Cyclacel Pharmaceuticals, Inc.
Form 10-K
March 29, 2016
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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, 2015
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

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, 2015 (based upon the closing sale price of $0.80 of such shares on The NASDAQ Global Market on June 30, 2015) was $17,662,869.

As of March 25, 2016, there were 35,582,492 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 26, 2016.

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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 propagate 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 apoptose. 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 a Phase 2 study for MDS and in a Phase 1/2 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, survival, metastatic spread and DNA damage repair. Seliciclib, our lead CDK inhibitor, is an oral, highly selective inhibitor of CDK2/9 enzymes that are central to the process of cell division and cell cycle control. To date, seliciclib has been evaluated in over 450 patients with various cancers, including non-small cell lung cancer, or NSCLC, and nasopharyngeal cancer, or NPC, and has shown signs of anticancer activity. We have retained worldwide rights to commercialize seliciclib.

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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. Seliciclib is also being evaluated in Investigator Sponsored Trials, or ISTs, to treat Cushing's disease and rheumatoid arthritis, and in a license and supply agreement for the treatment of cystic fibrosis.

Our second generation CDK inhibitor, CYC065, is a highly selective inhibitor of CDKs targeting CDK2/9 enzymes with potential utility in both hematological malignancies and solid tumors. CYC065 has increased anti-proliferative potency and improved pharmaceutical properties compared to seliciclib. CYC065 is in an on-going first-in-human, Phase 1 trial to assess its safety, tolerability, pharmacokinetics and pharmacodynamics in advanced cancer patients. CYC065 was selected from the Company's discovery program in Dundee, Scotland and its development was supported in part by a $1.9 million grant from the Biomedical Catalyst of the United Kingdom government.

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 that is active during cell division and which targets 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 $3.5 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 receptor, or AK/VEGFR 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 biological substances or effects whose presence in patient samples can serve as an indicator or marker of diseases, or may highlight patients more likely to respond to a particular treatment. 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 and that sapacitabine treatment increased a DNA damage marker in patient samples. 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 and PLK inhibitors, 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 a Phase 3 trial 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 Enrollment completed	DNA polymerase	G2 and S phase
Seliciclib + Sapacitabine	Cancer	Phase 1 trial on-going		
CYC065 CDK inhibitor	Cancer	Phase 1 first-in-human solid tumors and lymphoma; on-going	CDK2/9	G1/S checkpoint and others
CYC140 PLK inhibitor	Cancer	Preclinical	PLK1	G2/M checkpoint
Investigator Sponsored Trials				
Seliciclib, CYC202	Cushing's disease and rheumatoid arthritis	Phase 2 trial	CDK2/9	G1/S checkpoint and others
Licensing & Collaboration				
Seliciclib, CYC202	Cancer	Phase 2 trial		

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 within 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 Surveillance, Epidemiology, and End Results, or SEER, program of the National Cancer Institute, or NCI, the incidence rate of AML is approximately 20,000 in the United States. It is estimated that European incidence is approximately 22,000. 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 United States alone with some authors estimating incidence as 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.

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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 single-strand DNA breaks, or SSBs. 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 performed in December 2014 was 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 the time of the analysis. Furthermore, follow up of European patients at December 2014 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.

In accordance with the DSMB’s recommendations, we continue to follow-up patients as per the study protocol until the prespecified 424 events have been observed. This is estimated to occur in the first half of 2016. Approximately 4% of the prespecified events remain to be observed as of March 25, 2016.

In parallel to the follow-up of enrolled patients we have submitted, and have received validation of, a Pediatric Investigation Plan, or PIP, to the EMA. The EMA requires sponsors to agree to a PIP before a marketing authorization application, or MAA, can be accepted, and because the lead times can be long, we submitted the PIP ahead of any MAA submission. Depending on the final data, we may meet with regulatory authorities in Europe and the United States to discuss registration submissions for sapacitabine for the AML indication.

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

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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 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

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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.

We have recently completed enrollment of a patient cohort in an additional part of the MDS Phase 2 study in order to evaluate better dosing regimens. We will follow-up these additional Phase 2 patients until mature survival data become available. In parallel, we anticipate initiating a Phase 1/2 trial of sapacitabine in combination with other agents to determine safety and tolerability. We would expect to plan a Phase 2 randomized controlled trial, or RCT, of sapacitabine in combination with other agents following a review of all relevant clinical data with mature follow-up.

Median overall 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 5.9 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.

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.

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Cyclin Dependent Kinase Inhibitor program

Cyclin Dependent Kinase Inhibitors, or CDKs, are enzymes that are central to the process of cell division and cell cycle control and play pivotal roles in cancer cell growth, survival and DNA damage repair. Inhibition of CDKs 2 and 9 may also overcome aberrant cell cycle control in certain non-malignant diseases of proliferation.

Seliciclib

Seliciclib, is a novel, orally-available, CDK2/7/9 inhibitor which has a target profile 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 over 450 patients in several Phase 1 and 2 studies, including studies in NSCLC and NPC, and has shown signs of anti-cancer activity. We have retained worldwide rights to commercialize seliciclib.

Phase 1/2 clinical trial of seliciclib and sapacitabine 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 daily for 3 days (Day 8-11) for three week cycles. 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. The study is being conducted at Dana Farber Cancer Institute in Boston and the principal investigator is Geoffrey I. Shapiro, MD with participation from other Harvard Medical School hospitals.

At the 2013 American Society of Cancer Research Annual Meeting Dr Shapiro reported that of 38 patients with incurable solid tumors and adequate organ function enrolled in the Phase 1 study, 16 were BRCA mutation positive. 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 experienced durable partial responses, with a breast cancer patient receiving treatment over 234 weeks or 78 three-week cycles which is on-going. Researchers observed stable disease of 12 weeks or more in eight additional patients, including two BRCA positive patients with ovarian and breast cancers and whose stable disease lasted 64 and 21 weeks, respectively. 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.

As of December 2015, approximately 60 patients with various cancers have been enrolled, of which approximately two-thirds are BRCA positive.

Based on encouraging results from the initial patients and investigator interest the study has been expanded to evaluate an additional 20 breast cancer patients all of whom are required to test positive for BRCA in baseline biopsies. Patients will also undergo whole exome sequencing with the objective of further characterizing the genetic profiles of their tumors.

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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.

CYC065

CYC065 is a highly-selective, second generation inhibitor of CDK2 and CDK9 that causes apoptotic death of cancer cells at sub-micromolar concentrations and is bioavailable via oral and intravenous routes. Antitumor efficacy has been achieved in vivo with once a day oral dosing at well tolerated doses. Evidence from published preclinical studies show that CYC065 may benefit patients with adult and pediatric hematological malignancies, including certain AML, Acute Lymphocytic Leukemias, or ALL, Chronic Lymphocytic Leukemias, or CLL, Diffuse Large B-cell Lymphoma, or DLBCL, Multiple Myelomas or MM, and certain solid tumors, including breast and uterine cancers.

CYC065 is in an on-going, first-in-human, Phase 1 trial to assess its safety, tolerability, pharmacokinetics and pharmacodynamics in solid tumor and lymphoma patients. The trial is being conducted at the Dana Farber Cancer Institute in Boston and the principal investigator Dr Geoffrey I. Shapiro, M.D. CYC065 was selected from the Company's drug discovery program in Dundee, Scotland and its development was supported in part by a grant award of approximately $1.9 million from the Biomedical Catalyst of the United Kingdom government.

CYC065 is mechanistically similar but has much higher dose potency, in vitro and in vivo, improved metabolic stability and longer patent protection than seliciclib, Cyclacel's first generation CDK2/9 inhibitor. Translational biology data support development of CYC065 as a stratified medicine for solid and liquid tumors. CYC065 has been shown to reverse drug resistance associated with the addiction of cancer cells to cyclin E, a partner protein of CDK2, and inhibit CDK9-dependent oncogenic and leukemogenic pathways, including MYC and multilineage leukemia rearrangements, or MLL-r. Like seliciclib, CYC065 also represses the MCL-1-mediated survival pathway in cancer cells, leading to rapid induction of apoptosis in MCL-1 dependent cancer cells.

In 2011, independent investigators published preclinical evidence that CYC065 as a single-agent can induce tumor growth delay in HER2-positive breast cancer cells addicted to cyclin E and resistant to trastuzumab, or Herceptin®, while administration of CYC065 in combination with trastuzumab resulted in regression or sustained tumor growth inhibition.

Data presented at the 2015 Annual Meeting of the American Association of Cancer Research, or AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics demonstrated the mechanistic rationale for clinical development of CYC065 in oncology. Data showed that MLL gene status and levels of Bcl-2 family proteins correlated with sensitivity of AML cell lines to CYC065. Combination studies revealed the potential to combine CYC065 with available and experimental leukemia therapies, including cytarabine and Bcl-2 inhibitors, such as venetoclax. Potent anticancer activity of CYC065 was demonstrated in vivo in AML xenograft models resulting in over 90% inhibition of tumor growth. The potent in vitro and in vivo anti-cancer activity, opportunity for patient stratification and the ability to combine with anti-leukemic agents suggest that CYC065 may have therapeutic potential in AML.

Additionally data presented at the 2015 San Antonio Breast Cancer Symposium demonstrated in particular the mechanistic rationale for clinical development of CYC065 in basal-like triple negative breast cancer, or TNBC, a cancer with poor prognosis frequently associated with BRCA mutations. Molecular characteristics of TNBC include amplification or overexpression of Cyclin E, the partner protein of CDK2, and MYC. CYC065 directs a pro-apoptotic mechanism in breast cancer cell lines, which includes transcriptional down regulation of key pro-survival and oncogenic regulators, including MCL-1 and MYC.

CYC065 was shown to rapidly induce cell death in breast cancer cell lines, while transiently inducing G1 cell cycle arrest in non-malignant breast lines. CYC065's potent anticancer activity has been confirmed

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in breast cancer xenograft animal models. Like seliciclib, CYC065 effectively combined with sapacitabine in breast cancer cell lines.

In 2015, independent investigators presented data demonstrating that CYC065 prolongs survival in MYCN-addicted neuroblastoma models. The study evaluated the ability of CYC065 to inhibit cell proliferation and induce apoptosis of neuroblastoma cells in vitro and in vivo. In vivo efficacy was evaluated in subcutaneous xenograft models of both MYCN-amplified and non-amplified neuroblastoma cells and the Th-MYCN genetically-engineered mouse model of neuroblastoma. The study showed that neuroblastoma cell lines with MYCN amplification and high MYCN expression levels were sensitive to the CYC065 inhibitor. CYC065 also depleted MYCN protein in a time- and dose-dependent manner, blocked neuroblastoma cell proliferation and induced apoptosis which resulted in significantly reduced tumor burdens and prolonged survival in MYCN-addicted neuroblastoma models in vivo. Similar to palbociclib, a drug which targets CDK4/6 and the first CDK inhibitor to be recently approved by the FDA, we anticipate that CYC065 will likely be best used in combination with available anti-cancer agents. Depending on the data from the ongoing Phase 1 study, we are also interested in evaluating CYC065 in patients with hematological malignancies in light of profound signals of activity observed in preclinical studies.

PLK inhibitors

In our PLK inhibitor program we have discovered potent and selective small molecule inhibitors of PLK1, a kinase active during cell division, which target the mitotic phase of the cell cycle. At the 2012 Annual Meeting of the AACR, we reported that one of these compounds, CYC140, was selected for further preclinical development and showed potent activity and selectivity against a panel of esophageal cancer cell lines. 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. PLK was discovered by Professor David Glover, our Chief Scientist. We have received a grant award of approximately $3.5 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. Vascular endothelial growth factor receptor 2, or VEGFR2 is a receptor protein that plays a key regulatory role in the angiogenesis pathway, or blood vessel formation. VEGFR is targeted by approved drugs such as bevacizumab and sorafenib indicated for the treatment of several solid cancers, such as breast, colorectal, kidney, liver and lung.

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 and found that CYC3 acted 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. The collaborators reported that the combination merits further investigation and has the potential for improved therapeutic index in vivo. We have 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, but have no current plans to progress the program. We have retained worldwide rights to commercialize CYC116 and our other Aurora kinase inhibitors.

Investigator-Sponsored Trials

Preclinical results from several independent investigators suggest that cell cycle inhibitors, such as seliciclib and related 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,

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graft-versus-host disease, idiopathic pulmonary fibrosis, lupus nephritis, polycystic kidney disease and rheumatoid arthritis. Based on these data investigators have approached us to be provided with seliciclib so that they can evaluate it in various indications in clinical trials.

In this regard, there are on-going investigator sponsored trials, or ISTs, evaluating seliciclib in endocrinologic and inflammatory indications in patients who have failed prior treatments. In an IST at Cedars-Sinai, Los Angeles, the first patients are being treated in an on-going Phase 2 trial to evaluate seliciclib as a potential therapy for Cushing's disease caused by pituitary tumors. There are limited options for Cushing's disease patients today. The investigator was awarded a grant from The National Institute of Diabetes and Digestive and Kidney Diseases. In a European IST, seliciclib is being evaluated as a potential treatment for rheumatoid arthritis, or RA, where it may work for RA by targeting proliferating fibroblasts, a different type of approach than conventional RA therapies. This study is also being supported by an approximately $1.5 million grant from the United Kingdom's Medical Research Council.

Collaboration and Licensing Agreement

On June 29, 2015, we announced the execution of a collaboration, licensing and supply agreement with ManRos Therapeutics SA, or ManRos, for the exclusive development and commercialization of our oral seliciclib capsules by ManRos as a treatment for cystic fibrosis, or CF. Among other terms of the agreement, ManRos licensed rights to our proprietary clinical data to enable clinical development of seliciclib for CF indications. The agreement provides for our supply of seliciclib investigational product for initial and later stage clinical trials of seliciclib in CF and technical assistance related to our know-how to facilitate these trials. We have received upfront payments and will receive milestone payments and tiered royalties if seliciclib is commercialized for the treatment of CF.

As with all ISTs and the collaboration and licensing agreement, we do not control the timing or conduct of such studies and will report updates as the investigators may notify us from time to time.

