve from a company primarily involved in discovery and development to one also involved in the commercialization of drugs and devices, we may encounter difficulties in managing our growth and expanding our operations successfully.

In order to execute our business strategy, we will need to expand our development, control and regulatory capabilities and develop financial, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. If our operations expand, we expect that we will need to manage additional relationships with various collaborative partners, suppliers and other third parties. Our ability to manage our operations and any growth will require us to make appropriate changes and upgrades, as necessary, to our operational, financial and management controls, reporting systems and procedures wherever we may operate. Any inability to manage growth could delay the execution of our business plan or disrupt our operations.

Our drug candidates are subject to extensive regulation, which can be costly and time-consuming, and we may not obtain approvals for the commercialization of any of our drug candidates.

The clinical development, manufacturing, selling and marketing of our drug candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States, the European Union and elsewhere. These regulations also vary in important, meaningful ways from country to country. We are not permitted to market a potential drug in the United States until we receive approval of an NDA, from the FDA. We have not received an NDA approval from the FDA for any of our drug candidates.

Obtaining an NDA approval is expensive and is a complex, lengthy and uncertain process. The FDA approval process for a new drug involves completion of preclinical studies and the submission of the results of these studies to the FDA, together with proposed clinical protocols, manufacturing information, analytical data and other information in an IND, which must become effective before human clinical trials may begin. Clinical development typically involves three phases of study: Phase 1, 2 and 3. The most significant costs associated with clinical development are the pivotal or suitable for registration late Phase 2 or Phase 3 clinical trials as they tend to be the longest and largest studies conducted during the drug development process. After completion of clinical trials, an NDA may be submitted to the FDA. In responding to an NDA, the FDA may refuse to file the application, or if accepted for filing, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. In addition, failure to comply with the FDA and other applicable foreign and U.S. regulatory requirements may subject us to administrative or judicially imposed sanctions. These include warning letters, civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production and refusal to approve either pending NDAs, or supplements to approved NDAs. There is substantial time and expense invested in preparation and submission of an NDA or equivalents in other jurisdictions and regulatory approval is never guaranteed. Depending on the final data from our SEAMLESS study, we may meet with regulatory authorities in the United States and the European Union to discuss registration submissions for sapacitabine for the AML indication. In light of the futility cross reported by the SEAMLESS DSMB, there can be no assurance that data from SEAMLESS will be sufficient to submit registration submissions or that regulatory authorities will accept or validate any such submissions.

The FDA and other regulatory authorities in the United States, the European Union and elsewhere exercise substantial discretion in the drug approval process. The number, size and design of preclinical studies and clinical trials that will be required for FDA or other regulatory approval will vary depending on the drug candidate, the disease or condition for which the drug candidate is intended to be used and the regulations and guidance documents applicable to any particular drug candidate. The FDA or other regulators can delay, limit or deny approval of a drug candidate for many reasons, including, but not limited to:

- those discussed in the risk factor which immediately follows;
- the fact that the FDA or other regulatory officials may find that our or our third party manufacturer's processes or facilities are not in compliance with cGMPs; or

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- the fact that new regulations may be enacted by the FDA or other regulators may change their approval policies or adopt new regulations requiring new or different evidence of safety and efficacy for the intended use of a drug candidate.

Our applications for regulatory approval could be delayed or denied due to problems with studies conducted before we in-licensed the rights to some of our product candidates.

We currently license some of the compounds and drug candidates used in our research programs from third parties. These include sapacitabine which was licensed from Daiichi Sankyo. Our present research involving these compounds relies upon previous research conducted by third parties over whom we had no control and before we in-licensed the drug candidates. In order to receive regulatory approval of a drug candidate, we must present all relevant data and information obtained during our research and development, including research conducted prior to our licensure of the drug candidate. Although we are not currently aware of any such problems, any problems that emerge with preclinical research and testing conducted prior to our in-licensing may affect future results or our ability to document prior research and to conduct clinical trials, which could delay, limit or prevent regulatory approval for our drug candidates. Even if our product candidates receive regulatory approval, we may still face future development and regulatory difficulties.

Our product candidates, if approved, will also be subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information. In addition, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA and other regulatory requirements and requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to the FDA's Current Good Manufacturing Practice, or cGMP. As such, we and our contract manufacturers are subject to continual review and periodic inspections to assess compliance with cGMP. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We will also be required to report certain adverse reactions and production problems, if any, to the FDA and other regulatory agencies and to comply with certain requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. Accordingly, we may not promote our approved products, if any, for indications or uses for which they are not approved.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, it may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, the FDA and other regulatory agencies may:

- issue warning letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or our collaborators to enter into a consent decree or permanent injunction, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose other administrative or judicial civil or criminal penalties;

- withdraw regulatory approval;
- refuse to approve pending applications or supplements to approved applications filed by us or our potential future collaborators;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products.

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Even if we successfully complete the clinical trials of one or more of our product candidates, the product candidates may fail for other reasons.

Even if we successfully complete the clinical trials for one or more of our product candidates, the product candidates may fail for other reasons, including the possibility that the product candidates will:

- fail to receive the regulatory approvals required to market them as drugs;
- be subject to proprietary rights held by others requiring the negotiation of a license agreement prior to marketing;
- be difficult or expensive to manufacture on a commercial scale;
- have adverse side effects that make their use less desirable; or
- fail to compete with product candidates or other treatments commercialized by our competitors.

If we are unable to receive the required regulatory approvals, secure our intellectual property rights, minimize the incidence of any adverse side effects or fail to compete with our competitors' products, our business, financial condition, and results of operations could be materially and adversely affected.

We face intense competition and our competitors may develop drugs that are less expensive, safer, or more effective than our drug candidates.

A large number of drug candidates are in development for the treatment of leukemia, lung cancer, lymphomas and nasopharyngeal cancer. Several pharmaceutical and biotechnology companies have nucleoside analogs or other products on the market or in clinical trials which may be competitive to sapacitabine in both hematological and oncology indications. Our competitors, either alone or together with collaborators, may have substantially greater financial resources and research and development staff. Our competitors may also have more experience:

- developing drug candidates;
- conducting preclinical and clinical trials;
- obtaining regulatory approvals; and
- commercializing product candidates.

Our competitors may succeed in obtaining patent protection and regulatory approval and may market drugs before we do. If our competitors market drugs that are less expensive, safer, more effective or more convenient to administer than our potential drugs, or that reach the market sooner than our potential drugs, we may not achieve commercial success. Scientific, clinical or technical developments by our competitors may render our drug candidates obsolete or noncompetitive. We anticipate that we will face increased competition in the future as new companies enter the markets and as scientific developments progress. If our drug candidates obtain regulatory approvals, but do not compete effectively in the marketplace, our business will suffer.

The commercial success of our drug candidates depends upon their market acceptance among physicians, patients, healthcare providers and payors and the medical community.

If our drug candidates are approved, or approved together with another agent such as Dacogen® (decitabine) by the FDA or by another regulatory authority, the resulting drugs, if any, must still gain market acceptance among physicians, healthcare providers and payors, patients and the medical community. The degree of market acceptance of any of our approved drugs will depend on a variety of factors, including:

- timing of market introduction, number and clinical profile of competitive drugs;
- our ability to provide acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- pricing and cost-effectiveness, which may be subject to regulatory control;

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- availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third party payors; and

- prevalence and severity of adverse side effects; and other potential advantages over alternative treatment methods.

If any product candidate that we develop does not provide a treatment regimen that is at least as beneficial as the current standard of care or otherwise does not provide some additional patient benefit over the current standard of care, that product will not achieve market acceptance and we will not generate sufficient revenues to achieve profitability.

If our drug candidates or distribution partners' products fail to achieve market acceptance, we may not be able to generate significant revenue and our business would suffer.

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for our products, it is less likely that they will be widely used. Market acceptance and sales of our product candidates that we develop, if approved, will depend on reimbursement policies, and may be affected by future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. We cannot be certain that reimbursement will be available for our product candidates that we develop. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any of our product candidates.

Our business may be affected by the efforts of government and third-party payors to contain or reduce the cost of healthcare through various means. For example, the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010, referred to jointly as ACA, enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the pharmaceutical industry. With regard to pharmaceutical products, among other things, ACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare Part D program.

Although most of ACA has withstood court challenges, there are ongoing Congressional efforts to repeal ACA. This adds to the uncertainty of the legislative changes enacted as part of ACA, and we cannot predict the impact that ACA or any other legislative or regulatory proposals will have on our business. Regardless of whether or not ACA is overturned or repealed, we expect both government and private health plans to continue to require healthcare providers, including healthcare providers that may one day purchase our products, to contain costs and demonstrate the value of the therapies they provide.

The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect to experience pricing pressures in connection with the sale of products that we develop, due to the trend toward cost containment and additional legislative proposals.

If we are unable to compete successfully in our market place, it will harm our business.

There are existing products in the marketplace that compete with our products. Companies may develop new products that compete with our products. Certain of these competitors and potential competitors have longer operating histories, substantially greater product development capabilities and financial, scientific, marketing and sales resources.

Competitors and potential competitors may also develop products that are safer, more effective or have other potential advantages compared to our products. In addition, research, development and commercialization efforts by others could render our products obsolete or non-competitive. Certain of our competitors and potential competitors have

broader product offerings

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and extensive customer bases allowing them to adopt aggressive pricing policies that would enable them to gain market share. Competitive pressures could result in price reductions, reduced margins and loss of market share. We could encounter potential customers that, due to existing relationships with our competitors, are committed to products offered by those competitors. As a result, those potential customers may not consider purchasing our products. The failure to attract and retain skilled personnel and key relationships could impair our drug development and commercialization efforts.

We are highly dependent on our senior management and key clinical development, scientific and technical personnel. Competition for these types of personnel is intense. The loss of the services of any member of our senior management, clinical development, scientific or technical staff may significantly delay or prevent the achievement of drug development and other business objectives and could have a material adverse effect on our business, operating results and financial condition. We also rely on consultants and advisors to assist us in formulating our strategy. All of our consultants and advisors are either self-employed or employed by other organizations, and they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, that may affect their ability to contribute to us. We intend to expand and develop new drug candidates. We will need to hire additional employees in order to continue our clinical trials and market our drug candidates. This strategy will require us to recruit additional executive management and clinical development, scientific, technical and sales and marketing personnel. There is currently intense competition for skilled executives and employees with relevant clinical development, scientific, technical and sales and marketing expertise, and this competition is likely to continue. The inability to attract and retain sufficient clinical development, scientific, technical and managerial personnel could limit or delay our product development efforts, which would adversely affect the development of our drug candidates and commercialization of our potential drugs and growth of our business.

We may be exposed to product liability claims that may damage our reputation and we may not be able to obtain adequate insurance.

Because we conduct clinical trials in humans, we face the risk that the use of our drug candidates will result in adverse effects. We believe that we have obtained reasonably adequate product liability insurance coverage for our trials. We cannot predict, however, the possible harm or side effects that may result from our clinical trials. Such claims may damage our reputation and we may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limit of, our insurance coverage or if the amount of the insurance coverage is insufficient to meet any liabilities resulting from any claims.

We may also be exposed to additional risks of product liability claims. These risks exist even with respect to drugs that are approved for commercial sale by the FDA or other regulatory authorities in the United States, the European Union or elsewhere and manufactured in facilities licensed and regulated by the FDA or other such regulatory authorities. We have secured limited product liability insurance coverage, but may not be able to maintain such insurance on acceptable terms with adequate coverage, or at a reasonable cost. There is also a risk that third parties that we have agreed to indemnify could incur liability. Even if we were ultimately successful in product liability litigation, the litigation would consume substantial amounts of our financial and managerial resources and may exceed insurance coverage creating adverse publicity, all of which would impair our ability to generate sales of the litigated product as well as our other potential drugs.

We may be required to defend lawsuits or pay damages in connection with the alleged or actual violation of healthcare statutes such as fraud and abuse laws, and our corporate compliance programs can never guarantee that we are in compliance with all relevant laws and regulations.