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 $20.4 million at December 31, 2015 are sufficient through 2017. This is beyond the time of the data read-out of the SEAMLESS Phase 3 trial, estimated to occur in the first half of 2016, 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

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arrangements, and to leverage our sales and marketing capability by retaining co-promotion rights as 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 European Patent Office, or 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 20 patents granted in the United States, 10 granted by the EPO and 43 granted in other countries worldwide. In addition, we have a license to 51 patents granted in the US, by the EPO or worldwide.

We own 7 patent applications pending in the United States, 10 before the EPO and 25 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 6 pending patent applications worldwide to which we have 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

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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 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

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market exclusivity out to 2030. We also own patents issued in the United States or in Europe which claim 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. 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 agreement, assignment is defined to include many transactions of the type that we might wish to pursue,

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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 the EMA 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.

For example, 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 Investigational New Drug Application, or IND, 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;

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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 requirements, or cGMPs, regulations; and

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

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 and other nonclinical 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 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 adequacy of the preclinical testing or the proposed 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 site and it must monitor the clinical trial until completed. The FDA 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 Good Clinical Practice, or GCP, requirements, including those relating to informed consent.

Clinical Trials

For purposes of an NDA submission, 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 a Phase 4, which includes additional clinical trials to further assess the drug’s safety and effectiveness after NDA approval.

New Drug Application

The results of drug candidate development, nonclinical 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 deny approval of an NDA if the applicable regulatory criteria are not satisfied, or it may require additional

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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 or 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 nonclinical 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 submission 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.

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 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 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 expected to predict a 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 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.

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When appropriate, we and our collaborators may 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 the EMA 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 EMA 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 or EMA approvals are subject to continuing regulation by the FDA or EMA, including record-keeping requirements and reporting of adverse experiences associated with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA or EMA and certain state agencies and are subject to periodic unannounced inspections by the FDA or EMA 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 or EMA regulatory requirements. If our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA or EMA may halt our clinical trials, require us to recall a product from distribution, or withdraw approval of that product. The FDA or EMA 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 claims relating to safety and efficacy that are approved by the FDA or EMA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe approved 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 or EMA. Such off-label

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uses are common across certain medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA or EMA generally does not regulate the behavior of physicians in their choice of treatments. The FDA or EMA 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 AbbVie, Astra-Zeneca, Baxter/ Onconova, Boehringer Ingelheim, BMS/Innate, Celator, Celgene, CTI Biopharma, Daiichi Sankyo, Eisai, Lilly, GlaxoSmithKline, Johnson & Johnson, MEI Pharma, Otsuka, Pfizer, Sanofi, Synta Pharmaceuticals, Sunesis and Teva. Several pharmaceutical and biotechnology companies have CDK inhibitors in clinical trials including Bayer, Lilly, Merck, Nerviano Medical Sciences/Tiziana Life Sciences, Novartis, Otsuka-Astex , Pfizer, Piramal, Sanofi/Tolero, Tragara and MetaMax. 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, CASI Pharmaceuticals, Nerviano Medical Sciences, Nemucore, Otsuka-Taiho Oncology and Takeda-Millennium are conducting clinical development of Aurora kinase inhibitors for hemato-oncology indications. We believe that Arbutus Biopharma, Boehringer Ingelheim, GlaxoSmithKline, Merck, Nerviano Medical Sciences and Takeda-Millennium have commenced clinical trials with PLK1 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. As of December 31, 2015 we were not party to any material legal proceedings.

Employees

As of March 25, 2016, we had 16 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 the public reference facilities maintained by the SEC at SEC Headquarters, Public Reference Room, 100 F

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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 FDA and the EMA and in some cases agreed to 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 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 clinical 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 statistical analysis that will form the primary basis of an efficacy claim. If such an agreement is reached it will be binding on the FDA 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 product efficacy or safety was identified. An SPA, however, neither guarantees approval nor provides any assurance that a marketing application will 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. We completed enrollment of the SEAMLESS trial in December 2014.

In addition, the FDA or EMA 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 or EMA 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 EMA 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 and other good clinical practice requirements 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 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 unacceptable toxicity or adverse events 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 that 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, EMA 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 cause us to direct our resources inefficiently.

We are making some 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 and 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 EMA 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 EMA 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 drugs, 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 EMA 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 or an MAA from the EMA. We have not received an NDA or MAA approval from the FDA or EMA for any of our drug candidates.

Obtaining an NDA or MAA approval is expensive and is a complex, lengthy and uncertain process. For example, The FDA approval process for a new drug involves submission of an IND which must include information about preclinical studies proposed clinical protocols and manufacturing information. Clinical development under an IND typically involves three phases of study: Phase 1, 2 and 3. The most significant costs associated with clinical development are typically the pivotal 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 request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. If the NDA supports the safety and efficacy of the drug candidate and satisfies other requirements, the FDA may grant marketing approval. 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 EMA 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 approve any such submissions.

The FDA and other regulatory authorities in the United States, the EMA for 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 EMA 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 EMA 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 EMA 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 EMA 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 EMA regulatory requirements and requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to the FDA's or EMA'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 EMA 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 we or 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 EMA 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;

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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 decitabine by the FDA or EMA, 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, EMA 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 and elsewhere 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

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from 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 investigate or make allegations against us or any of our employees, or sanction or convict us or any of our employees, for violations of any of these legal requirements, this could have a material adverse effect on our business, including our stock price. Our activities could be subject to challenge for many reasons, including the broad scope and complexity of these laws and regulations, the difficulties in interpreting and applying these legal requirements, and the high degree of prosecutorial resources and attention being devoted to the biopharmaceutical industry and health care fraud by law enforcement authorities. During the last few years, numerous biopharmaceutical companies have paid multi-million dollar fines and entered into burdensome settlement agreements for alleged violation of these requirements, and other companies are under active investigation. Although we have developed and implemented corporate and field compliance programs as part of our commercialization efforts, we cannot assure you that we or our employees, directors or agents were, are or will be in compliance with all laws and regulations or that we will not come under investigation, allegation or sanction.

In addition, we may be required to prepare and report product pricing-related information to federal and state governmental authorities, such as the Department of Veterans Affairs and under the Medicaid program. The calculations used to generate the pricing-related information are complex and require the exercise of judgment. If we fail to accurately and timely report product pricing-related information or to comply with any of these or any other laws or regulations, various negative consequences could result, including criminal and/or civil prosecution, substantial criminal and/or civil penalties, exclusion of the approved product from coverage under governmental healthcare programs including Medicare and Medicaid, costly litigation and restatement of our financial statements. In addition, our efforts to comply with this wide range of laws and regulations are, and will continue to be, time-consuming and expensive.

If a supplier upon whom we rely fails to produce on a timely basis the finished goods in the volumes that we require or fails to meet quality standards and maintain necessary licensure from regulatory authorities, we may be unable to meet demand for our products, potentially resulting in lost revenues.

If any third party manufacturer service providers do not meet our or our licensor’s requirements for quality, quantity or timeliness, or do not achieve and maintain compliance with all applicable regulations, demand for our products or our ability to continue supplying such products could substantially decline. As the third party manufacturers are the sole supplier of the products any delays may impact our sales.

In all the countries where we may sell our products, governmental regulations exist to define standards for manufacturing, packaging, labeling and storing. All of our suppliers of raw materials and contract manufacturers must comply with these regulations. Failure to do so could result in supply interruptions. In the United States, the FDA requires that all suppliers of pharmaceutical bulk material and all manufacturers of pharmaceuticals for sale in or from the United States achieve and maintain compliance with the FDA’s cGMPs. Similar requirements exist in the European Union through the EMA. Failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on them or us, including fines, injunctions, civil penalties, disgorgement, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, before any product batch produced by our manufacturers can be shipped, it must conform to release specifications for the content of the pharmaceutical product. If the operations of one or more of our manufacturers were to become unavailable for any reason, any required FDA or EMA review and approval of the operations of an alternative supplier could cause a delay in the manufacture of our products.

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The commercialization of our products will be substantially dependent on our ability to develop effective sales and marketing capabilities.

For our product candidates currently under development, our strategy is to develop compounds through the Phase 2 stage of clinical testing and market or co-promote certain of our drugs. We currently have no sales, marketing or distribution capabilities. We will depend primarily on strategic alliances with third parties, which have established distribution systems and sales forces, to commercialize our drugs. To the extent that we are unsuccessful in commercializing any drugs ourselves or through a strategic alliance, product revenues may suffer, we may incur significant additional losses and our share price would be negatively affected.

If we market products in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare laws, commonly referred to as “fraud and abuse” laws, have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. Other jurisdictions, such as Europe, have similar laws. These laws include false claims and anti-kickback statutes. If we market our products and our products are paid for by governmental programs, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service covered by Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers or formulary managers, on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Most states also have statutes or regulations similar to the federal anti-kickback law and federal false claims laws, which apply to items and services covered by Medicaid and other state programs, or, in several states, apply regardless of the payor. Administrative, civil and criminal sanctions may be imposed under these federal and state laws.

Over the past few years, a number of pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product candidate and may have to limit its commercialization.

The use of our product candidates in clinical trials and the sale of any products for which we may obtain marketing approval expose us to the risk of product liability claims. Product liability claims may be brought against us or our collaborators by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against any such claims, we would incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- costs of related litigation;

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- substantial monetary awards to patients or other claimants;
- decreased demand for our product candidates and loss of revenues;
- impairment of our business reputation;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

We have obtained limited product liability insurance coverage for our clinical trials in the United States and in selected other jurisdictions where we are conducting clinical trials. Our primary product liability insurance coverage for clinical trials in the United States is currently limited to an aggregate of $5.0 million and outside of the United States we have coverage for lesser amounts that vary by country. As such, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to product liability. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash resources and adversely affect our business.

Defending against claims relating to improper handling, storage or disposal of hazardous chemical, radioactive or biological materials could be time consuming and expensive.

Our research and development involves the controlled use of hazardous materials, including chemicals, radioactive and biological materials such as chemical solvents, phosphorus and bacteria. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from those materials. Various laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development and production efforts.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

Risks Related to Our Business and Financial Condition

Raising additional capital in the future may not be available to us on reasonable terms, if at all, when or as we require additional funding. If we issue additional shares of our common stock or other securities that may be convertible into,

or exercisable or exchangeable for, our common stock, our existing stockholders would experience further dilution. If we fail to obtain additional funding, we may be unable to complete the development and commercialization of our lead drug candidate, sapacitabine, or continue to fund our research and development programs.

We have funded all of our operations and capital expenditures with proceeds from the issuance of public equity securities, private placements of our securities, interest on investments, licensing revenue,

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government grants, research and development tax credits and product revenue. In order to conduct the lengthy and expensive research, preclinical testing and clinical trials necessary to complete the development and marketing of our drug candidates, we will require substantial additional funds. We may have insufficient public equity available for issue to raise the required additional substantial funds to implement our operating plan and we may not be able to obtain the appropriate stockholder approvals necessary to increase our available public equity for issuance within a time that we may require additional funding. Based on our current operating plans of focusing on the advancement of sapacitabine, we expect our existing resources to be sufficient to fund our planned operations for at least the next twelve months. To meet our long-term financing requirements, we may raise funds through public or private equity offerings, debt financings or strategic alliances. Raising additional funds by issuing equity or convertible debt securities may cause our stockholders to experience substantial dilution in their ownership interests and new investors may have rights superior to the rights of our other stockholders. Raising additional funds through debt financing, if available, may involve covenants that restrict our business activities and options. To the extent that we raise additional funds through collaborations and licensing arrangements, we may have to relinquish valuable rights to our drug discovery and other technologies, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. Additional funding may not be available to us on favorable terms, or at all, particularly in light of the current economic conditions. If we are unable to obtain additional funds, we may be forced to delay or terminate our current clinical trials and the development and marketing of our drug candidates including sapacitabine.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As widely reported, global credit and financial markets have experienced extreme disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not continue to occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current financial markets deteriorate, or do not improve, it may make any necessary financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development or other operating or strategic plans for our business.

We are at an early stage of development as a company and we do not have, and may never have, any products that generate significant revenues.

We are at an early stage of development as a company and have a limited operating history on which to evaluate our business and prospects. While we earned modest product revenues from the ALIGN business prior to terminating operations effective September 30, 2012, we have not generated any product revenues from our product candidates currently in development. We cannot guarantee that any of our product candidates currently in development will ever become marketable products.

We must demonstrate that our drug candidates satisfy rigorous standards of safety and efficacy for their intended uses before the FDA,EMA and other regulatory authorities in the United States, the European Union and elsewhere. Significant additional research, preclinical testing and clinical testing is required before we can file applications with the FDA or EMA for approval of our drug candidates. In addition, to compete effectively, our drugs must be easy to administer, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives. Sapacitabine, our most advanced drug candidates for the treatment of cancer, is currently in Phase 3 for AML and Phase 2 for AML and MDS. A combination of sapacitabine and seliciclib is currently in a Phase 1/2 clinical trial and CYC065 is in a first-in-human Phase 1 study. We cannot be certain that the clinical development of these or any other drug candidates in preclinical testing or clinical development will be successful, that we will receive the regulatory approvals required to commercialize them or that any of our other research and drug discovery programs will yield a drug candidate suitable for investigation through clinical trials. Our commercial revenues from our product candidates currently in development, if any, will be derived from sales of drugs that will not become marketable for several years, if at all.

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We have a history of operating losses and we may never become profitable. Our stock is a highly speculative investment.

We have incurred operating losses in each year since beginning operations in 1996 due to costs incurred in connection with our research and development activities and selling, general and administrative costs associated with our operations, and we may never achieve profitability. As of December 31, 2014 and December 31, 2015, our accumulated deficit was $308.8 million and $323.2 million, respectively. Our net loss was $19.4 million and $14.3 million for the years ended December 31,2014 and 2015, respectively. Our drug candidates are in the mid-stages of clinical testing and we must conduct significant additional clinical trials before we can seek the regulatory approvals necessary to begin commercial sales of our drugs. We expect to incur continued losses for several years as we continue our research and development of our drug candidates, seek regulatory approvals and commercialize any approved drugs. If our drug candidates are unsuccessful in clinical trials or we are unable to obtain regulatory approvals, or if our drugs are unsuccessful in the market, we will not be profitable. If we fail to become and remain profitable, or if we are unable to fund our continuing losses, particularly in light of the current economic conditions, you could lose all or part of your investment.

If we fail to comply with the continued listing requirements of the NASDAQ Capital Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is currently listed for trading on the NASDAQ Capital Market. We must satisfy NASDAQ's continued listing requirements, including, among other things, a minimum stockholders' equity of $2.5 million and a minimum bid price for our common stock of $1.00 per share, or risk delisting, which would have a material adverse effect on our business. A delisting of our common stock from the NASDAQ Capital Market could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities.

On February 2, 2016, the Company received a letter from the Listing Qualifications Staff (the "Staff") of The NASDAQ Stock Market LLC ("NASDAQ") indicating that the Company had not regained compliance with the $1.00 minimum bid price requirement for continued listing on The NASDAQ Capital Market, as set forth in NASDAQ Listing Rule 5450(a)(1), by the end of the previously granted compliance period that expired on February 2, 2016. As a result, the Staff indicated that the Company would be subject to delisting unless it timely requests a hearing before a NASDAQ Listing Qualifications Panel (the "Panel").

The Company has scheduled a hearing before the Panel on March 31, 2016, at which it will present its plan to regain compliance with the minimum bid price requirement, and request a further extension of time to do so. The Panel has the discretion to grant the Company up to an additional 180 calendar days from the date of the Staff's notice, or until August 1, 2016, to regain compliance with the minimum bid price requirement. The hearing will automatically stay any delisting action pending the issuance of a final decision and the expiration of any further extension granted by the Panel. There can be no assurance that the Panel will grant the Company's request for continued listing.

We cannot be sure that our share price will comply with the requirements for continued listing of our common stock on The NASDAQ Capital Market in the future, or that we will comply with the other continued listing requirements. If our shares of Common Stock lose their status on the NASDAQ Capital Market, we believe that our shares of Common Stock would likely be eligible to be quoted on the inter-dealer electronic quotation and trading system operated by Pink OTC Markets Inc., commonly referred to as the Pink Sheets and now known as the OTCQB market. Our shares of Common Stock may also be quoted on the Over-the-Counter Bulletin Board, an electronic quotation service maintained by the Financial Industry Regulatory Authority. These markets are generally not considered to be as efficient as, and not as broad as, the NASDAQ Capital Market. Selling our shares of Common Stock on these markets could be more difficult because smaller quantities of shares would likely be bought and sold, and transactions could be delayed. In addition, in the event our shares of Common Stock are delisted,

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broker-dealers have certain regulatory burdens imposed upon them, which may discourage broker-dealers from effecting transactions in our Common Stock, further limiting the liquidity of our Common Stock. These factors could result in lower prices and larger spreads in the bid and ask prices for our Common Stock.

To the extent we elect to fund the development of a drug candidate or the commercialization of a drug at our expense, we will need substantial additional funding.

We plan to market drugs on our own, with or without a partner, that can be effectively commercialized and sold in concentrated markets that do not require a large sales force to be competitive. To achieve this goal, we will need to establish our own specialized sales force, marketing organization and supporting distribution capabilities. The development and commercialization of our drug candidates is very expensive, including our Phase 3 clinical trials for sapacitabine. To the extent we elect to fund the full development of a drug candidate or the commercialization of a drug at our expense, we will need to raise substantial additional funding to:

- fund research and development and clinical trials connected with our research;
- fund clinical trials and seek regulatory approvals;
- build or access manufacturing and commercialization capabilities;
- implement additional internal control systems and infrastructure;
- commercialize and secure coverage, payment and reimbursement of our drug candidates, if any such candidates receive regulatory approval;
- maintain, defend and expand the scope of our intellectual property; and
- hire additional management, sales and scientific personnel.

Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- the costs and timing of seeking and obtaining regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs associated with establishing sales and marketing capabilities;
- the costs of acquiring or investing in businesses, products and technologies;
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the effect of competing technological and market developments; and

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the payment, other terms and timing of any strategic alliance, licensing or other arrangements that we may establish.

If we are not able to secure additional funding when needed, especially in light of the current economic conditions and financial market turmoil, we may have to delay, reduce the scope of or eliminate one or more of our clinical trials or research and development programs or future commercialization efforts.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employment benefits liability, workers' compensation, products liability and clinical trials (U.S and foreign), and directors' and officers', employment practices and fiduciary liability insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

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Any future workforce and expense reductions may have an adverse impact on our internal programs, strategic plans, and our ability to hire and retain key personnel, and may also be distracting to our management.

Any workforce and expense reductions similar to those carried out in September 2008 and June 2009 could result in significant delays in implementing our strategic plans. In addition, employees, whether or not directly affected by such reduction, may seek future employment with our business partners or competitors. Although our employees are required to sign a confidentiality agreement at the time of hire, the confidential nature of certain proprietary information may not be maintained in the course of any such future employment. In addition, any workforce reductions or restructurings would be expected to involve significant expense as a result of contractual terms in certain of our existing agreements, including potential severance obligations. Further, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled personnel. We may have difficulty retaining and attracting such personnel as a result of a perceived risk of future workforce and expense reductions. Finally, the implementation of expense reduction programs may result in the diversion of the time and attention of our executive management team and other key employees, which could adversely affect our business.

Funding constraints may negatively impact our research and development, forcing us to delay our efforts to develop certain product candidates in favor of developing others, which may prevent us from commercializing our product candidates as quickly as possible.

Research and development is an expensive process. As part of our operating plan, we have decided to focus our clinical development priorities on sapacitabine, while still possibly continuing to progress additional programs pending the availability of clinical data and the availability of funds, at which time we will determine the feasibility of pursuing, if at all, further development of our CDK inhibitors , or additional programs. Because we have to prioritize our development candidates as a result of budget constraints, we may not be able to fully realize the value of our product candidates in a timely manner, if at all.

We are exposed to risks related to foreign currency exchange rates.

Some of our costs and expenses are denominated in foreign currencies. Most of our foreign expenses are associated with our research and development expenditures, including the operating costs of our United Kingdom-based wholly-owned subsidiary. When the United States dollar weakens against the British pound or the Euro, the United States dollar value of the foreign currency denominated expense increases, and when the United States dollar strengthens against the British pound or the Euro, the United States dollar value of the foreign currency denominated expense decreases. Consequently, changes in exchange rates, and in particular a weakening of the United States dollar, may adversely affect our results of operations.

Risks Related to our Intellectual Property

If we fail to enforce adequately or defend our intellectual property rights our business may be harmed.

Our commercial success depends in large part on obtaining and maintaining patent and trade secret protection for our drug candidates, the methods used to manufacture those drug candidates and the methods for treating patients using those drug candidates.

Sapacitabine is protected by granted, composition of matter patents claiming certain, stable crystalline forms of sapacitabine and their pharmaceutical compositions and therapeutic uses that expire in 2022 (and may be eligible for a Hatch-Waxman term restoration of up to five years, which could extend the expiration date to 2027); United States and European granted patents that expire in 2029, claiming the combination of sapacitabine with hypomethylating agents, including decitabine, which is being tested as the active arm in the SEAMLESS Phase 3 trial, and a United States granted patent claiming a specified method of administration of sapacitabine with patent exclusivity until July 2030. We have used a stable, crystalline form of sapacitabine in nearly all our Phase 1 and all our Phase 2 and Phase 3 clinical studies. We have also chosen this crystalline form for commercialization. Additional patents and applications claim certain medical uses, combinations, formulations and dosing regimens of sapacitabine which have emerged in our clinical trials, as well as a process for the preparation of sapacitabine.

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Seliciclib is protected by granted, composition of matter patents that expire in 2016. Additional patents and applications claim certain medical uses of seliciclib, including combination use with sapacitabine, which have emerged in our preclinical research and clinical trials. The latest to expire of the granted patents expires in 2028. Failure to obtain, maintain or extend the patents could adversely affect our business. We will only be able to protect our drug candidates and our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

Our ability to obtain patents is uncertain because legal means afford only limited protections and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Some legal principles remain unresolved and the breadth or interpretation of claims allowed in patents in the United States, the European Union or elsewhere can still be difficult to ascertain or predict. In addition, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or in interpretations of patent laws in the United States, the European Union or elsewhere may diminish the value of our intellectual property or narrow the scope of our patent protection. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products and technologies. In addition, we generally do not control the patent prosecution of subject matter that we license from others and have not controlled the earlier stages of the patent prosecution. Accordingly, we are unable to exercise the same degree of control over this intellectual property as we would over our own.

Even if patents are issued regarding our drug candidates or methods of using them, those patents can be challenged by our competitors who may argue such patents are invalid and/or unenforceable. Patents also will not protect our drug candidates if competitors devise ways of making or using these product candidates without legally infringing our patents. The FDA and FDA regulations and policies and equivalents in other jurisdictions provide incentives to manufacturers to challenge patent validity or create modified, non-infringing versions of a drug in order to facilitate the approval of abbreviated new drug applications for generic substitutes. These same types of incentives encourage manufacturers to submit NDAs that rely on literature and clinical data not prepared for or by the drug sponsor.

Proprietary trade secrets and unpatented know-how are also very important to our business. We rely on trade secrets to protect our technology, especially where we do not believe that patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third-party obtained illegally and is using trade secrets is expensive and time consuming, and the outcome is unpredictable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

If we do not obtain protection under the Hatch-Waxman Act and similar legislation outside of the United States by extending the patent terms and obtaining data exclusivity for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of sapacitabine and our other product candidates, if any, one or more of our United States patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, we may not be granted an extension because, for example, of failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than what we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

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Intellectual property rights for our drug candidate seliciclib are licensed from others, and any termination of these licenses could harm our business.

We have in-licensed certain patent rights in connection with the development program of our drug candidate seliciclib. Pursuant to the CNRS and Institut Curie license under which we license seliciclib, we are obligated to pay license fees, milestone payments and royalties and provide regular progress reports. We are also obligated to use reasonable efforts to develop and commercialize products based on the licensed patents. If we fail to satisfy any of our obligations under these licenses, they would be terminated, which could harm our business.

We may be subject to damages resulting from claims that our employees or we have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent our ability to commercialize certain potential drugs, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

Because we operate in the highly technical field of drug discovery and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We enter into confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

Intellectual property rights of third parties may increase our costs or delay or prevent us from being able to commercialize our drug candidates.

There is a risk that we are infringing or will infringe the proprietary rights of third parties because patents and pending applications belonging to third parties exist in the United States, the European Union and elsewhere in the world in the areas of our research. Others might have been the first to make the inventions covered by each of our or our licensors' pending patent applications and issued patents and might have been the first to file patent applications for these inventions. We are aware of several published patent applications, and understand that others may exist, that could support claims that, if granted and held valid, could cover various aspects of our developmental programs, including in some cases particular uses of our lead drug candidate 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 processes. 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. In addition, we understand that other applications and patents exist relating to potential uses of sapacitabine and seliciclib that are not part of our current clinical programs for these compounds. Numerous third-party United States and foreign issued patents and pending applications exist

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in the area of kinases, including CDK, PLK and AK for which we have research programs. For example, some pending patent applications contain broad claims that could represent freedom to operate limitations for some of our kinase programs should they be issued unchanged. Although we intend to continue to monitor these applications, we cannot predict what claims will ultimately be allowed and if allowed what their scope would be. In addition, because the patent application process can take several years to complete, there may be currently pending applications, unknown to us, which may later result in issued patents that cover the production, manufacture, commercialization or use of our drug candidates. If we wish to use the technology or compound claimed in issued and unexpired patents owned by others, we will need to obtain a license from the owner, enter into litigation to challenge the validity of the patents or incur the risk of litigation in the event that the owner asserts that we infringe its patents. 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 U.S. 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.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. Defending against third party claims, including litigation in particular, would be costly and time consuming and would divert management's attention from our business, which could lead to delays in our development or commercialization efforts. If third parties are successful in their claims, we might have to pay substantial damages or take other actions that are adverse to our business. As a result of intellectual property infringement claims, or to avoid potential claims, we might:

- be prohibited from selling or licensing any product that we may develop unless the patent holder licenses the patent to us, which it is not required to do;

- be required to pay substantial royalties or grant a cross license to our patents to another patent holder; decide to locate some of our research, development or manufacturing operations outside of Europe or the United States;

- be required to pay substantial damages for past infringement, which we may have to pay if a court determines that our product candidates or technologies infringe a competitor's patent or other proprietary rights; or

- be required to redesign the manufacturing process or formulation of a drug candidate so it does not infringe which may not be possible or could require substantial funds and time.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

If we choose to go to court to stop another party from using the inventions claimed in any patents we obtain, that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced against that third party. These lawsuits are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. In addition, there is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions.

There is also a risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to such patents. In addition, the United States Supreme Court has recently modified some tests used by the United States Patent and Trademark Office, or USPTO, in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of challenge of any patents we obtain or license.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection

could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside

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of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-United States patent agencies. The USPTO and various non-United States governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

The patent applications of pharmaceutical and biotechnology companies involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. The U.S. Patent and Trademark Office's, or USPTO's, standards are uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, and U.S. patents may be subject to reexamination proceedings in the USPTO (and foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent office), which proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. Similarly, opposition or invalidity proceedings could result in loss of rights or reduction in the scope of one or more claims of a patent in foreign jurisdictions. In addition, such interference, reexamination and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

In addition, changes in or different interpretations of patent laws in the United States and foreign countries may permit others to use our discoveries or to develop and commercialize our technology and products without providing any compensation to us or may limit the number of patents or claims we can obtain. In particular, there have been proposals to shorten the exclusivity periods available under U.S. patent law that, if adopted, could substantially harm our business. The product candidates that we are developing are protected by intellectual property rights, including patents and patent applications. If any of our product candidates becomes a marketable product, we will rely on our exclusivity under patents to sell the compound and recoup our investments in the research and development of the compound. If the exclusivity period for patents is shortened, then our ability to generate revenues without competition will be reduced and our business could be materially adversely impacted. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights. For example, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans and, in these countries, patent protection may not be available at all to protect our product candidates. In addition, U.S. patent laws may change, which could prevent or limit us from filing patent applications or patent claims to protect our products and/or technologies or limit the exclusivity periods that are available to patent holders. For example, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was recently signed into law and includes a number of significant changes to U.S. patent law. These include changes to transition from a "first-to-invent" system to a "first-to-file" system and to the way issued patents are challenged. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. The USPTO has been in the process of implementing regulations and procedures to administer the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act may affect our ability to obtain, enforce or defend our patents. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents.