Our commercialization efforts in the United States are subject to various federal and state laws pertaining to promotion and healthcare fraud and abuse, including federal and state anti-kickback, fraud and false claims laws. Anti-kickback laws make it illegal for a manufacturer to offer or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase of a product. The federal government has published many regulations relating to the anti-kickback statutes, including numerous safe harbors or exemptions for certain arrangements. False claims laws prohibit anyone from

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knowingly and willingly presenting, or causing to be presented for payment to third-party payers including Medicare and Medicaid, claims for reimbursed products or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services.

Our activities relating to the sale and marketing of our products will be subject to scrutiny under these laws and regulations. It may be difficult to determine whether or not our activities, comply with these complex legal requirements. Violations are punishable by significant criminal and/or civil fines and other penalties, as well as the possibility of exclusion of the product from coverage under governmental healthcare programs, including Medicare and Medicaid. If the government were to

86,408	\$8.25	140,608	\$7.00	27,103	\$23.00	1,379,649	\$9.34	Aggregate
proceeds if								
exercised	\$2,040,000	\$5,251,203	\$3,269,322	\$712,866	\$984,256	\$623,369	\$12,881,016	

8. Stockholders' Equity

On March 16, 2015, the Company issued and sold 1,575,758 shares of common stock in a private placement at a price of \$8.25 per share, for aggregate proceeds of \$13.0 million. In conjunction with this private placement, the Company issued warrants to purchase an aggregate of 393,939 shares of common stock at an exercise price of \$10.75 per share to the purchasers of the common stock. The Company paid \$833,000 in fees to its placement agents, along with the issuance of warrants to purchase an aggregate of 94,545 shares of common stock at an exercise price of \$10.75 per share. The Company valued these warrants as liability instruments and recorded a liability of \$4,210,000 as of March 16, 2015. In the first quarter of 2015, the Company recorded \$213,000 of other expenses representing the portion of the initial warrant value of the placement agent warrants related to the initial fair value of the warrants issued to the purchasers of the common stock. The remainder of the initial fair value of the warrants of \$3,996,000 was treated as a reduction of additional paid-in-capital. In addition, \$218,000 of the fees paid to its placement agent were expensed as other expenses in the three months ended March 31, 2015 as they also represented issuance costs related to the initial fair value of the warrants issued to the purchasers of the common stock.

9. Stock-Based Compensation

The Company's 2013 Stock Incentive Plan (Stock Incentive Plan) provides for the issuance of incentive awards in the form of non-qualified and incentive stock options, stock appreciation rights, stock grants and restricted stock units. The awards may be granted by the Company's Board of Directors to its employees, directors and officers and to consultants, agents, advisors and independent contractors who provide services to the Company or to a subsidiary of the Company. The exercise price for stock options must not be less than the fair market value of the underlying shares on the date of grant. Stock options expire no later than ten years from the date of grant and generally vest and typically become exercisable over a four-year period following the date of grant. Upon the exercise of stock options, the Company issues the resulting shares from shares reserved for issuance under the Stock Incentive Plan.

The Company accounts for stock options and restricted stock units related to its stock incentive plans under the provisions of ASC 718, which requires the recognition of the fair value of stock-based compensation. The fair value

of stock options was estimated using a Black-Scholes option valuation model. This model requires the input of subjective assumptions in implementing ASC 718, including expected dividend, expected life, expected volatility and forfeiture rate of each award, as well as the prevailing risk-free interest rate and the fair value of the underlying common stock on the date of grant. The fair value of equity-based awards is amortized over the vesting period of the award, and the Company has elected to use the straight-line method of amortization. The assumptions used in the Black-Scholes option valuation model for the three months ended March 31, 2016 are set forth below.

Expected Dividend: The Company does not anticipate paying any dividends on its common stock.

Expected Life: The expected life represents the period that the Company expects its stock-based awards to be outstanding. The Company's expected life assumption was based on the simplified method set forth in the SEC Staff Accounting Bulletin 110. The Company's estimation of the expected life for stock options granted to parties other than employees or directors is the contractual term of the option award.

Expected Volatility: Expected volatility is the measure by which the Company's stock price is expected to fluctuate during the expected term of an option. The Company's expected volatility represents the weighted average historical volatility of the shares of its common stock.

Risk-Free Interest Rate: The Company bases the risk-free interest rate used on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent remaining term. Where the expected term of its stock-based awards does not correspond with the terms for which interest rates are quoted, the Company performs a straight-line interpolation to determine the rate from the available term maturities.

Forfeiture Rate: The Company applies an estimated forfeiture rate that is derived from historical forfeited shares. If the actual number of forfeitures differs from our estimates, the Company may record additional adjustments to compensation expense in future periods.

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the stock option grants were as follows:

	March 31, 2016	
Risk-free interest rate	1.58 to 1.63	%
Expected volatility	113.0	%
Expected term (in years)	6.0	
Expected dividend yield	0.0	%

Stock-based compensation expense is reduced by an estimated forfeiture rate derived from historical employee termination behavior. If the actual number of forfeitures differs from the Company's estimates, the Company may record adjustments to increase or decrease compensation expense in future periods.

The estimated grant-date fair value of the Company's stock-based awards is amortized ratably over the awards' service periods. Stock-based compensation expense recognized was as follows:

	Three Months Ended March 31,	
	2016	2015
	(Unaudited)	(Unaudited)
Research and development	\$ 26,000	\$ 29,000
General and administrative	790,000	23,000
Total stock-based compensation	\$ 816,000	\$ 52,000

The following table summarizes stock option activity for the three months ended March 31, 2016:

	Options Outstanding				
	Shares Available For Grant	Shares	Weighted Average Exercise Price	Average Remaining Contractual Term (Years)	Intrinsic Value
Balance, December 31, 2015	723,431	669,769	\$ 8.68	9.29	\$-
Granted	(207,208)	207,208	2.83	-	-
Exercised	-	-	-	-	-
Forfeited	-	-	-	-	-
Expired	-	(4,000)	10.00	-	-
Balance, March 31, 2016	516,223	872,977	\$ 7.29	9.26	\$229,076
Vested or expected to vest at March 31, 2016		704,778	\$ 7.63	9.18	\$141,846
Exercisable at March 31, 2016		99,394	\$ 9.19	7.69	\$-

The intrinsic value of options exercisable as of March 31, 2016 was \$0.0, based on the Company's closing stock price of \$3.94 per share and a weighted average exercise price of \$9.19 per share.

During the first quarter of 2016, the Company issued 207,208 common stock options to its employees and an executive with an average exercise price \$2.83 per share. Included in this amount were 99,919 stock options, with an exercise price of \$2.85, to its Chief Financial Officer, pursuant to his employment agreement dated January 18, 2016. There were no grants of stock options to employees or directors during the three months ended March 31, 2015.

As of March 31, 2016, there was \$2.8 million of total unrecognized compensation expense related to unvested stock options, which the Company expects to recognize over the weighted average remaining period of 2.72 years.

Shares Reserved For Further Issuance

As of March 31, 2016, the Company had reserved shares of its common stock for future issuance as follows:

	Shares Reserved
Stock options outstanding	872,977
Available for future grants under the Stock Incentive Plan	516,223
Warrants	1,379,649
Total shares reserved	2,768,849

10. Collaborative and Other Agreements

In June 2013, the Company entered into a Collaborative Research and Development Agreement with the United States Army Medical Research and Materiel Command and the Walter Reed Army Institute of Research. The Collaborative Research and Development Agreement is focused on developing and commercializing bacteriophage therapeutics to treat *S. aureus* infections. During the three months ended March 31, 2016 and 2015, the Company recorded no payments to Walter Reed Army Institute of Research under the Collaborative Research and Development Agreement.

In March 2013, the Company entered into an Exclusive Channel Collaboration Agreement with Intrexon Corporation (the ECC Agreement"). This agreement allows the Company to utilize Intrexon's synthetic biology platform for the identification, development and production of bacteriophage-containing human therapeutics. The Company paid a

one-time technology access fee in 2013 to Intrexon of \$3,000,000 in common stock. Pursuant to the agreement, the Company is required to pay Intrexon, in cash or stock, milestone fees of \$2,500,000 for the initiation and commencement of the first Phase 2 trial and \$5,000,000 upon the first regulatory approval of any product in any major market country. With regard to each product sold by the Company, the Company is required to pay, in cash, tiered royalties on a quarterly basis based on net sales of AmpliPhi Products, calculated on a product-by-product basis. No milestones have been met and no milestone payments have been paid to Intrexon through March 31, 2016. During the three months ended March 31, 2016, the Company recorded \$54,000 in expenses under the Exclusive Channel Collaboration Agreement, with cash payments totaling \$56,000. During the three months ended March 31, 2015, the Company recorded \$22,000 in expenses under the Exclusive Channel Collaboration Agreement, with cash payments totaling \$3,000. On April 13, 2016, the Company provided written notice to Intrexon of its election to voluntarily terminate the ECC Agreement. As of March 31, 2016, the Company had a liability of \$54,000 recorded for amounts due to Intrexon. See *Note 13 – Subsequent Events*.

In April 2013, the Company entered into a collaboration agreement with the University of Leicester to develop a phage therapy that targets and kills all toxin types of *C. difficile*. In August 2013, the Company entered into a collaboration agreement with both the University of Leicester and the University of Glasgow to carry out certain animal model development work. Under these agreements, which are referred to collectively as the Leicester Development Agreements, the Company provides payments to the University of Leicester to carry out *in vitro* and to the University of Glasgow to carry out animal model development work on the University of Leicester's development of a bacteriophage therapeutic to resolve *C. difficile* infections. The Company licensed related patents, materials and know-how from the University of Leicester. Under the Leicester Development Agreements, the University of Leicester will provide the bacteriophage and act as overall project coordinator for the development work. All rights, title and interest to any intellectual property developed under the Leicester Development Agreements belong to the Company. Under the Leicester License Agreement, the Company has exclusive rights to certain background intellectual property of the University of Leicester, for which it will pay the University of Leicester royalties based on product sales and make certain milestone payments based on product development. In November 2015, the Company renewed this collaboration, effective as of November 12, 2015. This agreement expires November 12, 2018. During the three months ended March 31, 2016, the Company recorded \$43,000 in expenses to the University of Leicester under the Leicester Development Agreements, with cash payments totaling \$46,000. During the three months ended March 31, 2015, the Company recorded \$35,000 in expenses to the University of Leicester under the Leicester Development Agreements, with cash payments totaling \$50,000. During the three months ended March 31, 2016, the Company recognized no expense and made no payments to the University of Glasgow under the Leicester Development Agreements. During the three months ended March 31, 2015, the Company paid \$61,000 and expensed amounts to the University of Glasgow under the Leicester Development Agreements of \$13,000.

In September 2015, the Company entered into a non-exclusive patent license agreement with Takara Bio Inc. (the Takara Agreement). Under this agreement Takara licensed certain patents from the Company related to AAV1 Vector gene delivery systems, for which the Company is an exclusive licensor with the University of Pennsylvania. The Company received a \$40,000 non-refundable, up-front licensing payment and is entitled to receive royalties from Takara of 12.0% of net license product sales and 6.0% of service revenues associated with the licensed products. The agreement calls for minimum annual royalties of \$15,000 commencing on February 28, 2016. In addition, the Takara Agreement provides milestone fees to the Company of \$30,000 of the first \$1,000,000 of licensed product revenues by Takara and an additional \$40,000 when cumulative net sales of the licensed product by Takara exceed \$2,000,000. During the three months ended March 31, 2016, the Company recognized revenue of \$4,000 under the Takara Agreement.

11. Severance Charge

In September of 2014 and 2015 two executives separated from the Company. The Company recorded severance expenses in the respective periods and accrued severance related to the cash portion due over time.