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If we fail to obtain and maintain patent protection and trade secret protection of our product candidates, proprietary technologies and their uses, we could lose our competitive advantage and competition we face would increase, reducing our potential revenues and adversely affecting our ability to attain or maintain profitability.

Risks Related to Securities Regulations and Investment in Our Securities

Failure to achieve and maintain internal controls in accordance with Sections 302 and 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our business and stock price.

If we fail to maintain our internal controls or fail to implement required new or improved controls, as such control standards are modified, supplemented or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal controls over financial reporting. Effective internal controls are necessary for us to produce reliable financial reports and are important in the prevention of financial fraud. If we cannot produce reliable financial reports or prevent fraud, our business and operating results could be harmed.

We incur increased costs and management resources as a result of being a public company, and we may fail to comply with public company obligations.

As a public company, we face and will continue to face increased legal, accounting, administrative and other costs and expenses as a public company that we would not incur as a private company. Compliance with the Sarbanes Oxley Act of 2002, as well as other rules of the SEC, the Public Company Accounting Oversight Board and the NASDAQ Global Market resulted in a significant initial cost to us as well as an ongoing compliance cost. As a public company, we are subject to Section 404 of the Sarbanes Oxley Act relating to internal control over financial reporting. We have completed a formal process to evaluate our internal controls for purposes of Section 404, and we concluded that as of December 31, 2015, our internal control over financial reporting was effective. As our business grows and changes, there can be no assurances that we can maintain the effectiveness of our internal controls over financial reporting. In addition, our independent certified public accounting firm has not provided an opinion on the effectiveness of our internal controls over financial reporting for the year ended December 31, 2015 because we are a smaller reporting company. In the event our independent auditor is required to provide an opinion on such controls in the future, there is a risk that the auditor would conclude that such controls are ineffective.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our operating results could be harmed. We have completed a formal process to evaluate our internal control over financial reporting. However, guidance from regulatory authorities in the area of internal controls continues to evolve and substantial uncertainty exists regarding our on-going ability to comply by applicable deadlines. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Our common stock may have a volatile public trading price.

An active public market for our common stock has not developed. Our stock can trade in small volumes which may make the price of our stock highly volatile. The last reported price of our stock may not represent the price at which you would be able to buy or sell the stock. The market prices for securities of companies comparable to us have been highly volatile. Often, these stocks have experienced significant price and volume fluctuations for reasons that are both related and unrelated to the operating performance of the individual companies. In addition, the stock market as a whole and biotechnology and other life science stocks in particular have experienced significant recent volatility. Like our common stock, these stocks have experienced significant price and volume fluctuations for reasons unrelated to the operating performance of the individual companies. Factors giving rise to this volatility may include:

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- disclosure of actual or potential clinical results with respect to product candidates we are developing;

- regulatory developments in both the United States and abroad;

- developments concerning proprietary rights, including patents and litigation matters;

- public concern about the safety or efficacy of our product candidates or technology, or related technology, or new technologies generally;

- concern about the safety or efficacy of our product candidates or technology, or related technology, or new technologies generally;

- public announcements by our competitors or others; and

- general market conditions and comments by securities analysts and investors.

For example, on December 16, 2014 we announced the enrollment of 486 patients, continuation to final analysis and recommendations of the DSMB of the Company's Phase 3 SEAMLESS study of sapacitabine oral capsules in acute myeloid leukemia, or AML. The DSMB determined that the planned futility boundary has been crossed, but saw no reasons why patients should discontinue treatment on their assigned arm and recommended that recruited patients are followed up. As a result of this announcement, the last reported sale price of our common stock on The NASDAQ Global Market on December 16, 2014 dropped to $0.68 from a last reported sale price of our common stock on December 15, 2014 of $2.83.

Fluctuations in our operating losses could adversely affect the price of our common stock.

Our operating losses may fluctuate significantly on a quarterly basis. Some of the factors that may cause our operating losses to fluctuate on a period-to-period basis include the status of our preclinical and clinical development programs, level of expenses incurred in connection with our preclinical and clinical development programs, implementation or termination of collaboration, licensing, manufacturing or other material agreements with third parties, non-recurring revenue or expenses under any such agreement, and compliance with regulatory requirements. Period-to-period comparisons of our historical and future financial results may not be meaningful, and investors should not rely on them as an indication of future performance. Our fluctuating losses may fail to meet the expectations of securities analysts or investors. Our failure to meet these expectations may cause the price of our common stock to decline.

If securities or industry analysts do not publish research or reports about us, if they change their recommendations regarding our stock adversely or if our operating results do not meet their expectations, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us. If analysts do not publish research reports or one or more of these analysts who were publishing research cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, if one or more of the analysts who cover us downgrade our stock or if our operating results do not meet their expectations, our stock price could decline.

Anti-takeover provisions in our charter documents and provisions of Delaware law may make an acquisition more difficult and could result in the entrenchment of management.

We are incorporated in Delaware. Anti-takeover provisions of Delaware law and our amended and restated certificate of incorporation and amended and restated bylaws may make a change in control or efforts to remove management more difficult. Also, under Delaware law, our Board of Directors may adopt additional anti-takeover measures.

We have the authority to issue up to 5 million shares of preferred stock and to determine the terms of those shares of stock without any further action by our stockholders. If the Board of Directors exercises this power to issue preferred stock, it could be more difficult for a third party to acquire a majority of our outstanding voting stock and vote the stock they acquire to remove management or directors. Our amended and restated certificate of incorporation and amended and restated bylaws also provides staggered terms for

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the members of our Board of Directors. Under Section 141 of the Delaware General Corporation Law, our directors may be removed by stockholders only for cause and only by vote of the holders of a majority of voting shares then outstanding. These provisions may prevent stockholders from replacing the entire board in a single proxy contest, making it more difficult for a third-party to acquire control of us without the consent of our Board of Directors. These provisions could also delay the removal of management by the Board of Directors with or without cause. In addition, our directors may only be removed for cause and amended and restated bylaws limit the ability our stockholders to call special meetings of stockholders.

Under Section 203 of the Delaware General Corporation Law, a corporation may not engage in a business combination with any holder of 15% or more of its capital stock until the holder has held the stock for three years unless, among other possibilities, the Board of Directors approves the transaction. Our Board of Directors could use this provision to prevent changes in management. The existence of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our common stock.

Certain severance-related agreements in our executive employment agreements may make an acquisition more difficult and could result in the entrenchment of management.

In March 2008 (as subsequently amended, most recently as of January 1, 2014), we entered into employment agreements with our President and Chief Executive Officer and our Executive Vice President, Finance, Chief Financial Officer and Chief Operating Officer, which contain severance arrangements in the event that such executive’s employment is terminated without “cause” or as a result of a “change of control” (as each such term is defined in each agreement). The financial obligations triggered by these provisions may prevent a business combination or acquisition that would be attractive to stockholders and could limit the price that investors would be willing to pay in the future for our stock.

In the event of an acquisition of our common stock, we cannot assure our common stockholders that we will be able to negotiate terms that would provide for a price equivalent to, or more favorable than, the price at which our shares of common stock may be trading at such time.

We may not effect a consolidation or merger with another entity without the vote or consent of the holders of at least a majority of the shares of our preferred stock (in addition to the approval of our common stockholders), unless the preferred stock that remains outstanding and its rights, privileges and preferences are unaffected or are converted into or exchanged for preferred stock of the surviving entity having rights, preferences and limitations substantially similar, but no less favorable, to our convertible preferred stock.

In addition, in the event a third party seeks to acquire our company or acquire control of our company by way of a merger, but the terms of such offer do not provide for our preferred stock to remain outstanding or be converted into or exchanged for preferred stock of the surviving entity having rights, preferences and limitations substantially similar, but no less favorable, to our preferred stock, the terms of the Certificate of Designations of our preferred stock provide for an adjustment to the conversion ratio of our preferred stock such that, depending on the terms of any such transaction, preferred stockholders may be entitled, by their terms, to receive up to $10.00 per share in common stock, causing our common stockholders not to receive as favorable a price as the price at which such shares may be trading at the time of any such transaction. As of December 31, 2015, there were 335,273 shares of our preferred stock issued and outstanding. If the transaction were one in which proceeds were received by the Company for distribution to stockholders, and the terms of the Certificate of Designations governing the preferred stock were strictly complied with, approximately $4.0 million would be paid to the preferred holders before any distribution to the common stockholders, although the form of transaction could affect how the holders of preferred stock are treated. In such an event, although such a transaction would be subject to the approval of our holders of common stock, we cannot assure our common stockholders that we will be able to negotiate terms that would provide for a price equivalent to, or more favorable than, the price at which our shares of common stock may be trading at such time. Thus, the terms of our preferred stock might hamper a third party’s acquisition of our company.

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Our certificate of incorporation and bylaws and certain provisions of Delaware law may delay or prevent a change in our management and make it more difficult for a third-party to acquire us.

Our amended and restated certificate of incorporation and bylaws contain provisions that could delay or prevent a change in our Board of Directors and management teams. Some of these provisions:

- authorize the issuance of preferred stock that can be created and issued by the Board of Directors without prior stockholder approval, commonly referred to as "blank check" preferred stock, with rights senior to those of our common stock;

- provide for the Board of Directors to be divided into three classes; and

- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of large stockholders to complete a business combination with, or acquisition of, us. These provisions may prevent a business combination or acquisition that would be attractive to stockholders and could limit the price that investors would be willing to pay in the future for our stock. These provisions also make it more difficult for our stockholders to replace members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt to replace our current management team. Additionally, these provisions may prevent an acquisition that would be attractive to stockholders and could limit the price that investors would be willing to pay in the future for our common stock.

We may have limited ability to pay cash dividends on our preferred stock, and there is no assurance that future quarterly dividends will be declared.

Delaware law may limit our ability to pay cash dividends on our preferred stock. Under Delaware law, cash dividends on our preferred stock may only be paid from surplus or, if there is no surplus, from the corporation's net profits for the current or preceding fiscal year. Delaware law defines "surplus" as the amount by which the total assets of a corporation, after subtracting its total liabilities, exceed the corporation's capital, as determined by its board of directors.

Since we are not profitable, our ability to pay cash dividends will require the availability of adequate surplus. Even if adequate surplus is available to pay cash dividends on our preferred stock, we may not have sufficient cash to pay dividends on the preferred stock or we may choose not to declare the dividends.

Our common and preferred stock may experience extreme price and volume fluctuations, which could lead to costly litigation for us and make an investment in us less appealing.

The market price of our common and preferred stock may fluctuate substantially due to a variety of factors, including:

- additions to or departures of our key personnel;

- announcements of technological innovations or new products or services by us or our competitors; announcements concerning our competitors or the biotechnology industry in general;

- new regulatory pronouncements and changes in regulatory guidelines;

- general and industry-specific economic conditions;

- changes in financial estimates or recommendations by securities analysts;
- variations in our quarterly results; and
- announcements about our collaborators or licensors; and changes in accounting principles.

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The market prices of the securities of biotechnology companies, particularly companies like us without product revenues and earnings, have been highly volatile and are likely to remain highly volatile in the future. This volatility has often been unrelated to the performance of particular companies. In the past, companies that experience volatility in the market price of their securities have often faced securities class action litigation. Moreover, market prices for stocks of biotechnology-related and technology companies frequently reach levels that bear no relationship to the performance of these companies. These market prices generally are not sustainable and are highly volatile. Whether or not meritorious, litigation brought against us could result in substantial costs, divert our management's attention and resources and harm our financial condition and results of operations.

The future sale of our common and preferred stock and future issuances of our common stock upon conversion of our preferred stock could negatively affect our stock price and cause dilution to existing holders of our common stock.

If our common or preferred stockholders sell substantial amounts of our stock in the public market, or the market perceives that such sales may occur, the market price of our common and preferred stock could fall. If additional holders of preferred stock elect to convert their shares to shares of common stock at renegotiated prices, such conversion as well as the sale of substantial amounts of our common stock, could cause dilution to existing holders of our common stock, thereby also negatively affecting the price of our common stock. For example, in 2013, we issued an aggregate of 1,684,471 shares of our common stock in exchange for an aggregate of 877,869 shares of our preferred stock in arms-length negotiations between us and the other parties who had approached us to propose the exchanges.

If we exchange the convertible preferred stock for debentures, the exchange will be taxable but we will not provide any cash to pay any tax liability that any convertible preferred stockholder may incur.

An exchange of convertible preferred stock for debentures, as well as any dividend make-whole or interest make-whole payments paid in our common stock will be taxable events for United States federal income tax purposes, which may result in tax liability for the holder of convertible preferred stock without any corresponding receipt of cash by the holder. In addition, the debentures may be treated as having original issue discount, a portion of which would generally be required to be included in the holder's gross income even though the cash to which such income is attributable would not be received until maturity or redemption of the debenture. We will not distribute any cash to the holders of the securities to pay these potential tax liabilities.

If we automatically convert the preferred stock, there is a substantial risk of fluctuation in the price of our common stock from the date we elect to automatically convert to the conversion date.

We may automatically convert the preferred stock into common stock if the closing price of our common stock exceeds $246.75. There is a risk of fluctuation in the price of our common stock between the time when we may first elect to automatically convert the preferred and the automatic conversion date.

We do not intend to pay cash dividends on our common stock in the foreseeable future.

We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will depend on our financial condition, results of operations, capital requirements, the outcome of the review of our strategic alternatives and other factors and will be at the discretion of our Board of Directors. Accordingly, investors will have to rely on capital appreciation, if any, to earn a return on their investment in our common stock. Furthermore, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends.