The severance accrual as of December 31, 2015 and March 31, 2016 is as follows:

Accrued severance, December 31, 2015	\$ 308,000
Cash payments in 2016	(170,000)
Accrued severance, March 31, 2016	\$ 138,000

12. Legal Proceedings

The Company determines whether it should accrue an estimated loss for a contingency in a particular legal proceeding by assessing whether a loss is deemed probable and whether the amount can be reasonably estimated. Claim estimates that are probable and can be reasonably estimated are reflected as liabilities. Legal proceedings are inherently unpredictable and the matters in which the Company may be involved often will present complex legal and factual issues. Because of the uncertainties related to the Company's pending litigation, investigations, inquiries or claims, management is currently unable to predict the ultimate outcome of any litigation, investigation, inquiry or claim, determine whether a liability has been incurred, or make an estimate regarding the possible loss or range of loss that could result from an unfavorable outcome. It is reasonably possible that some of the matters which may be asserted could be decided unfavorably to the Company. An adverse ruling or outcome in any lawsuit involving the Company could materially affect its business, liquidity, consolidated financial position or results of operations. In view of the unpredictable nature of such matters, the Company cannot provide any assurances regarding the outcome of any litigation, investigation, inquiry or claim to which it is a party of the impact on the Company of an adverse ruling on

such matters.

On April 14, 2016, a complaint was filed against the Company and certain of its board members. See *Note 13 – Subsequent Events*.

13. Subsequent Events

Series B Convertible Preferred Stock Conversion

On April 8, 2016, certain holders (the “Holders”) of over two-thirds of the Company’s then-outstanding shares of Series B redeemable convertible preferred stock (“Series B Preferred”) elected to automatically convert all outstanding shares of Series B Preferred into shares of Common Stock in accordance with Section 4.4.4(b)(ii) of the Company’s Amended and Restated Articles of Incorporation (the “Conversion”). As a result of the Conversion, the 7,527,853 shares of Series B Preferred outstanding as of immediately prior to the Conversion have been converted into an aggregate of 1,505,560 shares of Common Stock.

On April 8, 2016, the Company entered into a Common Stock Issuance Agreement (the “Agreement”) with the Holders pursuant to which the Company agreed to issue the Holders an aggregate of 853,465 shares of the Company’s Common Stock (the “Shares”). Pursuant to the Agreement, the Company and the Holders also agreed to amend the Common Stock warrants issued to the Holders pursuant to that certain Subscription Agreement, dated June 25, 2013, in order to reduce the exercise price of such warrants from \$7.00 per share to \$4.05 per share and extend the expiration date thereof from June 26, 2018 to March 31, 2021 (the “Warrant Amendments”). As consideration for the Shares and the Warrant Amendments, the Holders waived their right to receive approximately \$2.2 million in aggregate cash payments to which they were entitled upon the Conversion in respect of accrued dividends on their former shares of Series B Preferred. The Holders also waived their registration rights with respect to certain future registration statements that may be filed, and certain future public offerings that may be conducted, by the Company.

Pursuant to the Agreement, if in the future the Company conducts one or more bona fide equity financings in which it sells shares of Common Stock or Preferred Stock at a price less than \$4.05 per share (each, a “dilutive financing”), the Company will be required to issue to the Holders additional shares of Common Stock based on a specified formula. The obligation to issue additional shares in the event of any such dilutive financing (i) only applies to the lowest priced financing conducted after the date of the Agreement, (ii) is subject to limitations under applicable NYSE MKT rules relating to the issuance of additional shares in a private placement at a price less than the greater of book or market value and (iii) will expire at such time the Company has raised \$10.0 million in gross proceeds from the sale of Common Stock and/or Preferred Stock in a bona fide financing or financings or June 30, 2018, whichever occurs first. The Company has agreed to seek shareholder approval of the issuance of up to 1,037,053 shares of Common Stock to the Holders in the future as required by the Agreement in connection with one or more dilutive financings. To the extent the Company is not permitted by applicable NYSE MKT rules to issue any additional shares of Common Stock that would otherwise be required to be issued pursuant to the terms of the Agreement as a result of a dilutive financing, the Company has agreed to pay the Holders a cash payment equal to the difference between the price per share in such dilutive financing and \$4.05 for each share issued to the Holders pursuant to the Conversion.

Litigation

On April 14, 2016, NRM VII Holdings I, LLC (“NRM”), an affiliate of Third Security, LLC (“Third Security”), filed a complaint against the Company and certain members of the Company’s Board in the Superior Court of California, County of San Diego. Third Security is one of the principal shareholders of the Company. The complaint alleges that the Company breached the implied covenant of good faith by entering into a scheme to force NRM to convert its Series B Shares into Common Shares. The complaint further alleges that the members of the Board who were named as defendants breached their fiduciary duty of good faith owed to NRM, as one of the Company’s shareholders, by participating in this transaction. The complaint seeks unspecified monetary damages and other relief. The Company plans to vigorously defend against the claims advanced.

Collaboration Agreement

On April 13, 2016, the Company provided written notice to Intrexon Corporation of its election to voluntarily terminate its ECC Agreement dated March 29, 2013 (see Note 10). The effective date of the termination will be 90 days following delivery of the termination notice. The Company will not incur any early termination penalties as a result of the termination of the ECC Agreement.

Item 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q, and the audited financial statements and notes thereto as of and for the year ended December 31, 2015 included in our Annual Report on Form 10-K filed with the SEC.

Statements contained in this report that are not statements of historical fact are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, without limitation, statements concerning product development plans, the use of bacteriophages to kill bacterial pathogens, having resources sufficient to fund our operations into the third quarter of 2016, future revenue sources, selling and marketing expenses, general and administrative expenses, clinical trial and other research and development expenses, capital resources, capital expenditures, tax credits and carry-forwards, and additional financings and litigation-related matters. Words such as “believe,” “anticipate,” “plan,” “expect,” “intend,” “will,” “goal,” “potential” and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements necessarily contain these identifying words. These statements are subject to risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under Part II, Item 1A, “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q. These forward-looking statements speak only as of the date on which they were made, and we undertake no obligation to update any forward-looking statements.

Overview

We are a biotechnology company focused on the discovery, development and commercialization of novel phage therapeutics. Phage therapeutics use bacteriophages, a family of viruses, to kill pathogenic bacteria. Phages have powerful and highly selective mechanisms of action that permit them to target and kill specific bacteria. We believe that phages represent a promising means to treat bacterial infections, especially those that have developed resistance to current therapies including the so-called multi-drug-resistant or “superbug” strains of bacteria.

Our goal is to be the leading developer of phage therapeutics. We are combining our expertise in the manufacture of drug-quality bacteriophages and our proprietary approach and expertise in identifying, characterizing and developing naturally occurring bacteriophages with that of our collaboration partners in bacteriophage biology, synthetic biology and manufacturing, to develop second-generation bacteriophage products.

Our lead product candidate is AB-SA01 for the treatment of *S. aureus* infections, including methicillin-resistant *S. aureus*, or MRSA. We also have AB-PA01 for the treatment of *P. aeruginosa* infections in development, and AB-CD01 for the treatment of *C. difficile* infections in preclinical development.

We have generally incurred net losses since our inception and our operations to date have been primarily limited to research and development and raising capital. We have raised approximately \$43.6 million in capital to support our operations since the shift in our focus to novel phage therapeutics in February 2011.

To date, we have not generated any product revenue and have primarily financed our operations through the sale and issuance of our equity securities and convertible notes. As of March 31, 2016, we had a cumulative deficit of \$365.6 million. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on completing the development and obtaining regulatory approval of our product candidates.

We currently expect to use our existing cash and cash equivalents for the continued research and development of our product candidates and for working capital and other general corporate purposes.

We expect our research and development expenses to increase for the foreseeable future as we continue development of our product candidates. We also expect to incur additional expenses associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses at least for the next several years. We do not expect to generate product revenue unless and until we successfully complete development and obtain marketing approval for at least one of our product candidates.

We may also use a portion of our existing cash and cash equivalents for the potential acquisition of, or investment in, product candidates, technologies, formulations or companies that complement our business, although we have no current understandings, commitments or agreements to do so. Our existing cash and cash equivalents will not be sufficient to enable us to complete all necessary development of any potential product candidates. Accordingly, we will be required to obtain further funding through one or more other public or private equity offerings, debt financings, collaboration or licensing arrangements or other sources. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs.

Recent Events

Series B Redeemable Convertible Preferred Stock Conversion

On April 8, 2016, certain holders (the “Holders”) of over two-thirds of our then-outstanding shares of Series B redeemable convertible preferred stock (“Series B Preferred”) elected to automatically convert all outstanding shares of Series B Preferred into shares of Common Stock in accordance with Section 4.4.4(b)(ii) of our Amended and Restated Articles of Incorporation (the “Conversion”). As a result of the Conversion, the 7,527,853 shares of Series B Preferred outstanding as of immediately prior to the Conversion have been converted into an aggregate of 1,505,560 shares of Common Stock.

On April 8, 2016, we entered into a Common Stock Issuance Agreement (the “Agreement”) with the Holders pursuant to which we agreed to issue the Holders an aggregate of 853,465 shares of our Common Stock (the “Shares”). Pursuant to the Agreement, the Company and the Holders also agreed to amend the Common Stock warrants issued to the Holders pursuant to that certain Subscription Agreement, dated June 25, 2013, in order to reduce the exercise price of such warrants from \$7.00 per share to \$4.05 per share and extend the expiration date thereof from June 26, 2018 to March 31, 2021 (the “Warrant Amendments”). As consideration for the Shares and the Warrant Amendments, the Holders waived their right to receive approximately \$2.2 million in aggregate cash payments to which they were entitled upon the Conversion in respect of accrued dividends on their former shares of Series B Preferred. The Holders also waived their registration rights with respect to certain future registration statements that may be filed, and certain future public offerings that may be conducted, by us.

Pursuant to the Agreement, if in the future we conduct one or more bona fide equity financings in which it sell shares of Common Stock or Preferred Stock at a price less than \$4.05 per share (each, a “dilutive financing”), we will be required to issue to the Holders additional shares of Common Stock based on a specified formula. The obligation to issue additional shares in the event of any such dilutive financing (i) only applies to the lowest priced financing conducted after the date of the Agreement, (ii) is subject to limitations under applicable NYSE MKT rules relating to the issuance of additional shares in a private placement at a price less than the greater of book or market value and (iii) will expire at such time we have raised \$10.0 million in gross proceeds from the sale of Common Stock and/or Preferred stock in a bona fide financing or financings or June 30, 2018, whichever occurs first. We have agreed to seek shareholder approval of the issuance of up to 1,037,053 shares of Common Stock to the Holders in the future as required by the Agreement in connection with one or more dilutive financings. To the extent we are not permitted by applicable NYSE MKT rules to issue any additional shares of Common Stock that would otherwise be required to be issued pursuant to the terms of the Agreement as a result of a dilutive financing, we have agreed to pay the Holders a cash payment equal to the difference between the price per share in such dilutive financing and \$4.05 for each share issued to the Holders pursuant to the Conversion.

Collaboration Agreement

On April 13, 2016, we provided written notice to Intrexon Corporation (“Intrexon”) of our election to voluntarily terminate that certain Exclusive Channel Collaboration Agreement, dated as of March 29, 2013, by and between us and Intrexon (the “ECC Agreement”). The effective date of termination (the “Termination Date”) will be 90 days following delivery of the termination notice. We will not incur any early termination penalties as a result of the termination of the ECC Agreement.

The ECC Agreement is directed towards the research, development and commercialization of new bacteriophage-based therapies for the treatment of bacterial infections caused by *P. aeruginosa* and *C. difficile*. A summary of the material terms of the ECC Agreement is contained in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission (“SEC”) on March 30, 2016, under Item 1. Business—*Exclusive Channel Collaboration with Intrexon*, and is incorporated herein by reference.

Results of Operations

Comparison of three months ended March 31, 2016 and 2015

Revenue

For each of the quarters ended March 31, 2016 and 2015, we recognized \$0.1 million in revenue primarily related to sublicensing agreements from our former gene therapy program.

Research and Development Expenses

Research and development expenses for the quarter ended March 31, 2016 totaled \$2.0 million compared to \$1.0 million incurred in the same period of 2015. This increase of \$1.0 million was primarily related to higher compensation costs of \$0.2 million, \$0.1 million of professional recruiting fees, and \$0.4 million for the expense recorded related to the assets acquired from Novolytics.

We anticipate that research and development spending in future periods will continue to increase as we initiate non-clinical research studies, hire additional research and development staff, advance our clinical trials, and continue our discovery efforts.

General and Administrative Expenses

General and administrative expenses for the quarter ended March 31, 2016 were \$2.6 million compared to \$1.4 million for the same period of 2015. The \$1.2 million increase was primarily attributable to \$0.9 million of compensation, including \$0.8 million of non-cash stock-based compensation, related to two new executives, and \$0.3 million for professional fees for legal, accounting and recruitment.

Other Income (Expense)

We recorded a gain of \$4,000 for the quarter ended March 31, 2016 related to the change in fair value of our warrant liability, which was primarily attributable to a decrease in the value of our common stock price during the period.

We recorded a gain of \$1.4 million for the quarter ended March 31, 2016 related to the change in fair value of our Series B preferred stock derivative liability. This gain was primarily attributable to a decrease in the estimated term of the derivative liability associated with the Series B preferred stock at March 31, 2016.

We will continue to adjust the liability related to our outstanding Series 2011 warrants to fair value until the earlier of exercise or expiration of the warrants or until terms of the warrants no longer require them to be accounted for as liability instruments. We continued to adjust the liability related to our Series B preferred stock derivative feature until the conversion of our Series B preferred stock into common stock in April 2016.

We also recorded expenses of \$0.4 million for the three months ended March 31, 2015 consisting of placement agent costs from our March 2015 private placement of common stock, which related to placement agent fees and the initial fair value of warrants issued to the placement agents. We had no comparable costs during the three months ended March 31, 2016.

Liquidity and Capital Resources

We have incurred net losses since inception through March 31, 2016 of \$365.6 million, of which \$315.5 million was incurred as a result of our prior focus on gene therapy in fiscal years 2010 and earlier. We have not generated any product revenues and do not expect to generate revenue from product candidates in the near term.

We had cash and cash equivalents of \$6.2 million and \$9.4 million at March 31, 2016 and December 31, 2015, respectively.

Net cash used in operating activities for the three months ended March 31, 2016 was \$3.1 million, as compared to \$2.3 million for the three months ended March 31, 2015. Net loss recorded during the three months ended March 31, 2016 was \$3.1 million, inclusive of a \$1.4 million non-cash gain on derivative liability. Net loss recorded during the three months ended March 31, 2015 was \$14.5 million, inclusive of a \$11.8 million non-cash loss on derivative liability. The net increase in cash used in operating activities of \$0.8 million, in addition to the effect of the non-cash derivative liability effects noted above, are primarily related to an increase in research and development efforts, payroll and non-cash stock based compensation, as well as an increase in professional services.

Net cash used in investing activities was \$0.1 million and \$0.0 million for three months ended March 31, 2016 and March 31, 2015, respectively. Net cash used in investing activities for the three months ended March 31, 2016 was primarily attributable to purchases of property and equipment.

Cash provided by financing activities for the three months ended March 31, 2015 was comprised of the gross proceeds of \$13.0 million from the March 2015 private placement of common stock and warrants to purchase common stock, less commissions and other cash expenses related to the issuance of approximately \$0.6 million. There were no financing activities for the three months ended March 31, 2016.

We will need to raise additional capital or incur indebtedness to continue to fund our future operations. Our future funding requirements will depend on many factors, including:

- the costs and timing of our research and development activities;
- the progress and cost of our clinical trials and other research and development activities;
- the cost and timing of securing manufacturing capabilities for our clinical product candidates and commercial products, if any;
- the terms and timing of any collaborative, licensing, acquisition or other arrangements that we may establish;
- the costs and timing of seeking regulatory approvals;
- the costs of filing, prosecuting and enforcing any patent applications, claims, patents and other intellectual property rights; and
- the costs of lawsuits involving us or our product candidates.

We may seek to raise capital through a variety of sources, including:

- the public equity market;

- private equity financings;
- collaborative arrangements;

- licensing arrangements; and/or
- public or private debt.

We believe our existing resources are sufficient to fund our planned operations into the third quarter of 2016. This estimate is based on our current product development calendar, projected staffing expenses, working capital requirements, and capital expenditure plans.

Our ability to raise additional funds will depend on our clinical and regulatory events, our ability to identify promising in-licensing opportunities and factors related to financial, economic and market conditions, many of which are beyond our control. We cannot be certain that sufficient funds will be available to us when required or on satisfactory terms. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, any of which could delay or require that we curtail our development programs or otherwise have a material adverse effect on our business, financial condition and results of operations. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to our existing stockholders.

If we are unable to secure additional financing on a timely basis or on terms favorable to us, we may be required to significantly reduce or refocus our operations or to obtain funds through additional arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, any of which could delay or require that we curtail or eliminate some or all of our development programs or otherwise have a material adverse effect on our business, financial condition and results of operations. This uncertainty around our ability to secure additional financing creates substantial doubt about our ability to continue as a going concern.

Contractual Obligations and Commitments

As of March 31, 2016, there have been no material changes, outside of the ordinary course of business, in our outstanding contractual obligations from those disclosed within “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, as contained in our Annual Report on Form 10-K for the year ended December 31, 2015.

Off-Balance Sheet Arrangements

As of March 31, 2016, we did not have off-balance sheet arrangements.

Recent Accounting Pronouncements

Refer to Note 3 of the Condensed Consolidated Notes to the Consolidated Financial Statements contained elsewhere in this report.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this report. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective disclosure controls system, misstatements due to error or fraud may occur and not be detected.

Based on this evaluation, our Chief Executive Officer and Chief Financial Officer, have concluded that our disclosure controls and procedures were not effective at the reasonable assurance level during the period covered by this report.

Changes in Internal Control Over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, other than the following:

- the appointment of an experienced Chief Financial Officer in January 2016 with significant experience in public company reporting and complex transactions; and
- the engagement of consultants with experience in the review of unique and complex accounting topics, who consulted with management on complex transactions and reporting.

Remediation of Material Weakness

We continue to review, document and test our internal control over financial reporting. We also continue to take steps to remediate certain identified deficiencies in our internal control over financial reporting as of December 31, 2015 in the area of complex and non-routine transactions. Although efforts remain in process, steps taken during the last fiscal quarter that resulted in improvements to our internal control over financial reporting included the following:

- commenced designing additional training programs for relevant personnel and development of specific review procedures regarding the review of complex and non-routine transactions; and
- implemented standardized financial control and reporting processes.

The remediation actions will be monitored by the Audit Committee of our Board of Directors.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On April 14, 2016, NRM VII Holdings I, LLC (“NRM”), an affiliate of Third Security, LLC (“Third Security”), filed a complaint against us and certain members of our Board in the Superior Court of California, County of San Diego. Third Security is one of our principal shareholders. The complaint alleges that we breached the implied covenant of good faith by entering into a scheme to force NRM to convert its shares of Series B redeemable convertible preferred stock into shares of our common stock. The complaint further alleges that the members of the Board who were named as defendants breached their fiduciary duty of good faith owed to NRM, as one of our shareholders, by participating in this transaction. The complaint seeks unspecified monetary damages and other relief. We plan to vigorously defend against the claims advanced.

Claim estimates that are probable and can be reasonably estimated are reflected as liabilities. Because of the uncertainties related to our pending litigation, investigations, inquiries or claims, management is currently unable to predict the ultimate outcome of any litigation, investigation, inquiry or claim, determine whether a liability has been incurred, or make an estimate regarding the possible loss or range of loss that could result from an unfavorable outcome. It is reasonably possible that some of the matters, which are pending or may be asserted, could be decided unfavorably to us. Although we maintain liability insurance coverage to protect our assets from losses arising out of or involving activities associated with ongoing and normal business operations, our insurance may not cover, or may not adequately cover, any liabilities that we incur. An adverse ruling or outcome in any lawsuit involving us could materially affect our business, liquidity, consolidated financial position or results of operations. In view of the unpredictable nature of such matters, we cannot provide any assurances regarding the outcome of any litigation, investigation, inquiry or claim to which we are a party or the impact on us of an adverse ruling of such matters.

Item 1A. Risk Factors

You should consider carefully the following information about the risks described below, together with the other information contained in this Quarterly Report and in our other public filings in evaluating our business. The risk factors set forth below that are marked with an asterisk () did not appear as separate risk factors in, or contain changes to the similarly titled risk factors included in, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2015. If any of the following risks actually occur, our business, financial condition, results of operations, and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.*

Risks Related to Our Financial Condition and Need for Additional Capital

*We have incurred losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future, and our future profitability is uncertain.**

We have incurred losses in each year since our inception in 1992. Prior to our merger with Biocontrol in January 2011, our accumulated deficit was \$315.5 million. Since January 2011 through March 31, 2016, we have incurred a cumulative deficit of \$50.1 million, and we expect to incur losses for the foreseeable future. We have devoted, and

will continue to devote for the foreseeable future, substantially all of our resources to research and development of our product candidates. For the three months ended March 31, 2016 we had an operating loss of \$3.1 million. Additional information regarding our results of operations may be found in our consolidated financial statements and in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this report.

Clinical trials and activities associated with discovery research are costly. We do not expect to generate any revenue from the commercial sales of our product candidates in the near term, and we expect to continue to have significant losses for the foreseeable future.

To attain ongoing profitability, we will need to develop products successfully and market and sell them effectively, or rely on other parties to do so. We cannot predict when we will achieve ongoing profitability, if at all. We have never generated revenue from the commercial sales of our product candidates, and there is no guarantee that we will be able to do so in the future. If we fail to become profitable, or if we are unable to fund our continuing losses, we would be unable to continue our research and development programs.

We have never generated any revenue from product sales and may never be profitable.

Our ability to generate meaningful revenue and achieve profitability depends on our ability, and the ability of any third party with which we may partner, to successfully complete the development of, and obtain the regulatory approvals necessary to, commercialize our product candidates. We do not anticipate generating revenues from product sales for the foreseeable future, if ever. If any of our product candidates fail in clinical trials or if any of our product candidates do not gain regulatory approval, or if any of our product candidates, if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our ability to generate future revenues from product sales depends heavily on our success in:

- completing research and preclinical and clinical development of our product candidates;
- seeking and obtaining regulatory and marketing approvals for product candidates for which we complete clinical trials;
- developing a sustainable, scalable, reproducible, and transferable manufacturing process for our product candidates;
- launching and commercializing product candidates for which we obtain regulatory and marketing approval, either by establishing a sales force, marketing and distribution infrastructure, or by collaborating with a partner;
- obtaining market acceptance of any approved products;
- addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure, as needed;
- identifying and validating new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product. Our expenses could increase

beyond expectations if we are required by the FDA, the EMA, or other foreign regulatory authorities to perform clinical trials and other studies in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

*We will need to raise additional capital to continue operations.**

Our consolidated financial statements for the quarter ended March 31, 2016 were prepared under the assumption that we would continue our operations as a going concern. However, we have had recurring losses from operations, negative operating cash flow and an accumulated deficit.

We do not generate any cash from operations and must raise additional funds in order to continue operating our business. We expect to continue to fund our operations primarily through equity and debt financings in the future. If additional capital is not available to us when needed or on acceptable terms, we may not be able to continue to operate our business pursuant to our business plan or we may have to discontinue our operations entirely. As of March 31, 2016, we had cash and cash equivalents of \$6.2 million. We believe that our existing resources will be sufficient to fund our planned operations into the third quarter of 2016.

Developing drugs and conducting clinical trials is expensive. Our future funding requirements will depend on many factors, including:

- the costs and timing of our research and development activities;
- the progress and cost of our clinical trials and other research and development activities;
- the cost and timing of securing manufacturing capabilities for our clinical product candidates and commercial products, if any;
- the terms and timing of any collaborative, licensing, acquisition or other arrangements that we may establish;
- the costs and timing of seeking regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent applications, claims, patents and other intellectual property rights; and
- the costs of lawsuits involving us or our product candidates.