The number of shares of common stock which are registered, including the shares to be issued upon exercise of our outstanding warrants, is significant in relation to our currently outstanding common stock and could cause downward pressure on the market price for our common stock.

The number of shares of common stock registered for resale, including those shares which are to be issued upon exercise of our outstanding warrants, is significant in relation to the number of shares of common stock currently outstanding. If the security holder determines to sell a substantial number of

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shares into the market at any given time, there may not be sufficient demand in the market to purchase the shares without a decline in the market price for our common stock. Moreover, continuous sales into the market of a number of shares in excess of the typical trading volume for our common stock, or even the availability of such a large number of shares, could depress the trading market for our common stock over an extended period of time.

If persons engage in short sales of our common stock, including sales of shares to be issued upon exercise of our outstanding warrants, the price of our common stock may decline.

Selling short is a technique used by a stockholder to take advantage of an anticipated decline in the price of a security. In addition, holders of options and warrants will sometimes sell short knowing they can, in effect, cover through the exercise of an option or warrant, thus locking in a profit. A significant number of short sales or a large volume of other sales within a relatively short period of time can create downward pressure on the market price of a security. Further sales of common stock issued upon exercise of our outstanding warrants could cause even greater declines in the price of our common stock due to the number of additional shares available in the market upon such exercise, which could encourage short sales that could further undermine the value of our common stock. You could, therefore, experience a decline in the value of your investment as a result of short sales of our common stock.

We are exposed to risk related to the marketable securities we may purchase.

We may invest cash not required to meet short term obligations in short term marketable securities. We may purchase securities in United States government, government-sponsored agencies and highly rated corporate and asset-backed securities subject to an approved investment policy. Historically, investment in these securities has been highly liquid and has experienced only very limited defaults. However, recent volatility in the financial markets has created additional uncertainty regarding the liquidity and safety of these investments. Although we believe our marketable securities investments are safe and highly liquid, we cannot guarantee that our investment portfolio will not be negatively impacted by recent or future market volatility or credit restrictions.

Our management team will have broad discretion over the use of the net proceeds from the sale of our common stock through Cantor Fitzgerald & Co., or Cantor.

On July 10, 2015 we entered into a Controlled Equity Offering™ Sales Agreement with Cantor, as sales agent, pursuant to which we may sell through Cantor up to an aggregate of $8.35 million in shares of our common stock. Our management will use its discretion to direct the net proceeds from the sale of those shares. We intend to use all of the net proceeds, together with cash on hand, for general corporate purposes. General corporate purposes may include working capital, capital expenditures, development costs, strategic investments or possible acquisitions. Our management's judgments may not result in positive returns on your investment and you will not have an opportunity to evaluate the economic, financial or other information upon which our management bases its decisions. As of December 31, 2015, we have raised net proceeds of $0.6 million.

The sale of our common stock through Cantor may cause substantial dilution to our existing stockholders and the sale, actual or anticipated, of the shares of common stock to be sold through Cantor could cause the price of our common stock to decline.

We have the right to sell up to $8.35 million of our shares of common stock through Cantor, as agent. Any actual or anticipated sales of shares through Cantor may cause the trading price of our common stock to decline. Additional issuances of shares through Cantor may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock through Cantor, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of sales of our shares through Cantor, and the Agreement may be terminated by us at any time at our discretion upon 10 days' notice without any penalty or cost to us.

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Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful stockholder claims against us and may reduce the amount of money available to us.

As permitted by Section 102(b)(7) of the Delaware General Corporation Law, our restated certificate of incorporation limits the liability of our directors to the fullest extent permitted by law. In addition, as permitted by Section 145 of the Delaware General Corporation Law, our restated certificate of incorporation and restated bylaws provide that we shall indemnify, to the fullest extent authorized by the Delaware General Corporation Law, each person who is involved in any litigation or other proceeding because such person is or was a director or officer of our company or is or was serving as an officer or director of another entity at our request, against all expense, loss or liability reasonably incurred or suffered in connection therewith. Our restated certificate of incorporation provides that the right to indemnification includes the right to be paid expenses incurred in defending any proceeding in advance of its final disposition, provided, however, that such advance payment will only be made upon delivery to us of an undertaking, by or on behalf of the director or officer, to repay all amounts so advanced if it is ultimately determined that such director is not entitled to indemnification.

If we do not pay a proper claim for indemnification in full within 60 days after we receive a written claim for such indemnification, except in the case of a claim for an advancement of expenses, in which case such period is 20 days, our restated certificate of incorporation and our restated bylaws authorize the claimant to bring an action against us and prescribe what constitutes a defense to such action.

Section 145 of the Delaware General Corporation Law permits a corporation to indemnify any director or officer of the corporation against expenses (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with any action, suit or proceeding brought by reason of the fact that such person is or was a director or officer of the corporation, if such person acted in good faith and in a manner that he reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, if he or she had no reason to believe his or her conduct was unlawful. In a derivative action, (i.e., one brought by or on behalf of the corporation), indemnification may be provided only for expenses actually and reasonably incurred by any director or officer in connection with the defense or settlement of such an action or suit if such person acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, except that no indemnification shall be provided if such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the court in which the action or suit was brought shall determine that the defendant is fairly and reasonably entitled to indemnity for such expenses despite such adjudication of liability.

The rights conferred in the restated certificate of incorporation and the restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons. We have entered into indemnification agreements with each of our officers and directors.

The above limitations on liability and our indemnification obligations limit the personal liability of our directors and officers for monetary damages for breach of their fiduciary duty as directors by shifting the burden of such losses and expenses to us. Although we obtained coverage under our directors' and officers' liability insurance, certain liabilities or expenses covered by our indemnification obligations may not be covered by such insurance or the coverage limitation amounts may be exceeded. As a result, we may need to use a significant amount of our funds to satisfy our indemnification obligations, which could severely harm our business and financial condition and limit the funds available to stockholders who may choose to bring a claim against our company.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our corporate headquarters in Berkeley Heights, New Jersey and we have a research and development facility in Dundee, Scotland. We believe that our existing facilities are adequate to accommodate our business needs.

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Item 3. Legal Proceedings

From time to time, we may be involved in routine litigation incidental to the conduct of our business. As of December 31, 2015, we were not a party to any material legal proceedings.

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

Item 5.

Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is traded on The NASDAQ Global Market, or NASDAQ, under the symbol "CYCC". Our preferred stock currently trades on NASDAQ under the symbol "CYCCP". The following table summarizes, for the periods indicated, the high and low sales prices for the common stock as reported by NASDAQ:

	High	Low
2015		
Quarter ended March 31, 2015	$ 2.13	$ 0.51
Quarter ended June 30, 2015	$ 1.10	$ 0.68
Quarter ended September 30, 2015	$ 0.80	$ 0.49
Quarter ended December 31, 2015	$ 1.05	$ 0.47
2014		
Quarter ended March 31, 2014	$ 4.84	$ 3.19
Quarter ended June 30, 2014	$ 3.87	$ 2.88
Quarter ended September 30, 2014	$ 3.58	$ 2.90
Quarter ended December 31, 2014	$ 3.72	$ 0.61

Holders of Common Stock

On March 23, 2016, we had approximately 49 registered holders of record of our 35,582,492 shares of common stock outstanding. On March 23 2016, the closing sale price of our common stock as reported by NASDAQ was $0.41 per share.

Dividends

We have never declared nor paid any cash dividends on our common stock and do not currently anticipate declaring or paying any cash dividends on our outstanding shares of common stock in the foreseeable future. We are, however, required to make or accrue quarterly dividend payments on our Preferred Stock. Except for dividends that may be paid on the Preferred Stock, we currently intend to retain all of our future earnings, if any, to finance operations. Any future determination relating to our dividend policy will be made at the discretion of our Board of Directors and will depend on a number of factors, including future earnings, capital requirements, financial conditions, future prospects, contractual restrictions and other factors that our Board of Directors may deem relevant.

Item 6.

Selected Financial Data

Smaller reporting companies are not required to provide information in response to this item.

Item 7.

Management's Discussion and Analysis of Financial Condition and Results of Operations

Cautionary Statement Regarding Forward-Looking Statements

This report contains certain statements that may be deemed 'forward-looking statements' within the meaning of United States securities laws. All statements, other than statements of historical fact, that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future are forward-looking statements. Such statements are based upon certain assumptions and assessments made by our management in light of their experience and their perception of historical trends, current

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conditions, expected future developments and other factors they believe to be appropriate. Certain factors that could cause results to differ materially from those projected or implied in the forward looking statements are set forth in this Annual Report on Form 10-K for the year ended December 31, 2015 under the caption “Item 1A — Risk factors”. We encourage you to read those descriptions carefully. We caution you not to place undue reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless an earlier date is indicated) and we undertake no obligation to update or revise the statements except as required by law. Such forward-looking statements are not guarantees of future performance and actual results will likely differ, perhaps materially, from those suggested by such forward-looking statements.

Overview

During 2015, our focus has been on our SEAMLESS Phase 3 study, which completed enrollment in December 2014 and is currently in the follow-up phase, as well as evaluating sapacitabine in other indications including in combination with our CDK inhibitor seliciclib in solid tumors in a Phase 1/2 study. Additionally, we advanced development of our second-generation CDK inhibitor CYC065, into a first-in-human study in solid tumors and lymphomas and progressed our PLK-1 inhibitor in IND-directed studies with the support of government funding.

Corporate Developments

During 2015, we strengthened our cash position with completion of an underwritten offering for net proceeds of approximately $9.2 million. We also raised net proceeds of approximately $1.4 million under our common stock purchase agreements with Aspire and $0.5 million under a Controlled Equity OfferingSM Sales Agreement with Cantor Fitzgerald & Co., or Cantor”. At December 31, 2015, we had $20.4 million in cash and cash equivalents. We expect these cash resources are sufficient through 2017 and to reach beyond the top-line analysis of SEAMLESS, estimated in the first half of 2016, and continue our existing programs.

Recent Events

Deficiency and Compliance Notice from The NASDAQ Stock Market

On February 2, 2016, the Company received a letter from the Listing Qualifications Staff, or the Staff of The NASDAQ Stock Market LLC, or NASDAQ , indicating that the Company had not regained compliance with the $1.00 minimum bid price requirement for continued listing on The NASDAQ Capital Market, as set forth in NASDAQ Listing Rule 5450(a)(1), by the end of the previously granted compliance period that expired on February 2, 2016. As a result, the Staff indicated that the Company would be subject to delisting unless it timely requests a hearing before a NASDAQ Listing Qualifications Panel, or the Panel.

The Company has scheduled a hearing before the Panel on March 31, 2016, at which it will present its plan to regain compliance with the minimum bid price requirement, and request a further extension of time to do so. The Panel has the discretion to grant the Company up to an additional 180 calendar days from the date of the Staff’s notice, or until August 1, 2016, to regain compliance with the minimum bid price requirement. The hearing will automatically stay any delisting action pending the issuance of a final decision and the expiration of any further extension granted by the Panel. There can be no assurance that the Panel will grant the Company’s request for continued listing.

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Dividend on Preferred Stock

On December 24, 2015, the Board of Directors declared a quarterly cash dividend in the amount of $0.15 per share on the Company's Preferred Stock. The cash dividend was paid on February 1, 2016 to the holders of record of the Preferred Stock as of the close of business on January 21, 2016.

Results of Operations

Years Ended December 31, 2014 and 2015.

Results of Continuing Operations

Revenues

The following table summarizes the components of our revenues for the years ended December 31, 2014 and 2015 (in $000s except percentages):

	Years Ended December 31,		Difference	
	2014	2015	$	%
Grant revenue	$ 1,734	$ 1,694	(40)	(2)
Collaboration and research and development revenue	—	250	250	—
Total Revenue	$ 1,734	$ 1,944	210	12

Grant revenue is recognized as we incur and pay for qualifying costs and services under the applicable grant. Grant revenue is derived from various United Kingdom government and European Union grant awards. For each of the years ended December 31, 2014 and 2015, we had grant revenue of approximately $1.7 million in respect of the CYC065 and CYC140 programs. Collaboration and research and development revenue represents and up-front milestone payments in respect of a collaboration, licensing and supply agreement with ManRos Therapeutics SA or ManRos, entered into in June 2015.

The future

We expect to recognize approximately $0.9 million in grant revenue for the CYC140 program through November 2016 from the Biomedical Catalyst of the United Kingdom government. Receipt of further revenue under the ManRos agreement is dependent on the clinical progress of the program, which we do not control.

Research and development

We expense all research and development costs as they are incurred. Research and development expenses primarily include:

- Clinical trial and regulatory-related costs;
- Payroll and personnel-related expenses, including consultants and contract research;
- Preclinical studies and laboratory supplies and materials;
- Technology license costs; and
- Rent and facility expenses for our laboratories.

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The following table provides information with respect to our research and development expenditures for the years ended December 31, 2014 and 2015 (in $000s except percentages):

	Years Ended December 31,		Difference	
	2014	2015	$	%
Sapacitabine	$ 14,757	$ 8,228	(6,529)	(44)
Other costs related to research and development programs and management	3,520	4,154	634	18
Total research and development	$ 18,277	$ 12,382	(5,895)	(32)

Research and development expenses represented 76% and 68% of our operating expenses for the years ended December 31, 2014 and 2015, respectively. Included in research and development expenses is stock-based compensation of approximately $0.4 million for December 31, 2014 and $0.2 million for the year ended December 31, 2015.

Research and development expenditures decreased by approximately $5.9 million to $12.4 million for the year ended December 31, 2015 from $18.3 million for the year ended December 31, 2014. The decrease was primarily due to the reduction in costs associated with the SEAMLESS Phase 3 trial which completed patient enrollment at the end of 2014 and is now in the follow-up phase, partially offset by increased expenditures related to grant funded programs and costs associated with the first-in-human study for CYC065 initiated in 2015.