We will need to raise additional capital to support our product development activities in 2016 and beyond. We may seek funds through arrangements with collaborators or others that may require us to relinquish rights to the products candidates that we might otherwise seek to develop or commercialize independently. We cannot be certain that we will be able to enter into any such arrangements on reasonable terms, if at all.

We may seek to raise capital through a variety of sources, including:

- the public equity market;
- private equity financings;
- collaborative arrangements;
- licensing arrangements; and/or
- public or private debt.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Our ability to raise additional funds will depend, in part, on the status of our product development activities and other business operations, as well as factors related to financial, economic, and market conditions, many of which are beyond our control. We cannot be certain that sufficient funds will be available to us when required or on acceptable terms, if at all. Raising additional capital through the sale of securities could cause significant dilution to our stockholders. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through additional arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, any of which could delay or require that we curtail or eliminate some or all of our development programs or otherwise have a material adverse effect on our business, financial condition and results of operations. In addition, we may have to delay, reduce the scope of or eliminate some of our research and development, which could delay the time to market for any of our product candidates, if adequate funds are not available.

If we are unable to secure additional financing on a timely basis or on terms acceptable to us, we may be required to cease or reduce certain research and development projects, to sell some or all of our technology or assets or to merge all or a portion of our business with another entity. Insufficient funds may require us to delay, scale back, or eliminate some or all of our activities, and if we are unable to obtain additional funding, there is uncertainty regarding our continued existence.

A complaint has been filed against us and the members of our Board of Directors by one of our principal shareholders.*

On April 8, 2016, certain holders (the “Holders”) of over two-thirds of our then-outstanding shares of Series B redeemable convertible preferred stock (“Series B Preferred”) elected to automatically convert all outstanding shares of Series B Preferred into shares of Common Stock in accordance with Section 4.4.4(b)(ii) of our Amended and Restated Articles of Incorporation, as amended (the “Conversion”). As a result of the Conversion, the 7,527,853 shares of Series B Preferred outstanding as of immediately prior to the Conversion were automatically converted into an aggregate of 1,505,560 shares of our common stock. On April 8, 2016, we entered into a Common Stock Issuance Agreement (the “CSIA”) with the Holders pursuant to which we issued to the Holders an aggregate of 853,465 shares of our Common Stock (the “Shares”) and amended the common stock warrants issued to the Holders pursuant to that certain Subscription Agreement, dated June 25, 2013, in order to reduce the exercise price of such warrants from \$7.00 per share to \$4.05 per share and extend the expiration date thereof from June 26, 2018 to March 31, 2021 (the “Warrant Amendments”). As consideration for the Shares and the Warrant Amendments, the Holders waived their right to receive approximately \$2.2 million in aggregate cash payments to which they were entitled upon the Conversion in respect of accrued dividends on their former shares of Series B Preferred.

On April 14, 2016, NRM VII Holdings I, LLC (“NRM”), who was not a party to the CSIA, filed a complaint against us and each of the current members of our board of directors in the Superior Court of California, County of San Diego. Prior to the Conversion, NRM held approximately 28.5% of our outstanding shares of Series B Preferred. The complaint alleges that we breached the implied covenant of good faith by entering into a scheme to force NRM to convert its Series B Preferred into common stock. The complaint further alleges that the current members of our board of directors breached their fiduciary duty of good faith owed to NRM, as one of our shareholders, by participating in this transaction. The complaint seeks unspecified monetary damages and other relief. We plan to vigorously defend against the claims advanced.

Litigation is subject to inherent uncertainties, and an adverse result in the matter described above or other matters that may arise from time to time could have a material adverse effect on our business, results of operations and financial condition. Any litigation to which we are subject may be costly and, further, could require significant involvement of our senior management and may divert management’s attention from our business and operations. In addition, our share price may be negatively impacted due to the negative publicity, expenses incurred in connection with our defense, management distraction, and/or other factors related to this litigation. In addition, litigation of this nature may negatively impact our ability to attract and retain strategic partners, as well as qualified board members and management personnel.

There is substantial doubt about our ability to continue as a going concern, which may affect our ability to obtain future financing and may require us to curtail our operations.*

Our financial statements as of March 31, 2016 were prepared under the assumption that we will continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. At March 31, 2016, we had cash and cash equivalents of \$6.2 million. Our ability to continue as a going concern depends on our ability to raise substantial additional funds through public or private equity offerings, collaborative or licensing arrangements and/or debt financing.

Taxing authorities could reallocate our taxable income among our subsidiaries, which could increase our overall tax liability.

We are organized in the United States, and we currently have subsidiaries in the United Kingdom, Australia and Slovenia. If we succeed in growing our business, we expect to conduct increased operations through our subsidiaries in various tax jurisdictions pursuant to transfer pricing arrangements between us and our subsidiaries. If two or more affiliated companies are located in different countries, the tax laws or regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arms' length and that appropriate documentation is maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities.

If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arms' length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

Our ability to use our net operating tax loss carryforwards and certain other tax attributes may be limited.*

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"). These limitations apply if an "ownership change," as defined by Section 382 of the Code, occurs. If we have experienced an "ownership change" at any time since our formation, we may already be subject to limitations on our ability to utilize our existing net operating

losses and other tax attributes to offset taxable income. In addition, future changes in our stock ownership (including in connection with future private or public offerings, as well as changes that may be outside of our control), may trigger an “ownership change” and, consequently, limitations under Sections 382 and 383 of the Code. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. We have not completed a study to assess whether an “ownership change” has occurred or whether there have been multiple “ownership changes” since our formation, due to the complexity and cost associated with such a study, and the fact that there may be additional ownership changes in the future.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired and our public reporting may be unreliable.*

We are required to maintain internal control over financial reporting adequate to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements in accordance with generally accepted accounting principles. In connection with the restatement of our consolidated financial statements for the second quarter of 2015 and for the quarterly and annual periods of 2014, we determined that we had a material weakness as of December 31, 2014 and December 31, 2015, namely that our internal control over financial reporting, including control over the evaluation and review of complex and non-routine transactions, were not effective. A material weakness means a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the registrant’s annual or interim financial statements will not be prevented or detected on a timely basis.

We do not expect that our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. Over time, controls may become inadequate because changes in conditions or deterioration in the degree of compliance with policies or procedures may occur. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. As a result, we cannot assure you that significant deficiencies or material weaknesses in our internal control over financial reporting will not be identified in the future.

We are taking steps to remediate the material weakness in our internal control over financial reporting, including designing additional training programs for relevant personnel and developing specific review procedures regarding the review of complex and non-routine transactions. However, we cannot assure you that these efforts will remediate our material weakness in a timely manner, or at all. If we are unable to successfully remediate our material weakness, or identify any future material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports and we may experience a loss of public confidence, which could have an adverse effect on our business, financial condition and the market price of our common stock and other securities.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the NYSE MKT to implement provisions of the Sarbanes-Oxley Act, imposes significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years following their initial public offering. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than expected and thereby incur unexpected expenses.

We expect the rules and regulations applicable to public companies to result in us continuing to incur substantial legal and financial compliance costs. These costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business.

Risks Related to Our Business

We are seeking to develop antibacterial agents using bacteriophage technology, a novel approach, which makes it difficult to predict the time and cost of development. No bacteriophage products have been approved in the United States or elsewhere.

We are developing our product candidates with bacteriophage technology. We have not, nor to our knowledge has any other company, received regulatory approval from the FDA or equivalent foreign agencies for a pharmaceutical drug based on this approach. While *in vitro* studies have characterized the behavior of bacteriophages in cell cultures and there exists a body of literature regarding the use of phage therapy in humans, the safety and efficacy of phage therapy in humans has not been extensively studied in well-controlled modern clinical trials. Most of the prior research on phage-based therapy was conducted in the former Soviet Union prior to and immediately after World War II and lacked appropriate control group design or lacked control groups at all. Furthermore, the standard of care has changed substantially during the ensuing decades since those studies were performed, diminishing the relevance of prior claims of improved cure rates. We cannot be certain that our approach will lead to the development of approvable or marketable drugs.

Developing phage-based therapies on a commercial scale will also require developing new manufacturing processes and techniques. We and our third-party collaborators may experience delays in developing manufacturing capabilities for our product candidates, and may not be able to do so at the scale required to efficiently conduct the clinical trials required to obtain regulatory approval of our product candidates, or to manufacture commercial quantities of our products, if approved.

In addition, the FDA or other regulatory agencies may lack experience in evaluating the safety and efficacy of drugs based on these approaches, which could lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates.

Delays in our clinical trials could result in us not achieving anticipated developmental milestones when expected, increased costs and delay our ability to obtain regulatory approval for and commercialize our product candidates.

Delays in our ability to commence or enroll patients for our clinical trials could result in us not meeting anticipated clinical milestones and could materially impact our product development costs and delay regulatory approval of our product candidates. Planned clinical trials may not be commenced or completed on schedule, or at all. Clinical trials can be delayed for a variety of reasons, including:

- delays in the development of manufacturing capabilities for our product candidates to enable their consistent production at clinical trial scale;
- failures in our internal manufacturing operations that result in our inability to consistently and timely produce bacteriophages in sufficient quantities to support our clinical trials;
- the availability of financial resources to commence and complete our planned clinical trials;
- delays in reaching a consensus with clinical investigators on study design;
- delays in reaching a consensus with regulatory agencies on trial design or in obtaining regulatory approval to commence a trial;
- delays in obtaining clinical materials;
- slower than expected patient recruitment for participation in clinical trials;

- failure by clinical trial sites, other third parties, or us to adhere to clinical trial agreements;
- delays in reaching agreement on acceptable clinical trial agreement terms with prospective sites or obtaining institutional review board approval; and
- adverse safety events experienced during our clinical trials.

If we do not successfully commence or complete our clinical trials on schedule, the price of our common stock may decline.

Completion of clinical trials depends, among other things, on our ability to enroll a sufficient number of patients, which is a function of many factors, including:

- the therapeutic endpoints chosen for evaluation;
- the eligibility criteria defined in the protocol;
- the perceived benefit of the product candidate under study;
- the size of the patient population required for analysis of the clinical trial's therapeutic endpoints;
- our ability to recruit clinical trial investigators and sites with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- competition for patients from clinical trials for other treatments.

We may experience difficulties in enrolling patients in our clinical trials, which could increase the costs or affect the timing or outcome of these clinical trials. This is particularly true with respect to diseases with relatively small patient populations.

We have not completed formulation development of any of our product candidates.

The development of our bacteriophage product candidates requires that we isolate, select and combine a number of bacteriophages that target the desired bacteria for that product candidate. The selection of bacteriophages for any of our product candidates is based on a variety of factors, including without limitation the ability of the selected phages, in combination, to successfully kill the targeted bacteria, the degree of cross-reactivity of the individual phages with the same part of the bacterial targets, the ability of the combined phages to satisfy regulatory requirements, our ability to manufacture sufficient quantities of the phages, intellectual property rights of third parties, and other factors. While we have selected an initial formulation of AB-SA01 for the treatment of *S. aureus* infections, there can be no assurance that this will be the final formulation of AB-SA01 for commercialization. In addition, we have initiated final phage selection for AB-PA01, our *P. aeruginosa* product. AB-CD01, which is our *C. difficile* product, is at an earlier stage. If we are unable to complete formulation development of our product candidates in the time frame that we have anticipated, then our product development timelines, and the regulatory approval of our product candidates, could be delayed.

Our product candidates must undergo rigorous clinical testing, such clinical testing may fail to demonstrate safety and efficacy and any of our product candidates could cause undesirable side effects, which would substantially delay or prevent regulatory approval or commercialization.

Before we can obtain regulatory approval for a product candidate, we must undertake extensive clinical testing in humans to demonstrate safety and efficacy to the satisfaction of the FDA or other regulatory agencies. Clinical trials of new drug candidates sufficient to obtain regulatory marketing approval are expensive and take years to complete.

We cannot be certain of successfully completing clinical testing within the time frame we have planned, or at all. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent us from receiving regulatory approval or commercializing our product candidates, including the following:

- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing or to abandon programs;
- the results obtained in earlier stage clinical testing may not be indicative of results in future clinical trials;
- clinical trial results may not meet the level of statistical significance required by the FDA or other regulatory agencies;
- we, or regulators, may suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks; and
- our product candidates may have unintended or undesirable effects on patients that may delay or preclude regulatory approval of our product candidates or limit their commercial use, if approved.

Results from preclinical studies and Phase 1 or 2 clinical trials of our product candidates may not be predictive of the results of later stage human clinical trials.

Preclinical studies, including studies of our product candidates in animal disease models, may not accurately predict the result of human clinical trials of those product candidates. In particular, promising animal studies suggesting the efficacy of prototype phage products in the treatment of bacterial infections, such as *P. aeruginosa* and *S. aureus*, may not predict the ability of these products to treat similar infections in humans. Our phage technology may be found not to be efficacious in treating bacterial infections alone or in combination with other agents, when studied in human clinical trials.

To satisfy FDA or foreign regulatory approval standards for the commercial sale of our product candidates, we must demonstrate in adequate and controlled clinical trials that our product candidates are safe and effective. Success in early clinical trials, including Phase 2 trials, does not ensure that later clinical trials will be successful. Our initial results from early stage clinical trials also may not be confirmed by later analysis or subsequent larger clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials and most product candidates that commence clinical trials are never approved for commercial sale.

We must continue to develop manufacturing processes for our product candidates and any delay in or our inability to do so would result in delays in our clinical trials.

We are developing novel manufacturing processes for our product candidates at our facility in Ljubljana, Slovenia. The manufacturing processes for our product candidates, and the scale up of such processes for clinical trials, is novel, and there can be no assurance that we will be able to complete this work in a timely manner, if at all. Any delay in the development or scale up of these manufacturing processes could delay the start of clinical trials and harm our business. Our facility in Slovenia must also undergo ongoing inspections by JAZMP, the Slovenian agency that regulates and supervises pharmaceutical products in Slovenia, for compliance with their and the European Medicines Agency's, or EMA's, current good manufacturing practice regulations, or cGMP regulations, before the respective product candidates can be approved for use in clinical trials or commercialization. In the event these facilities do not receive a satisfactory cGMP inspection for the manufacture of our product candidates, we may need to fund additional modifications to our manufacturing process, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as a delay of up to several years in obtaining approval for such product candidate.

Our manufacturing facility will be subject to ongoing periodic inspection by the European regulatory authorities, including JAZMP, and the FDA for compliance with European and FDA cGMP regulations. Compliance with these regulations and standards is complex and costly, and there can be no assurance that we will be able to comply. Any failure to comply with applicable regulations could result in sanctions being imposed (including fines, injunctions and civil penalties), failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecution.

We may conduct clinical trials for our products or product candidates outside the United States and the FDA may not accept data from such trials.

We are currently conducting an investigator-sponsored clinical trial of AB-SA01 at the University of Adelaide in Australia for chronic rhinosinusitis, and may seek to conduct one or more other clinical trials in the future outside the

United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of such study data by the FDA is subject to certain conditions. For example, the study must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The study population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical studies conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, such studies would be subject to the applicable local laws and FDA acceptance of the data would be dependent upon its determination that the studies also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept any such data, it would likely result in the need for additional trials, which would be costly and time consuming and delay aspects of our business plan.

We may need to license additional intellectual property rights.

The development and commercialization of phage-based antibacterial agents may require us to obtain rights to intellectual property from third parties. For example, pursuant to our Collaborative Research and Development Agreement with the United States Army Medical Research and Materiel Command and the Walter Reed Army Institute of Research, we are currently focusing on developing bacteriophage therapeutics to treat *S. aureus* infections. To the extent the intellectual property is generated from the United States Army Medical Research and Materiel Command or Walter Reed Army Institute of Research that is used in a commercial product, we may be obligated to make payments such as royalties, licensing fees and milestone payments. We may also determine that it is necessary or advisable to license other intellectual property from third parties. There can be no assurance that such intellectual property rights would be available on commercially reasonable terms, if at all.

We are conducting an investigator-sponsored clinical trial of AB-SA01 at the University of Adelaide. To the extent that intellectual property is generated as a result of the study that is used in a commercial product, we may be obligated to make payments, such as royalties, licensing fees, and milestone payments. There can be no assurance that such intellectual property rights would be available on commercially reasonable terms, if at all.

We are subject to significant regulatory approval requirements, which could delay, prevent or limit our ability to market our product candidates.

Our research and development activities, preclinical studies, clinical trials and the anticipated manufacturing and marketing of our product candidates are subject to extensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in Europe and elsewhere. There can be no assurance that our manufacturing facilities will satisfy the requirements of the FDA or comparable foreign authorities. We require the approval of the relevant regulatory authorities before we may commence commercial sales of our product candidates in a given market. The regulatory approval process is expensive and time-consuming, and the timing of receipt of regulatory approval is difficult to predict. Our product candidates could require a significantly longer time to gain regulatory approval than expected, or may never gain approval. We cannot be certain that, even after expending substantial time and financial resources, we will obtain regulatory approval for any of our product candidates. A delay or denial of regulatory approval could delay or prevent our ability to generate product revenues and to achieve profitability.

Changes in regulatory approval policies during the development period of any of our product candidates, changes in, or the enactment of, additional regulations or statutes, or changes in regulatory review practices for a submitted product application may cause a delay in obtaining approval or result in the rejection of an application for regulatory approval.

Regulatory approval, if obtained, may be made subject to limitations on the indicated uses for which we may market a product. These limitations could adversely affect our potential product revenues. Regulatory approval may also require costly post-marketing follow-up studies. In addition, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping related to the product will be subject to extensive ongoing regulatory requirements. Furthermore, for any marketed product, its manufacturer and its manufacturing facilities will be subject to continual review and periodic inspections by the FDA or other regulatory authorities. Failure to comply with applicable regulatory requirements may, among other things, result in fines, suspensions of regulatory approvals, product recalls, product seizures, operating restrictions and criminal prosecution.

A variety of risks associated with our international operations could materially adversely affect our business.

In addition to our U.S. operations, we have operations and subsidiaries in the United Kingdom, Australia and Slovenia. We face risks associated with our international operations, including possible unfavorable regulatory, pricing and reimbursement, political, tax and labor conditions, which could harm our business. We are subject to numerous risks associated with international business activities, including:

- compliance with differing or unexpected regulatory requirements for the development, manufacture and, if approved, commercialization of our product candidates;
- difficulties in staffing and managing foreign operations;
- foreign government taxes, regulations and permit requirements;
- U.S. and foreign government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;
- anti-corruption laws, including the Foreign Corrupt Practices Act, or the FCPA;
- economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular foreign countries;
- fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;
- compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- changes in diplomatic and trade relationships; and
- challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States.

These and other risks associated with our international operations may materially adversely affect our business, financial condition and results of operations.

We do not have a sales force and do not currently have plans to develop one.

The commercial success of any of our product candidates will depend upon the strength of sales and marketing efforts for them. We do not have a sales force and have no experience in sales, marketing or distribution. To successfully commercialize our product candidates, we will need to develop such a capability ourselves or seek assistance from a third party with a large distribution system and a large direct sales force. We may be unable to put such a plan in place. In addition, if we arrange for others to market and sell our products, our revenues will depend upon the efforts of those parties. Such arrangements may not succeed. Even if one or more of our product candidates is approved for marketing, if we fail to establish adequate sales, marketing and distribution capabilities, independently or with others, our business will be materially harmed.

Our success depends in part on attracting, retaining and motivating our personnel.*

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. As of May 6, 2016, we had 30 employees. Our success will depend on our ability to retain and motivate personnel and hire additional qualified personnel when required. Competition for qualified personnel in the biotechnology field is intense. We face competition for personnel from other biotechnology and pharmaceutical companies, universities, public and private research institutions and other organizations. We also face competition from other more well-funded and well-established businesses and we may also be viewed as a riskier choice from a job stability perspective due to our relative newer status than longer existing biotech and pharmaceutical companies. We may not be able to attract and retain qualified personnel on acceptable terms given the competition for such personnel. If we are unsuccessful in our retention, motivation and recruitment efforts, we may be unable to execute our business strategy.

We must manage a geographically dispersed organization.

While we are a small company, we currently have operations in the United States, United Kingdom, Australia and Slovenia. In the future, we may also locate facilities in other locations based on proximity to personnel with the expertise needed to research, develop and manufacture phage-based therapeutics, costs of operations or other factors. Managing our organization across multiple locations and multiple time zones may reduce our efficiency, increase our expenses and increase the risk of operational difficulties in the execution of our plans.

Risks Related to Our Reliance on Third Parties

We rely on third parties for aspects of product development.

We rely on third parties such as the University of Leicester and the U.S. Army for certain aspects of product development. We are working with the University of Leicester for research and development of product candidates to treat *C. difficile* infections. We are working with the U.S. Army for research and development of product candidates to treat *S. aureus* infections. Because we rely on third parties to conduct these activities, we have less control over the success of these programs than we would if we were conducting them on our own. Factors beyond our control that could impact the success of these programs include the amount of resources devoted to the programs by the applicable third party, the staffing of those projects by third-party personnel, and the amount of time such personnel devote to our programs compared to other programs. Failure of our third-party collaborators to successfully complete the projects that we are working on with them could result in delays in product development and the need to expend additional

resources, increasing our expenses beyond current expectations.

We will rely on third parties to conduct our clinical trials, and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our product candidates.

We expect to use third parties, such as clinical research organizations or the U.S. Army, to assist in conducting our clinical trials. However, we may face delays outside of our control if these parties do not perform their obligations in a timely or competent fashion or if we are forced to change service providers. This risk is heightened for clinical trials conducted outside of the United States, where it may be more difficult to ensure that clinical trials are conducted in compliance with FDA requirements. Any third party that we hire to conduct clinical trials may also provide services to our competitors, which could compromise the performance of their obligations to us. If we experience significant delays in the progress of our clinical trials and in our plans to submit Biologics License Applications, the commercial prospects for product candidates could be harmed and our ability to generate product revenue would be delayed or prevented.

Risks Related to Our Intellectual Property

We are dependent on patents and proprietary technology. If we fail to adequately protect this intellectual property or if we otherwise do not have exclusivity for the marketing of our products, our ability to commercialize products could suffer.

Our commercial success will depend in part on our ability to obtain and maintain patent protection sufficient to prevent others from marketing our product candidates, as well as to defend and enforce these patents against infringement and to operate without infringing the proprietary rights of others. Protection of our product candidates from unauthorized use by third parties will depend on having valid and enforceable patents cover our product candidates or their manufacture or use, or having effective trade secret protection. If our patent applications do not result in issued patents, or if our patents are found to be invalid, we will lose the ability to exclude others from making, using or selling the inventions claimed therein. We have a limited number of patents and pending patent applications.

The patent positions of biotechnology companies can be uncertain and involve complex legal and factual questions. This is due to inconsistent application of policy and changes in policy relating to examination and enforcement of biotechnology patents to date on a global scale. The laws of some countries may not protect intellectual property rights to the same extent as the laws of countries having well-established patent systems, and those countries may lack adequate rules and procedures for defending our intellectual property rights. Also, changes in either patent laws or in interpretations of patent laws may diminish the value of our intellectual property. We are not able to guarantee that all of our patent applications will result in the issuance of patents and we cannot predict the breadth of claims that may be allowed in our patent applications or in the patent applications we may license from others.

Central provisions of The Leahy-Smith America Invents Act, or the America Invents Act went into effect on September 16, 2012 and on March 16, 2013. The America Invents Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are being filed, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as inter partes review, or IPR, and post-grant review, that allow third parties to challenge the validity of an issued patent in front of the United States PTO Patent Trial and Appeal Board. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. IPRs permit any person (except a party who has been litigating the patent for more than a year) to challenge the validity of the patent on the grounds that it was anticipated or made obvious by prior art. Patents covering pharmaceutical products have been subject to attack in IPRs from generic drug companies and from hedge funds. If it is within nine months of the issuance of the challenged patent, a third party can petition the United States PTO for post-grant review, which can be based on any invalidity grounds and is not limited to prior art patents or printed publications.