The future

We anticipate that overall research and development expenditures for the year ended December 31, 2016 will decrease compared to the year ended December 31, 2015, as we are in the patient follow-up phase of SEAMLESS and clinical study sites are being closed. However, we will continue to incur costs for recruited patients who remain on study and costs related to clinical site closures. The timing and extent of SEAMLESS expenditures, including the possibility of registration submissions to regulatory authorities in Europe and the United States, are dependent upon final data, which is expected during the first half of 2016, after the prespecified number of events have been observed in accordance with the study protocol. Expenditure on grant funded programs will reduce as the CYC065 grant ended in December 2015 and the CYC140 grant ends in 2016.

General and administrative

General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. The following table summarizes the total general and administrative expenses for the years ended December 31, 2014 and 2015 (in $000s except percentages):

	Years Ended December 31,		Difference	
	2014	2015	$	%
General and administrative	$ 5,894	$ 5,732	(162)	(3)

Total general and administrative expenses represented 24% and 32% of our operating expenses for the years ended December 31, 2014 and 2015, respectively. Included in general and administrative expenses is stock-based compensation of approximately $0.8 million for December 31, 2014 and $0.5 million for the year ended December 31, 2015.

Our general and administrative expenditures decreased slightly from $5.9 million for the year ended December 31, 2014 compared to $5.7 million for the year ended December 31, 2015. The net decrease in expenditures was primarily attributable to decreases in stock-based compensation expense of $0.3 million.

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The future

We expect general and administrative expenditures for the year ended December 31, 2016 compared to our expenditures for the year ended December 31, 2015 to remain relatively flat.

Other income (expense), net

The following table summarizes the other income (expense) for years ended December 31, 2014 and 2015 (in $000s except percentages):

	Years Ended December 31,		Difference	
	2014	2015	$	%
Change in valuation of financial instruments associated with stock purchase agreement	$ (342)	$ (51)	291	(85)
Change in valuation of liabilities measured at fair value	20	—	(20)	(100)
Foreign exchange gains (losses)	(10)	(368)	(358)	3,580
Interest income	6	9	3	50
Other income, net	114	94	(20)	(18)
Total other income (expense), net	$ (212)	$ (316)	(104)	49

Total other income (expense), net, increased by approximately $0.1 million, from total other expense, net of approximately $0.2 million for the year ended December 31, 2014 to total other expense, net of approximately $0.3 million for the year ended December 31, 2015.

Change in valuation of financial instruments associated with stock purchase agreement

The remaining fair value of the right to sell additional shares under the November 2013 Purchase Agreement with Aspire was recognized during the year ended December 31, 2015 when we sold all remaining shares of common stock that were subject to the agreement and the agreement automatically terminated by its terms. Prior to termination, the fair value was remeasured each reporting period. The Company recognized an expense of approximately $0.3 million and $0.1 for the years ended December 31, 2014 and 2015, respectively.

Foreign exchange gains (losses)

Foreign exchange gains (losses) increased by $0.4 million to a loss of approximately $368,000 for the year ended December 31, 2015 compared to a loss of approximately $10,000 for the year ended December 31, 2014. Foreign exchange gains (losses) are reported in the consolidated statement of operations as a separate line item within other income (expense), net. These changes are primarily due to exchange rates fluctuations between the British Pound and the U.S. Dollar.

We have a number of intercompany loans in place between our parent company based in New Jersey and our subsidiary based in Scotland. The intercompany loans outstanding are not expected to be repaid in the foreseeable future and the nature of the funding advanced is of a long-term investment nature. Therefore all unrealized foreign exchange gains or losses arising on the intercompany loans are recognized in other comprehensive income until repayment of the intercompany loan becomes foreseeable. Unfavorable unrealized foreign exchange movements related to intercompany loans totaled $8.4 million for the year ended December 31, 2014. Unfavorable unrealized foreign exchange movements related to intercompany loans totaled $6.5 million for the year ended December 31, 2015.

The future

We expect other income, net for the year ended December 31, 2016 to be similar to the year ended December 31, 2015.

As the funding advanced through intercompany loans is that of a long-term investment in nature, unrealized foreign exchange gains and losses on such funding will be recognized in other comprehensive income until repayment of the intercompany loan becomes foreseeable.

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Income tax benefit

Credit is taken for research and development tax credits, which are claimed from the United Kingdom's taxation and customs authority, in respect of qualifying research and development costs incurred.

The following table summarizes total income tax benefit for the years ended December 31, 2014 and 2015 (in $000s except percentages):

	Years Ended December 31,		Difference	
	2014	2015	$	%
Income tax benefit	$ 3,243	$ 2,144	(1,099)	(34)

The income tax benefit decreased by approximately $1.1 million to $2.1 million for the year ended December 31, 2015 from $3.2 million for the year ended December 31, 2014. The level of tax credits recoverable is linked directly to qualifying research and development expenditure incurred in any one year.

The future

We expect to continue to be eligible to receive United Kingdom research and development tax credits for the foreseeable future and will elect to do so. The amount of tax credits we will receive is entirely dependent on the amount of eligible expenses we incur. As we expect our eligible expenses to be lower in the fiscal year ended December 31, 2016, the level of tax credits recoverable is anticipated to be lower in 2016 compared to the fiscal year ended December 31, 2015.

Results of Discontinued Operations

The following table summarizes our net income from discontinued operations for the years ended December 31, 2014 and 2015 (in $000s except percentages):

	Years Ended December 31,		Difference	
	2014	2015	$	%
Income from discontinued operations	$ 29	$ —	(29)	(100)
Income tax on discontinued operations	(10)	—	10	(100)
Net income from discontinued operations	$ 19	$ —	(19)	(100)

In August 2012, we entered into a termination and settlement agreement with Sinclair Pharmaceuticals Limited, or Sinclair, to terminate, effective September 30, 2012, the distribution agreements relating to the promotion and sale of Xclair®, Numoisyn® Lozenges and Numoisyn® Liquid, which we refer to collectively as the ALIGN products). The operating results associated with the ALIGN products are classified within net income from discontinued operations in the consolidated statements of operations for the years ended December 31, 2014 and 2015.

Net income from discontinued operations decreased by approximately $19,000 from income of $19,000 for the year ended December 31, 2014 to income of $0 for the year ended December 31, 2015.

The future

We ceased operations associated with the ALIGN products effective September 30, 2012. We have received all expected payments in accordance with our termination agreement with Sinclair. We expect discontinued operations to have a minimal impact on our results of operations for the year ended December 31, 2016.

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Liquidity and Capital Resources

The following is a summary of our key liquidity measures as of December 31, 2014 and 2015 (in $000s):

	December 31, 2014	December 31, 2015
Cash and cash equivalents	$ 24,189	$ 20,440
Working capital:		
Current assets	$ 29,000	$ 24,566
Current liabilities	(7,493)	(5,753)
Total working capital	$ 21,507	$ 18,813

Since our inception, we have relied primarily on the proceeds from sales of common and preferred equity securities to finance our operations and internal growth. Additional funding has come through research and development tax credits, government grants, the sale of product rights, interest on investments, licensing revenue, and a limited amount of product revenue from operations discontinued in September 2012. We have incurred significant losses since our inception. As of December 31, 2015, we had an accumulated deficit of $323.1 million.

Cash Flows

Cash provided by (used in) operating, investing and financing activities

Cash provided by (used in) operating, investing and financing activities for the years ended December 31, 2014 and 2015 is summarized as follows (in $000s):

	Years Ended December 31,	
	2014	2015
Net cash used in operating activities	$ (18,702)	$ (14,460)
Net cash provided by investing activities	$ 75	$ 62
Net cash provided by financing activities	$ 12,200	$ 10,860
Cash flows from discontinued operations		
Net cash provided by investing activities	$ 384	$ 96

Operating activities

Net cash used in operating activities decreased by $4.2 million, from $18.7 million for the year ended December 31, 2014 to $14.5 million for the year ended December 31, 2015. The decrease in cash used by operating activities was primarily the result of a decrease in research and development costs related to the ongoing SEAMLESS trial.

Investing activities

Net cash provided by investing activities was flat at approximately $0.1 million for the years ended December 31, 2014 and December 31, 2015.

Financing activities

Net cash provided by financing activities was $10.9 million for the year ended December 31, 2015, primarily as a result of approximately $9.2 million in net proceeds from the issuance of common stock in March 2015, $1.4 million in net proceeds from the issuance of common stock under a stock purchase agreement with Aspire entered into in November 2013 and $0.5 million in net proceeds from the issuance of common stock under a Controlled Equity OfferingSM Sales Agreement with Cantor entered into in July 2015 offset by $0.2 million in dividend payments to the holders of our Preferred Stock.

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Net cash provided by financing activities was $12.2 million for the year ended December 31, 2014, primarily as a result of approximately $9.3 million in net proceeds from the issuance of common stock in April 2014 and $3.0 million in net proceeds from the issuance of common stock under a stock purchase agreement with Aspire entered into in November 2013 and offset by $0.2 million in dividend payments to the holders of our Preferred Stock.

Operating Capital and Capital Expenditure Requirements

We expect to continue to incur substantial operating losses in the future and cannot guarantee that we will generate any significant product revenues until a product candidate has been approved by the FDA or EMA in other countries and successfully commercialized.

We believe that existing funds together with cash generated from operations, such as the R&D tax credit, and recent financing activities are sufficient to satisfy our planned working capital, capital expenditures and other financial commitments through 2017. However, we do not currently have sufficient funds to complete development and commercialization of any of our drug candidates. Current business and capital market risks could have a detrimental effect on the availability of sources of funding and our ability to access them in the future, which may delay or impede our progress of advancing our drugs currently in the clinical pipeline to approval by the FDA or EMA for commercialization. Additionally, we plan to continue to evaluate in-licensing and acquisition opportunities to gain access to new drugs or drug targets that would fit with our strategy. Any such transaction would likely increase our funding needs in the future.

Our future funding requirements will depend on many factors, including but not limited to:

- the rate of progress and cost of our clinical trials, preclinical studies and other discovery and research and development activities;

- the costs associated with establishing manufacturing and commercialization capabilities;

- the costs of acquiring or investing in businesses, product candidates and technologies;

- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

- the costs and timing of seeking and obtaining FDA and EMA approvals;

- the effect of competing technological and market developments; and

- the economic and other terms and timing of any collaboration, licensing or other arrangements into which we may enter.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through public or private equity offerings, debt financings or strategic collaborations. Although we are not reliant on institutional credit finance and therefore not subject to debt covenant compliance requirements or potential withdrawal of credit by banks, we are reliant on the availability of funds and activity in equity markets. We do not know whether additional funding will be available on acceptable terms, or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more of our clinical trials or research and development programs or make changes to our operating plan. In addition, we may have to partner one or more of our product candidate programs at an earlier stage of development, which would lower the economic value of those programs to us.

Off-Balance Sheet Arrangements

As of December 31, 2015, we had no off-balance sheet arrangements.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and related disclosure of

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contingent assets and liabilities. We review our estimates on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates. We believe the judgments and estimates required by the following accounting policies to be critical in the preparation of our consolidated financial statements.

Clinical Trial Accounting

Data management and monitoring of our clinical trials are performed with the assistance of contract research organizations, or CROs, or clinical research associates, or CRAs, in accordance with our standard operating procedures. Typically, CROs and CRAs bill monthly for services performed, and others bill based upon milestones achieved. For outstanding amounts, we accrue unbilled clinical trial expenses based on estimates of the level of services performed each period. Costs of setting up clinical trial sites for participation in the trials are expensed immediately as research and development expenses. Clinical trial costs related to patient enrollment are accrued as patients are entered into and progress through the trial. Any initial payment made to the clinical trial site is recognized upon execution of the clinical trial agreements and expensed as research and development expenses.

Research and Development Expenditures

Research and development expenses consist primarily of costs associated with our product candidates, upfront fees, milestones, compensation and other expenses for research and development personnel, supplies and development materials, costs for consultants and related contract research, facility costs and depreciation. Expenditures relating to research and development are expensed as incurred.

Stock-based Compensation

We grant stock options, restricted stock units and restricted stock to officers, employees, directors and consultants under the Company’s 2015 Equity Incentive Plan, or the 2015 Plan. The 2015 Plan replaced the Company’s Amended and Restated Equity Incentive Plan which expired in 2015. We measure compensation cost for all stock-based awards at fair value on date of grant and recognize compensation over the requisite service period for awards expected to vest. The fair value of restricted stock and restricted stock units is determined based on the number of shares granted and the quoted price of our common stock on the date of grant. The determination of grant-date fair value for stock option awards is estimated using an option-pricing model, which includes variables such as the expected volatility of our share price, the anticipated exercise behavior of our employees, interest rates, and dividend yields. These variables are projected based on our historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for share-based payments.

The fair value is recognized as an expense over the requisite service period, net of estimated forfeitures, using the straight-line attribution method. The estimation of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from our current estimates, such amounts are recorded as a cumulative adjustment in the period estimates are revised. We consider many factors when estimating expected forfeitures, including types of awards, employee class, and historical experience.

Revenue Recognition

Collaboration, supply and licensing agreements

Consideration received is allocated to each of the separable elements in an arrangement using the relative selling price method. An element is separable if it has value to the customer on a stand-alone basis. The selling price used for each separable element will be based on vendor-specific objective evidence, or VSOE, if available, third party evidence if VSOE is not available, or estimated selling price if neither VSOE nor third party evidence is available. Revenue is recognized for each separate element when persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured.

Royalty income is recognized when the licensee sells the underlying product.

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In June 2015, the Company entered into a collaboration, licensing and supply agreement with ManRos for the exclusive development and commercialization of the Company's oral seliciclib capsules by ManRos as a treatment for cystic fibrosis , orCF. Among other terms of the agreement, ManRos licensed rights to the Company's proprietary clinical data to enable clinical development of seliciclib for CF indications. The agreement provides for supply of seliciclib investigational product for initial and later stage clinical trials of seliciclib in CF and technical assistance related to the Company's know-how to facilitate these trials. The Company received an up-front payment in July 2015 and reached a development milestone in September 2015. The Company will receive further milestone payments and tiered royalties, if seliciclib is commercialized for the treatment of CF. The upfront and milestone payments have been allocated to the separate elements within the arrangement and recognized over the period in which the elements are being delivered. In the year ended December 31, 2015, the Company recognized revenue of $0.2 million.