In post-issuance proceedings, United States PTO rules and regulations generally tend to favor patent challengers over patent owners. For example, unlike in district court litigation, claims challenged in post-issuance proceedings are given their broadest reasonable meaning, which increases the chance a claim might be invalidated by prior art or lack support in the patent specification. The United States Supreme Court is currently reviewing whether it is proper for the United States PTO to give claims their broadest reasonable meaning in post-issuance proceedings. As another example, unlike in district court litigation, there is no presumption of validity for an issued patent, and thus, a challenger's burden to prove invalidity is by a preponderance of the evidence, as opposed to the heightened clear and convincing evidence standard. As a result of these rules and others, statistics released by the United States PTO show a high percentage of claims being invalidated in post-issuance proceedings. Moreover, with few exceptions, there is no standing requirement to petition the United States PTO for inter partes review or post-grant review. In other words, companies that have not been charged with infringement or that lack commercial interest in the patented subject matter can still petition the United States PTO for review of an issued patent. Thus, even where we have issued patents, our rights under those patents may be challenged and ultimately not provide us with sufficient protection against competitive products or processes.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not be the first to file patent applications for our inventions;
- others may independently develop similar or alternative product candidates to any of our product candidates that fall outside the scope of our patents;
- our pending patent applications may not result in issued patents;
- our issued patents may not provide a basis for commercially viable products or may not provide us with any competitive advantages or may be challenged by third parties;
- others may design around our patent claims to produce competitive products that fall outside the scope of our patents;
- we may not develop additional patentable proprietary technologies related to our product candidates; and

we are dependent upon the diligence of our appointed agents in national jurisdictions, acting for and on our behalf, which control the prosecution of pending domestic and foreign patent applications and maintain granted domestic and foreign patents.

An issued patent does not guarantee us the right to practice the patented technology or commercialize the patented product. Third parties may have blocking patents that could be used to prevent us from commercializing our patented products and practicing our patented technology. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to prevent competitors from marketing the same or related product candidates or could limit the length of the term of patent protection of our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent. Patent term extensions may not be available for these patents.

We rely on trade secrets and other forms of non-patent intellectual property protection. If we are unable to protect our trade secrets, other companies may be able to compete more effectively against us.

We rely on trade secrets to protect certain aspects of our technology, including our proprietary processes for manufacturing and purifying bacteriophages. Trade secrets are difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be made public during the regulatory approval process. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secret information is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to or may not protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we are sued for infringing intellectual property rights of third parties or if we are forced to engage in an interference proceeding, it will be costly and time-consuming, and an unfavorable outcome in that litigation or interference would have a material adverse effect on our business.

Our ability to commercialize our product candidates depends on our ability to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Numerous United States and foreign patents and patent applications, which are owned by third parties, exist in the general field of anti-infective products or in fields that otherwise may relate to our product candidates. If we are shown to infringe, we could be enjoined from use or sale of the claimed invention if we are unable to prove that the patent is invalid. In addition, because patent applications can take many years to issue, there may be currently pending patent applications, unknown to us, which may later result in issued patents that our product candidates may infringe, or which may trigger an interference proceeding regarding one of our owned or licensed patents or applications. There could also be existing patents of which we are not aware that our product candidates may inadvertently infringe or which may become involved in an interference proceeding.

The biotechnology and pharmaceutical industries are characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. For so long as our product candidates are in clinical trials, we believe our clinical activities fall within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As our clinical investigational drug product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. While we attempt to ensure that our active clinical investigational drugs and the methods we employ to manufacture them, as well as the methods for their use we intend to promote, do not infringe other parties' patents and other proprietary rights, we cannot be certain they do not, and competitors or other parties may assert that we infringe their proprietary rights in any event.

We may be exposed to future litigation based on claims that our product candidates, or the methods we employ to manufacture them, or the uses for which we intend to promote them, infringe the intellectual property rights of others. Our ability to manufacture and commercialize our product candidates may depend on our ability to demonstrate that the manufacturing processes we employ and the use of our product candidates do not infringe third-party patents. If third-party patents were found to cover our product candidates or their use or manufacture, we could be required to pay damages or be enjoined and therefore unable to commercialize our product candidates, unless we obtained a license. A license may not be available to us on acceptable terms, if at all.

Risks Related to Our Industry

If our competitors are able to develop and market products that are more effective, safer or more affordable than ours, or obtain marketing approval before we do, our commercial opportunities may be limited.

Competition in the biotechnology and pharmaceutical industries is intense and continues to increase. Some companies that are larger and have significantly more resources than we do are aggressively pursuing antibacterial development programs, including traditional therapies and therapies with novel mechanisms of action. In addition, other companies are developing phage-based products for non-therapeutic uses, and may elect to use their expertise in phage development and manufacturing to try to develop products that would compete with ours.

We also face potential competition from academic institutions, government agencies and private and public research institutions engaged in the discovery and development of drugs and therapies. Many of our competitors have significantly greater financial resources and expertise in research and development, preclinical testing, conducting clinical trials, obtaining regulatory approvals, manufacturing, sales and marketing than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical companies.

Our competitors may succeed in developing products that are more effective, have fewer side effects and are safer or more affordable than our product candidates, which would render our product candidates less competitive or noncompetitive. These competitors also compete with us to recruit and retain qualified scientific and management personnel, establish clinical trial sites and patient registration for clinical trials, as well as to acquire technologies and technology licenses complementary to our programs or advantageous to our business. Moreover, competitors that are able to achieve patent protection, obtain regulatory approvals and commence commercial sales of their products before we do, and competitors that have already done so, may enjoy a significant competitive advantage.

The Generating Antibiotics Incentives Now Act, or the GAIN Act, is intended to provide incentives for the development of new, qualified infectious disease products. These incentives may result in more competition in the market for new antibiotics, and may cause pharmaceutical and biotechnology companies with more resources than we have to shift their efforts towards the development of products that could be competitive with our product candidates.

There is a substantial risk of product liability claims in our business. If we do not obtain sufficient liability insurance, a product liability claim could result in substantial liabilities.

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and marketing of human therapeutic products. Regardless of merit or eventual outcome, product liability claims may result in:

- delay or failure to complete our clinical trials;
- withdrawal of clinical trial participants;
- decreased demand for our product candidates;
- injury to our reputation;
- litigation costs;
- substantial monetary awards against us; and

- diversion of management or other resources from key aspects of our operations.

If we succeed in marketing products, product liability claims could result in an FDA investigation of the safety or efficacy of our products, our manufacturing processes and facilities or our marketing programs. An FDA investigation could also potentially lead to a recall of our products or more serious enforcement actions, or limitations on the indications, for which they may be used, or suspension or withdrawal of approval.

We have product liability insurance that covers our clinical trials up to a \$10.0 million annual per claim and aggregate limit. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates or any other compound that we may develop. However, insurance coverage is expensive and we may not be able to maintain insurance coverage at a reasonable cost or at all, and the insurance coverage that we obtain may not be adequate to cover potential claims or losses.

Even if we receive regulatory approval to market our product candidates, the market may not be receptive to our product candidates upon their commercial introduction, which would negatively affect our ability to achieve profitability.

Our product candidates may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any approved products will depend on a number of factors, including:

- the effectiveness of the product;
- the prevalence and severity of any side effects;
- potential advantages or disadvantages over alternative treatments;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- the price of the product, both in absolute terms and relative to alternative treatments; and
- sufficient third-party coverage or reimbursement.

If our product candidates receive regulatory approval but do not achieve an adequate level of acceptance by physicians, healthcare payors and patients, we may not generate product revenues sufficient to attain profitability.

Foreign governments tend to impose strict price controls, which may adversely affect our future profitability.

In some foreign countries, particularly in the European Union, prescription drug pricing 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. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our profitability will be negatively affected.

We may incur significant costs complying with environmental laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities.

Our research and development activities use biological and hazardous materials that are dangerous to human health and safety or the environment. We are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes resulting from these materials. We are also subject to regulation by the Occupational Safety and Health Administration, or OSHA, state and federal environmental protection agencies and to regulation under the Toxic Substances Control Act. OSHA, state governments or federal Environmental Protection Agency, or EPA, may adopt regulations that may affect our research and development programs. We are unable to predict whether any agency will adopt any regulations that could have a material adverse effect on our operations. We have incurred, and will continue to incur, capital and operating expenditures and other costs in the ordinary course of our business in complying with these laws and regulations.

Although we believe our safety procedures for handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could significantly exceed our insurance coverage.

Risks Related to Our Common Stock

The price of our common stock has been and may continue to be volatile.

The stock markets in general, the markets for biotechnology stocks and, in particular, the stock price of our common stock, have experienced extreme volatility. The market for our common stock is characterized by significant price volatility when compared to the shares of larger, more established companies that trade on a national securities exchange and have large public floats, and we expect that our share price will continue to be more volatile than the shares of such larger, more established companies for the indefinite future. The volatility in our share price is attributable to a number of factors. Our common shares are, compared to the shares of such larger, more established companies, sporadically and thinly traded. As a consequence of this limited liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of those shares in either direction. The price for our shares could, for example, decline precipitously in the event that a large number of shares of our common stock are sold on the market without commensurate demand. We are also a speculative or “risky” investment due to the early stage of our drug development programs and our lack of profits to date, and uncertainty of future market acceptance for our potential products. As a consequence of this enhanced risk, more risk-averse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares on the market more quickly and at greater discounts than would be the case with the stock of a larger, more established company that has a large public float and broader stockholder base. Many of these factors are beyond our control and may decrease the market price of our common stock, regardless of our operating performance. We cannot make any predictions or projections as to what the prevailing market price for our common shares will be at any time, including as to whether our common stock will sustain their current market prices, or as to what effect that the sale of shares or the availability of common stock for sale at any time will have on the prevailing market price.

Price declines in our common stock could also result from general market and economic conditions and a variety of other factors, including:

- adverse results or delays in our clinical trials;
- adverse actions taken by regulatory agencies with respect to our product candidates, clinical trials or the manufacturing processes of our product candidates;
- announcements of technological innovations, patents or new products by our competitors;
- regulatory developments in the United States and foreign countries;
- any lawsuit involving us or our product candidates;
- announcements concerning our competitors, or the biotechnology or pharmaceutical industries in general;
- developments concerning any strategic alliances or acquisitions we may enter into;
- actual or anticipated variations in our operating results;
- changes in recommendations by securities analysts or lack of analyst coverage;
- deviations in our operating results from the estimates of analysts;

- sales of our common stock by our executive officers, directors and principal stockholders or sales of substantial amounts of common stock; and
- loss of any of our key scientific or management personnel.

In the past, following periods of volatility in the market price of a particular company's securities, litigation has often been brought against that company. Any such lawsuit could consume resources and management time and attention, which could adversely affect our business.

We may be required to issue a significant number of additional shares of common stock for no additional consideration and/or make cash make-whole payments to certain of our stockholders.*

We may be required to issue a significant number of additional shares of common stock for no additional consideration and/or make cash make-whole payments to the Holders. Pursuant to the CSIA, we agreed that if in the future we conduct one or more bona fide equity financings in which we sell shares of our common stock or preferred stock at a price of less than \$4.05 per share (each, a "Dilutive Financing"), we will issue to the Holders, for no additional consideration, a number of additional shares of common stock ("Additional Shares") based on a specified formula (such rights of the Holders to receive Additional Shares, the "Additional Issuance Rights"). Specifically, in the event we conduct a Dilutive Financing, the Holders will be entitled to receive (absent consideration of any applicable restrictions on the number of shares that can be issued in a non-public offering under NYSE MKT rules and interpretations without shareholder approval) in the aggregate a number of Additional Shares equal to (A) the product of (x) 1,037,053 multiplied by (y) a fraction, the numerator of which is \$4.05 and the denominator of which is the lowest price per share paid by investors in such Dilutive Financing (the "Effective Price") less (B) 1,037,053 and all Additional Shares issued previously to the Holders pursuant to the Additional Issuance Rights. The CSIA includes a provision intended to limit our obligation to issue Additional Shares to the extent such Additional Shares would exceed the 20% limit on the number of shares that can be issued without shareholder approval pursuant to Section 713(a) of the NYSE MKT Company Guide.

Pursuant to Section 713(a) of the NYSE MKT Company Guide, shareholder approval is generally required prior to the issuance of common stock or common stock equivalents in connection with a transaction other than a public offering involving the sale, issuance, or potential issuance by the issuer of common stock or common stock equivalents equal to 20% or more of the outstanding shares of common stock as of immediately prior to the transaction for less than the greater of book or market value of the stock (the "NYSE 20% Cap").

Any Additional Shares that we issue pursuant to the Additional Issuance Rights would be aggregated with the 853,465 shares of common stock issued to the Holders on April 8, 2016 pursuant to the CSIA for purposes of determining whether the total number of Additional Shares to be issued would equal or exceed the NSYE 20% Cap. Accordingly, absent shareholder approval, the maximum number of Additional Shares that we can issue pursuant to Section 713(a) of the NYSE MKT Company Guide without shareholder approval is 323,235 shares. We agreed to seek shareholder approval at our 2016 Annual Meeting of Shareholders (the "annual meeting") of the issuance by us to the Holders of up to an aggregate of 1,037,053 shares of common stock as and to the extent required pursuant to the CSIA (the "Proposal"). If the shareholders do not approve the Proposal at the annual meeting, then in lieu of issuing any Additional Shares that would have been required to be issued to a Holder pursuant to the operation of the Additional Issuance

Rights but for the limitations imposed by NYSE 20% Cap (the “Excess Shares”), we will, to the extent legally permitted, pay to such Holder a cash amount per Excess Share equal to the difference between the lowest price per share paid by investors in such Dilutive Financing and \$4.05, less any cash payment per share previously made to such Holder pursuant to the CSIA (the “Cash Make-Whole”).

Shareholders will incur dilution of their percentage ownership interest in our common stock to the extent we issue Additional Shares to the Holders pursuant to the Additional Issuance Rights. Shareholders will incur greater ownership interest dilution to the extent the Proposal is approved and we become required to issue some or all of the 1,037,053 Additional Shares. In addition, because the Additional Shares will be issued for no additional consideration, any such issuance would reduce our net tangible book value per share. However, to the extent Additional Shares are not issued when otherwise required by the CSIA due to the NYSE 20% Cap, any payments by us in satisfaction of the Cash Make-Whole would also reduce our net tangible book value per share of as well as our overall net tangible book value.

If the Cash Make-Whole would be triggered by a proposed Dilutive Financing, the potential payment obligations could make such Dilutive Financing less feasible and financially viable for us, particularly if the proceeds to be received by us in such financing would not significantly exceed the Cash Make-Whole payments, and thereby jeopardize our ability to raise capital in a Dilutive Financing that could otherwise provide us with needed cash resources. Even if we are able to complete a Dilutive Financing, any Cash Make-Whole payments would deplete our cash resources at a time when our cash resources are limited.

There can be no assurance of whether the Proposal will be approved at the annual meeting. Any issuance or potential issuance of Additional Shares and/or payment or potential payment of Cash Make-Whole payments could adversely affect our stock price, make it more difficult for us to raise capital, and have a material adverse effect on our business, results of operations and financial condition.

A significant number of shares of our common stock are subject to issuance upon exercise or conversion of outstanding warrants, options and convertible securities, which upon such exercise or conversion may result in dilution to our security holders.*

As of March 31, 2016, we had outstanding warrants to purchase 1,379,649 shares of our common stock at an average exercise price of \$9.34 per share, and outstanding options to purchase 872,977 shares of our common stock at an average exercise price of \$7.29 per share. The exercise price and/or the number of shares of common stock issuable upon exercise of the warrants may be adjusted in certain circumstances, including certain issuances of securities at a price equal to or less than the then current exercise price, subdivisions and stock splits, stock dividends, combinations, reorganizations, reclassifications, consolidations, mergers or sales of properties and assets and upon the issuance of certain assets or securities to holders of our common stock, as applicable. Although we cannot determine when these warrants or options will ultimately be exercised, it is reasonable to assume that such warrants and options will be exercised only if the exercise price is below the market price of our common stock. To the extent any of our outstanding warrants or options are exercised, additional shares of our common stock will be issued that will generally be eligible for resale in the public market (subject to limitations under Rule 144 under the Securities Act with respect to shares held by our affiliates), which will result in dilution to our security holders. The issuance of additional securities could also have an adverse effect on the market price of our common stock.

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

As of March 31, 2016, our executive officers, directors, principal stockholders and their affiliates beneficially owned a majority of our outstanding voting stock. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

Provisions of Washington law and our current articles of incorporation and bylaws may discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management. *

Provisions of Washington law and our current articles of incorporation and bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. In addition, 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 or remove our board of directors. These provisions include:

- authorizing the issuance of “blank check” preferred stock without any need for action by stockholders;
- providing for a classified board of directors with staggered terms;
- requiring supermajority stockholder voting to effect certain amendments to our articles of incorporation and bylaws; and
- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

In addition, because we are incorporated in Washington, we are governed by the provisions of Chapter 23B.19 of the Washington Business Corporation Act, which, among other things, restricts the ability of stockholders owning 10% or more of our outstanding voting stock from merging or combining with us. These provisions could discourage potential acquisition attempts and could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower than it would without these provisions.

Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if an offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

We have never paid dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future.*

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

Maintaining and improving our financial controls and the requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified board members.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act and the rules of the NYSE MKT. The requirements of these rules and regulations increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and place strain on our personnel, systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Ensuring that we have adequate internal financial and accounting controls and procedures in place is a costly and time-consuming effort that needs to be re-evaluated frequently.

We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Implementing any appropriate changes to our internal controls may require specific compliance training for our directors, officers and employees, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud.

In accordance with NYSE MKT rules, we are required to maintain a majority independent board of directors. The various rules and regulations applicable to public companies make it more difficult and more expensive for us to maintain directors' and officers' liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to maintain coverage. If we are unable to maintain adequate directors' and officers' insurance, our ability to recruit and retain qualified officers and directors will be significantly curtailed.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We currently have three securities analysts and may never obtain additional research coverage by other securities and industry analysts. If no additional securities or industry analysts commence coverage of our company, the trading price for our stock could be negatively impacted. If we obtain additional securities or industry analyst coverage and if one or more of the analysts who covers 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 us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

We are an "emerging growth company" and we cannot be certain if the reduced disclosure requirements applicable to "emerging growth companies" will make our common stock less attractive to investors.

We are an "emerging growth company," as defined under the JOBS Act. For so long as we are an "emerging growth company," we intend to take advantage of certain exemptions from reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We could be an “emerging growth company” for up to five years, although we may lose such status earlier, depending on the occurrence of certain events. We will remain an “emerging growth company” until the earliest to occur of (i) the last day of the fiscal year (a) following the fifth anniversary of our initial public offering conducted after we became a reporting company under the Exchange Act pursuant to our registration statement on Form 10 (File No. 000-23930), (b) in which we have total annual gross revenue of at least \$1.0 billion or (c) in which we are deemed to be a “large accelerated filer” under the Exchange Act, which means that the market value of our common stock that is held by non-affiliates exceeds \$700 million as of June 30th of the prior year, and (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

We cannot predict if investors will find our common stock less attractive or our company less comparable to certain other public companies because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, “emerging growth companies” can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not “emerging growth companies.”

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to decline.*

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Certain holders of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

In Amendment No. 1 to Schedule 13D filed with the Securities and Exchange Commission by Third Security on April 15, 2016, Third Security and its affiliates, including NRM and Intrexon Corporation, declared their intention to liquidate their holdings in our equity securities. The timing and actual liquidation of securities by such persons is subject to compliance with applicable law. Furthermore, such declaration is not binding upon Third Security and its affiliates and thus such liquidation may never occur.

Future sales and issuances of our common stock or rights to purchase common stock by us, 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 decline.

We expect that significant additional capital will be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating as a public company. To the extent we raise additional capital by issuing equity or convertible securities, our stockholders may experience substantial dilution. 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 superior to our existing stockholders.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

See the Exhibit Index following the signature page of this report, which is incorporated herein by reference.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

AMPLIPHI BIOSCIENCES
CORPORATION

Date: May 12, 2016 By/s/ Michael Scott Salka
Name: Michael Scott Salka
Title: Chief Executive Officer
(Principal Executive Officer)

By/s/ Steve R. Martin
Name: Steve R. Martin
Title: Chief Financial Officer
(Principal Financial Officer)

EXHIBIT INDEX

Number	Description
3.1	Amended and Restated Articles of Incorporation of the Registrant, as amended (incorporated by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q, filed on November 16, 2015).
3.2	Amended and Restated Bylaws of the Registrant, as amended (incorporated by reference to Exhibit 3.2 to the Quarterly Report on Form 10-Q, filed on November 16, 2015).
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
4.3	Form of Warrant to Purchase Shares of Common Stock issued to purchasers in June 2013, July 2013 and December 2013 in connection with private placements (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
4.4	Subscription Agreement to Purchase Series B Preferred Stock and Common Stock Warrants, dated June 26, 2013 (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
4.5	Registration Rights Agreement, dated December 16, 2013, by and among the Registrant and certain purchasers of the Registrant's Common Stock (incorporated by reference to Exhibit 4.4 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
4.6	Subscription Agreement to Purchase Common Stock and Warrants, dated December 16, 2013 (incorporated by reference to Exhibit 4.5 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
4.7	Subscription Agreement to Purchase Common Stock and Warrants, dated March 10, 2015 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed March 19, 2015).
4.8	Form of Common Stock Warrant issued to purchasers in March 2015 private placement (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, filed March 19, 2015).
4.9	Registration Rights Agreement, dated March 10, 2015, by and among the Registrant and certain purchasers of the Registrant's Common Stock (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, filed March 19, 2015).
4.10	Form of Amendment to Warrants to Purchase Shares of Common Stock issued to purchasers in June 2013, July 2013 and December 2013 in connection with private placements (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed on May 15, 2015).

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- 4.11 Form of Warrant to Purchase Shares of Common Stock issued in connection with the Registrant's acquisition of Biocontrol Ltd in December 2011 (incorporated by reference to Exhibit 4.11 to the Annual Report on Form 10-K, filed on March 30, 2016).
- 4.12 Form of Warrant to Purchase Shares of Common Stock issued in connection with the issuance of convertible notes of the Registrant in February 2013, March 2013, April 2013 and May 2013 (incorporated by reference to Exhibit 4.12 to the Annual Report on Form 10-K, filed on March 30, 2016).
- 4.13 Form of Warrant to Purchase Shares of Common Stock issued in connection with the Registrant's acquisition of certain assets of Novolytics Limited in February 2016 (incorporated by reference to Exhibit 4.13 to the Annual Report on Form 10-K, filed on March 30, 2016).
- 4.14 Common Stock Issuance Agreement, dated April 8, 2016, by and among the Registrant and the persons and entities listed on Exhibit A thereto (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, filed on April 8, 2016).
- 10.1 Asset Purchase Agreement, dated as of January 4, 2016, by and between the Registrant and Novolytics Limited (incorporated by reference to Exhibit 10.26 to the Annual Report on Form 10-K, filed on March 30, 2016).
- 10.2+ Offer Letter, dated as of January 18, 2016, by and between the Registrant and Steve R. Martin (incorporated by reference to Exhibit 99.1 to the Current Report on Form 8-K, filed on January 19, 2016).
- 31.1 Certification of the Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a).
- 31.2 Certification of Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a).
- 32.1 Certification of the Principal Executive Officer Required by Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. 1350.
- 32.2 Certification of the Principal Financial Officer Required by Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. 1350.
- 101.INS XBRL Instance Document.
- 101.SCH XBRL Taxonomy Extension Schema Document.
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document.

101.DEF XBRL Taxonomy Extension Definition Linkbase Document.

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document.

101.LAB XBRL Taxonomy Extension Label Linkbase Document.

+ Indicates management contract or compensatory plan.

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