Grant revenue

Grant revenues from government agencies and private research foundations are recognized as the related qualified research and development costs are incurred, up to the limit of the prior approval funding amounts. Grant revenues are not refundable.

Accounting Standards Adopted in the Period

On January 1, 2015, the Company adopted guidance issued by the Financial Accounting Standards Board which changed the criteria for reporting discontinued operations and enhanced disclosure in this area. Under the new guidance, only disposals representing a strategic shift in operations should be presented as discontinued operations. This guidance has been adopted prospectively to all disposals (or classifications as held for sale) of components of an entity occurring after January 1, 2015 and all businesses or nonprofit activities that, on acquisition, are classified as held for sale, that occur after January 1, 2015. The adoption of this guidance has not had a material impact on the Company's consolidated financial statements.

Recent Accounting Pronouncements Not Yet Effective

In May 2014, the FASB issued new guidance on accounting for revenue from contracts with customers. This new guidance will replace existing revenue guidelines with a new model, in which revenue is recognized upon transfer of control over goods or services to a customer. In August 2015, the FASB deferred the effective date of the guidance, which will now be effective for the Company on January 1, 2018, for both interim and annual periods. Early adoption is permitted for both interim and annual periods commencing on January 1, 2017. The guidance can be adopted using either a full retrospective (with certain practical expedients) or a modified retrospective method of transition. Under the modified retrospective approach, financial statements will be prepared for the year of adoption using the new standard, but prior periods will not be adjusted. Instead, companies will recognize a cumulative catch-up adjustment to the opening balance of retained earnings at the effective date for contracts that still require performance by the company, and disclose all line items in the year of adoption as if they were prepared under current revenue requirements. At this time, the Company has not decided on which method it will use to adopt the new standard, nor has it determined the effects of the new guidelines on its results of operations and financial position. For the foreseeable future, the Company's revenues will be limited to grants received from government agencies or nonprofit organizations and revenues from collaboration, supply and licensing agreements, and we are evaluating the effects of the new standard on these types of revenue streams.

Item 7A.

Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, we are not required to provide information response to this item.

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Item 8.
Financial Statements and Supplementary Data

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

Cyclacel Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Cyclacel Pharmaceuticals, Inc. and subsidiaries as of December 31, 2014 and 2015, and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity and cash flows for the years then ended. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Cyclacel Pharmaceuticals, Inc. and subsidiaries as of December 31, 2014 and 2015, and the results of their operations and their cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

/s/ RSM US LLP

RSM US LLP (formerly McGladrey LLP)

New York, New York

March 29, 2016

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CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(In $000s, except share, per share, and liquidation preference amounts)

	December 31, 2014	2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,189	$ 20,440
Prepaid expenses and other current assets	4,640	4,051
Current assets of discontinued operations	171	75
Total current assets	29,000	24,566
Property, plant and equipment (net)	387	198
Long-term assets of discontinued operations	—	—
Total assets	$ 29,387	$ 24,764
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,792	$ 1,940
Accrued and other current liabilities	4,626	3,738
Other liabilities measured at fair value	—	—
Current liabilities of discontinued operations	75	75
Total current liabilities	7,493	5,753
Other liabilities	206	176
Total liabilities	7,699	5,929
Commitments and contingencies	—	
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2014 and 2015; 335,273 shares issued and outstanding at December 31, 2014 and 2015. Aggregate preference in liquidation of $3,989,749 at December 31, 2014 and 2015	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2014 and 2015; 23,199,469 and 35,582,492 shares issued and outstanding at December 31, 2014 and 2015, respectively	23	35
Additional paid-in capital	330,962	342,555
Accumulated other comprehensive income (loss)	(480)	(596)
Accumulated deficit	(308,817)	(323,159)
Total stockholders' equity	21,688	18,835
Total liabilities and stockholders' equity	$ 29,387	$ 24,764

The accompanying notes are an integral part of these consolidated financial statements.
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CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In $000s, except share and per share amounts)

	Year Ended December 31, 2014	Year Ended December 31, 2015
Revenues:		
Grant revenue	$ 1,734	$ 1,694
Collaboration and research and development revenue	—	250
Total revenues	1,734	1,944
Operating expenses:		
Research and development	18,277	12,382
General and administrative	5,894	5,732
Total operating expenses	24,171	18,114
Operating loss	(22,437)	(16,170)
Other income (expense):		
Change in valuation of financial instruments associated with stock purchase agreement	(342)	(51)
Change in valuation of liabilities measured at fair value	20	—
Foreign exchange gains	(10)	(368)
Interest income	6	9
Other income, net	114	94
Total other income (expense), net	(212)	(316)
Loss from continuing operations before taxes	(22,649)	(16,486)
Income tax benefit	3,243	2,144
Net loss from continuing operations	(19,406)	(14,342)
Discontinued operations:		
Income from discontinued operations	29	—
Income tax on discontinued operations	(10)	—
Net income from discontinued operations	19	—
Net loss	(19,387)	(14,342)
Deemed dividend on convertible exchangeable preferred shares	—	—
Dividend on convertible exchangeable preferred shares	(200)	(201)
Net loss applicable to common shareholders	$ (19,587)	$ (14,543)
Basic and diluted earnings per common share:		
Net loss per share, continuing operations – basic and diluted	$ (0.89)	$ (0.45)
Net income per share, discontinued operations – basic and diluted	$ 0.00	$ 0.00
Net loss per share – basic and diluted	$ (0.89)	$ (0.45)
Weighted average common shares outstanding	21,955,381	32,557,146

The accompanying notes are an integral part of these consolidated financial statements.

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CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In $000s)

	Year Ended December 31, 2014	Year Ended December 31, 2015
Net loss from continuing operations	$ (19,406)	$ (14,342)
Net income from discontinued operations, net of tax	19	—
Net loss	(19,387)	(14,342)
Translation adjustment	8,020	6,420
Unrealized foreign exchange loss on intercompany loans	(8,391)	(6,536)
Comprehensive loss	$ (19,758)	$ (14,458)

The accompanying notes are an integral part of these consolidated financial statements.

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CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(In $000s, except share amounts)

	Preferred Stock		Common Stock		Additional paid-in capital	Accumulated other comprehensive income/(loss)	Accumulated Deficit	Total
	No.	Amount	No.	Amount				
Balance at December 31, 2013	335,273	$ —	19,369,332	$ 19	$ 317,543	$ (109)	$ (289,430)	$ 28,023
Issue of common stock for cash on registered direct offering, net of expenses	—	—	2,857,143	3	9,286	—	—	9,289
Issue of common stock on share purchase agreement	—	—	950,000	1	3,131	—	—	3,132
Stock-based awards exercised	—	—	22,994	—	(21)	—	—	(21)
Stock-based compensation	—	—	—	—	1,223	—	—	1,223
Preferred stock dividends	—	—	—	—	(200)	—	—	(200)
Unrealized foreign exchange on intercompany loans	—	—	—	—	—	(8,391)	—	(8,391)
Translation adjustment	—	—	—	—	—	8,020	—	8,020
Loss for the year	—	—	—	—	—	—	(19,387)	(19,387)
Balance at December 31, 2014	335,273	$ —	23,199,469	$ 23	$ 330,962	$ (480)	$ (308,817)	$ 21,688
Issue of common stock for cash	—	—	10,000,000	10	9,161			9,171

on registered direct offering, net of expenses								
Issue of common stock upon draw down of Committed Equity Finance Facility	—	—	879,583	1	483	—	—	484
Issue of common stock on share purchase agreement	—	—	1,414,424	1	1,405	—	—	1,406
Stock-based awards vested	—	—	89,016	—	—	—	—	
Stock-based compensation	—	—	—	—	745	—	—	745
Preferred stock dividends	—	—	—	—	(201)	—	—	(201)
Unrealized foreign exchange on intercompany loans	—	—	—	—	—	(6,536)	—	(6,536)
Translation adjustment	—	—	—	—	—	6,420	—	6,420
Loss for the year	—	—	—	—	—	—	(14,342)	(14,342)
Balance at December 31, 2015	335,273	$ —	35,582,492	$ 35	$ 342,555	$ (596)	$ (323,159)	$ 18,835

The accompanying notes are an integral part of these consolidated financial statements.

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CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In $000s)

	Year Ended December 31, 2014	Year Ended December 31, 2015
Operating activities:		
Net loss	$ (19,387)	$ (14,342)
Change in valuation of liabilities at fair value	(20)	—
Change in valuation of financial instruments associated with stock purchase agreement	342	51
Depreciation	174	210
Stock-based compensation	1,223	745
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,700)	342
Accounts payable and other current liabilities	666	(1,466)
Net cash used in operating activities	(18,702)	(14,460)
Investing activities:		
Purchase of property, plant and equipment	(309)	(34)
Minimum royalty payments received from termination of ALIGN license agreement	384	96
Net cash provided by investing activities	75	62
Financing activities:		
Proceeds from issuance of common stock and warrants, net of issuance costs	12,421	11,061
Proceeds from the exercise of stock options and warrants, net of issuance costs	(21)	—
Payment of preferred stock dividend	(200)	(201)
Net cash provided by financing activities	12,200	10,860
Effect of exchange rate changes on cash and cash equivalents	(530)	(211)
Net decrease in cash and cash equivalents	(6,957)	(3,749)
Cash and cash equivalents, beginning of period	31,146	24,189
Cash and cash equivalents, end of period	$ 24,189	$ 20,440
Supplemental cash flow information:		
Cash received during the period for:		
Interest	6	10
Taxes	1,811	2,861
Cash flow from discontinued operations:		
Net cash provided by investing activities	384	96
Non cash financing activities:		
Accrual of preferred stock dividends	50	50

The accompanying notes are an integral part of these consolidated financial statements.

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CYCLACEL PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1.
Organization of the Company

Cyclacel Pharmaceuticals, Inc. ("Cyclacel" or "the Company"), a biopharmaceutical company, is a pioneer in the field of cell cycle biology with a vision to improve patient healthcare with orally available innovative medicines. Cyclacel's 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.

Cyclacel's clinical development priorities are focused on sapacitabine, an orally available, cell cycle modulating nucleoside analog and the cyclin dependent kinase inhibitor program.

Sapacitabine is being evaluated in the SEAMLESS Phase 3 study, which completed enrollment in December 2014 and is being conducted under a Special Protocol Assessment ("SPA") agreement with the US Food and Drug Administration ("FDA") for the front-line treatment of acute myeloid leukemia ("AML") in the elderly and in other indications including myelodysplastic syndromes ("MDS"). Sapacitabine is also being evaluated in an oral regimen in combination with seliciclib in a Phase 1 study of patients with Homologous Recombination (HR) repair-deficient breast, ovarian and pancreatic cancers, including BRCA positive tumors. Sapacitabine has been evaluated in over 1,000 patients with various cancers. The FDA and the European Medicines Agency ("EMA") have designated sapacitabine as an orphan drug for the treatment of both AML and MDS.

In Cyclacel's second development program the Company is evaluating cyclin dependent kinase, or CDK, inhibitors. CDKs are involved in cancer cell growth, survival, metastatic spread and DNA damage repair. Seliciclib, Cyclacel's lead CDK inhibitor, is an oral, highly selective inhibitor of CDK enzymes that are central to the process of cell division and cell cycle control. Seliciclib has been evaluated in over 450 patients with various cancers, including non-small cell lung cancer, or NSCLC, and nasopharyngeal cancer, or NPC, and has shown signs of anticancer activity. Cyclacel has 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 Cyclacel's own drug candidate, sapacitabine. Seliciclib is also being evaluated in Investigator Sponsored Trials, or ISTs, to treat Cushing's disease and rheumatoid arthritis, or RA.

Cyclacel's second generation CDK inhibitor, CYC065, is a highly selective inhibitor of CDKs targeting CDK2/9 enzymes with potential utility in both hematological malignancies and solid tumors. CYC065 has increased anti-proliferative potency and improved pharmaceutical properties compared to seliciclib. CYC065 is in an on-going first-in-human, Phase 1 trial to assess its safety, tolerability, pharmacokinetics and pharmacodynamics in advanced cancer patients. CYC065 was selected from the Company's drug discovery program in Dundee, Scotland and its development was supported in part by a $1.9 million grant from the Biomedical Catalyst of the United Kingdom government.

In addition to these development programs, in Cyclacel's polo-like kinase ("PLK") inhibitor program, the Company has discovered CYC140 and other potent and selective small molecule inhibitors of PLK1, a kinase that is active during cell division, which targets the mitotic phase of the cell cycle. PLK was discovered by Professor David Glover, the Company's Chief Scientist. The Company has received a grant award of approximately $3.5 million from the Biomedical Catalyst of the United Kingdom government to complete IND-directed preclinical development of CYC140.

Cyclacel currently retains virtually all marketing rights worldwide to the compounds associated with the Company's drug programs.

As of December 31, 2015, 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.

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Capital Resources

We believe that existing funds together with cash generated from operations, such as the R&D tax credit, and recent financing activities are sufficient to satisfy our planned working capital, capital expenditures and other financial commitments through 2017.This is beyond the availability of mature data for final analysis of the SEAMLESS Phase 3 trial, which is expected to occur in the first half of 2016, but will not be sufficient to complete development of other indications or existing product candidates or to commercialize any of the Company's product candidates. On July 10, 2015, Cyclacel entered into a Controlled Equity OfferingSM Sales Agreement with Cantor Fitzgerald & Co., as sales agent ("Cantor") under which it may, from time to time, sell shares of common stock having an aggregate offering price of up to $8.35 million through Cantor. As of December 31, 2015 approximately $0.5 million net proceeds have been received through the sale of shares under the agreement.

Basis of Presentation

The accompanying consolidated financial statements as of December 31, 2014 and 2015, and for each of the two years in the period ended December 31, 2015, have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The consolidated financial statements include the financial statements of Cyclacel Pharmaceuticals, Inc. and all of the Company's wholly owned subsidiaries. All intercompany balances and transactions have been eliminated.

2.

Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and related disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Critical estimates include inputs used to determine clinical trial accruals, research and development expenditures, stock-based compensation expense and the recognition of revenue. Cyclacel reviews its estimates on an ongoing basis. The estimates are based on historical experience and on various other assumptions that the Company believes to be reasonable under the circumstances. Actual results may differ from these estimates. Cyclacel believes the judgments and estimates required by the following accounting policies to be significant in the preparation of the Company's consolidated financial statements.

Risks and Uncertainties

Drug candidates developed by the Company typically will require approvals or clearances from the FDA, EMA or other similar regulatory agencies in other countries prior to commercial sales. There can be no assurance that the Company's drug candidates will receive any of the required approvals or clearances. If the Company was denied approval or clearance or such approval was delayed, or is unable to obtain the necessary financing to complete development and approval, there will be a material adverse impact on the Company's financial condition and results of operations. The Company has relied upon government grants to fund its earlier stage programs and does not expect to be able to continue to be successful in obtaining government grants to fund the Company's research and development expenditure.

Foreign Currency and Currency Translation

Transactions that are denominated in a foreign currency are remeasured into the functional currency at the current exchange rate on the date of the transaction. Any foreign currency-denominated monetary assets and liabilities are subsequently remeasured at current exchange rates, with gains or losses recognized as foreign exchange (losses) gains in the statement of operations.

The assets and liabilities of the Company's international subsidiary are translated from its functional currency into United States dollars at exchange rates prevailing at the balance sheet date. Average rates of exchange during the period are used to translate the statement of operations, while historical rates of exchange are used to translate any equity transactions.

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Translation adjustments arising on consolidation due to differences between average rates and balance sheet rates, as well as unrealized foreign exchange gains or losses arising from translation of intercompany loans that are of a long-term-investment nature, are recorded in other comprehensive loss.

Segments

After considering its business activities and geographic reach, the Company has concluded that it operates in just one operating segment being the discovery, development and commercialization of novel, mechanism-targeted drugs to treat cancer and other serious disorders, with development operations in two geographic areas, namely the United States and the United Kingdom.

Cash and Cash Equivalents

Cash equivalents are stated at cost, which is substantially the same as fair value. The Company considers all highly liquid investments with an original maturity of three months or less at the time of initial purchase to be cash equivalents and categorizes such investments as held to maturity. The objectives of the Company's cash management policy are to safeguard and preserve funds, to maintain liquidity sufficient to meet Cyclacel's cash flow requirements and to attain a market rate of return.

The Company's cash balance at December 31, 2015 was $20.4 million and it maintains its cash accounts in several entities both within the United States and the United Kingdom. The total cash balances for amounts held in the United States are insured by the Federal Deposit Insurance Corporation up to $250,000 per account. The Company has cash balances exceeding the balance insured by the FDIC that totaled approximately $16.3 million at December 31, 2015. The total cash balances for amounts held in the United Kingdom are insured by the UK Government Financial Services Compensation Scheme ("FSCS") up to £75,000 per account. The Company has cash balances exceeding the balance insured by the FSCS that totaled approximately $2.0 million at December 31, 2015.

Fair Value of Financial Instruments

Financial instruments consist of cash and cash equivalents, accounts payable, accrued liabilities, financial instruments associated with stock purchase agreements and other arrangements. The carrying amounts of cash and cash equivalents, accounts payable, and accrued liabilities approximate their respective fair values due to the nature of the accounts, notably their short maturities. The financial instruments associated with stock purchase agreements and certain other liabilities are measured at fair value using applicable inputs as described in Note 5 — Fair Value.

Property, Plant and Equipment

The components of property, plant and equipment are stated at cost and depreciated on a straight-line basis over the estimated useful lives of the related assets, which are generally three to five years. Amortization of leasehold improvements is performed using the straight-line method over the shorter of the remaining lease term or the estimated useful life of the related assets, currently between five and fifteen years. Upon sale or retirement of assets, the costs and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss on sale is reflected as a component of operating income or loss. Expenditures for maintenance and repairs are charged to operating expenses as incurred.

The Company did not sell any fixed assets during the years ended December 31, 2014 or 2015.

Impairment of Long-lived Assets

The Company reviews property, plant and equipment for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. The Company assesses the recoverability of the potentially affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows.

Impairment, if any, is measured as the amount by which the carrying amount of a long-lived asset (or asset group) exceeds its fair value.

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Revenue Recognition

Collaboration, supply and licensing agreements

Consideration received is allocated to each of the separable elements in an arrangement using the relative selling price method. An element is separable if it has value to the customer on a stand-alone basis. The selling price used for each separable element will be based on vendor-specific objective evidence ("VSOE") if available, third party evidence if VSOE is not available, or estimated selling price if neither VSOE nor third party evidence is available. Revenue is recognized for each separate element when persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured.

Royalty income is recognized when the licensee sells the underlying product.

In June 2015, the Company entered into a collaboration, licensing and supply agreement with ManRos Therapeutics SA ("ManRos"), for the exclusive development and commercialization of the Company's oral seliciclib capsules by ManRos as a treatment for cystic fibrosis ("CF"). Among other terms of the agreement, ManRos licensed rights to the Company's proprietary clinical data to enable clinical development of seliciclib for CF indications. The agreement provides for supply of seliciclib investigational product for initial and later stage clinical trials of seliciclib in CF and technical assistance related to the Company's know-how to facilitate these trials. The Company received an up-front payment in July 2015 and reached a development milestone in September 2015. The Company will receive further milestone payments and tiered royalties, if seliciclib is commercialized for the treatment of CF. The upfront and milestone payments have been allocated to the separate elements within the arrangement and recognized over the period in which the elements are being delivered. In the year ended December 31, 2015, the Company recognized revenue of $250,000.

Grant revenue

Grant revenues from government agencies and private research foundations are recognized as the related qualified research and development costs are incurred, up to the limit of the prior approval funding amounts. Grant revenues are not refundable.

Clinical Trial Accounting

Data management and monitoring of the Company's clinical trials are performed with the assistance of contract research organizations ("CROs") or clinical research associates ("CRAs") in accordance with the Company's standard operating procedures. Typically, CROs and CRAs bill monthly for services performed, and others bill based upon milestones achieved. For outstanding amounts, the Company accrues unbilled clinical trial expenses based on estimates of the level of services performed each period. Costs of setting up clinical trial sites for participation in the trials are recognized upon execution of the clinical trial agreement and expensed immediately as research and development expenses. Clinical trial costs related to patient enrollment are accrued as patients are entered into and progress through the trial.

Research and Development Expenditures

Research and development expenses consist primarily of costs associated with the Company's product candidates, upfront fees, milestones, compensation and other expenses for research and development personnel, supplies and development materials, costs for consultants and related contract research, facility costs and depreciation. Expenditures relating to research and development are expensed as incurred.

Patent Costs

Patent prosecution costs are charged to operations as incurred as recoverability of such expenditure is uncertain.

Leased Assets

The costs of operating leases are charged to operations on a straight-line basis over the lease term.

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Income Taxes

The Company accounts for income taxes under the liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company applies the accounting guidance codified in ASC 740 "Income taxes" ("ASC 740") related to accounting for uncertainty in income taxes. ASC 740 specifies the accounting for uncertainty in income taxes recognized in a company's financial statements by prescribing a minimum probability threshold a tax position is required to meet before being recognized in the financial statements.

Credit is taken in the accounting period for research and development tax credits, which will be claimed from H.M. Revenue & Customs ("HMRC"), the United Kingdom's taxation and customs authority, in respect of qualifying research and development costs incurred in the same accounting period.

Net Loss Per Common Share

The Company calculates net loss per common share in accordance with ASC 260 "Earnings Per Share" ("ASC 260"). Basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the period.

The following potentially dilutive shares of common stock have not been included in the computation of diluted net loss per share for all periods as the result would be anti-dilutive.

	Year Ended December 31, 2014	Year Ended December 31, 2015
Stock options	1,010,298	2,475,579
Restricted Stock Units	89,016	—
Convertible preferred stock	20,381	20,381
Common stock warrants	1,341,129	544,117
Total shares excluded from calculation	2,460,824	3,040,077

Fair Value Measurements

Inputs used to determine fair value of financial and non-financial assets and liabilities are categorized using a fair value hierarchy that prioritizes observable and unobservable inputs into three broad levels, from Level 1, for quoted prices (unadjusted) in active markets for identical assets or liabilities, to Level 3, for unobservable inputs (see Note 5 — Fair Value). Management reviews the categorization of fair value inputs on a periodic basis and may determine that it is necessary to transfer an input from one level of the fair value hierarchy to another based on changes in events or circumstances, such as a change in the observability of an input. Any such transfer will be recognized at the end of the reporting period.

Stock-based Compensation

The Company grants stock options, restricted stock units and restricted stock to officers, employees and directors under the 2015 Equity Incentive Plan ("2015 Plan"), which was approved on May 22, 2015 and which replaced the Amended and Restated Equity Incentive Plan ("2006 Plan"), which was approved on March 16, 2006, amended on May 21, 2007, amended again and restated on April 14, 2008 and later amended on May 23, 2012. Under both plans, the Company has granted various types of awards, which are described more fully in Note 6 — Stock-Based Compensation Arrangements. The Company accounts for these awards under ASC 718 "Compensation — Stock Compensation" ("ASC 718").

ASC 718 requires measurement of compensation cost for all stock-based awards at fair value on date of grant and recognition of compensation over the requisite service period for awards expected to vest. The fair value of restricted stock and restricted stock units is determined based on the number of shares granted

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and the quoted price of the Company's common stock on the date of grant. The determination of grant-date fair value for stock option awards is estimated using the Black-Scholes model, which includes variables such as the expected volatility of the Company's share price, the anticipated exercise behavior of employees, interest rates, and dividend yields. These variables are projected based on historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for share-based payments. Such value is recognized as expense over the requisite service period, net of estimated forfeitures, using the straight-line attribution method. The estimation of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from current estimates, such amounts are recorded as a cumulative adjustment in the period estimates are revised. The Company considers many factors when estimating expected forfeitures, including type of awards granted, employee class, and historical experience. Actual results and future estimates may differ substantially from current estimates.

Comprehensive Income (Loss)

In accordance with ASC 220 "Comprehensive Income" ("ASC 220"), all components of comprehensive income (loss), including net income (loss), are reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income (loss) and other comprehensive income (loss), including foreign currency translation adjustments, are reported, net of any related tax effect, to arrive at comprehensive income (loss). No taxes were recorded on items of other comprehensive income.

Recent Events

Deficiency and Compliance Notice from The NASDAQ Stock Market

On February 2, 2016, the Company received a letter from the Listing Qualifications Staff (the "Staff") of The NASDAQ Stock Market LLC ("NASDAQ") indicating that the Company had not regained compliance with the $1.00 minimum bid price requirement for continued listing on The NASDAQ Capital Market, as set forth in NASDAQ Listing Rule 5450(a)(1), by the end of the previously granted compliance period that expired on February 2, 2016. As a result, the Staff indicated that the Company would be subject to delisting unless it timely requests a hearing before a NASDAQ Listing Qualifications Panel (the "Panel").

The Company has scheduled a hearing before the Panel on March 31, 2016, at which it will present its plan to regain compliance with the minimum bid price requirement, and request a further extension of time to do so. The Panel has the discretion to grant the Company up to an additional 180 calendar days from the date of the Staff's notice, or until August 1, 2016, to regain compliance with the minimum bid price requirement. The hearing will automatically stay any delisting action pending the issuance of a final decision and the expiration of any further extension granted by the Panel. There can be no assurance that the Panel will grant the Company's request for continued listing.

Accounting Standards Adopted in the Period

On January 1, 2015, the Company adopted guidance issued by the Financial Accounting Standards Board ("FASB") which changed the criteria for reporting discontinued operations and enhanced disclosure in this area. Under the new guidance, only disposals representing a strategic shift in operations should be presented as discontinued operations. This guidance has been adopted prospectively to all disposals (or classifications as held for sale) of components of an entity occurring after January 1, 2015 and all businesses or nonprofit activities that, on acquisition, are classified as held for sale, that occur after January 1, 2015. The adoption of this guidance has not had a material impact on the Company's consolidated financial statements.

Recent Accounting Pronouncements Not Yet Effective

In February 2016, the FASB issued guidance on accounting for leases. The guidance requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases along with additional qualitative and quantitative guidance. The guidance is effective for fiscal years beginning after December 15, 2018. The impact of the adoption of this guidance has not yet been evaluated.

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In January 2016, the FASB issued guidance requiring all equity investments to be measured at fair value with changes in the fair value recognized through net income (other than those accounted for under equity method of accounting or those that result in consolidation of the investee) and amended certain fair value disclosures requirements. The guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

In November 2015, the FASB issued guidance on the classification of deferred taxes on the balance sheet. The guidance is effective for fiscal periods beginning after December 15, 2016, and interim periods within those annual periods. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

In September 2015, the FASB issued guidance that requires an acquirer in a business combination to recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. The guidance should be applied prospectively and is effective for fiscal years beginning after December 15, 2015, including interim periods within those fiscal years. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

In July 2015, the FASB issued guidance to simplify the measurement of inventory. Effective for periods beginning after December 15, 2016, inventory measured using the first-in-first-out or average costs methods will be reported at the lower of cost or realizable value. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

In April 2015, the FASB issued guidance on a customer's accounting for fees in a cloud computing arrangement. The guidance is adopted on a retrospective basis. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

In February 2015, the FASB issued guidance on consolidation, which changes the analysis an entity must perform to determine whether it should consolidate certain legal entities. This guidance is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2015. Early adoption is permitted. The guidance can be adopted using either a full retrospective or a modified retrospective method of transition. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

In November 2014, the FASB issued guidance on how current US GAAP should be interpreted in evaluating the economic characteristics and risks of a host contract in a hybrid financial instrument that is issued in the form of a share. The guidance clarifies that an entity should include all relevant terms and features, including the embedded derivative feature being evaluated for bifurcation, in evaluating the nature of the host contract. The guidance is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2015. Early adoption is permitted. The guidance can be adopted on prospectively or on a modified retrospective basis. The Company is currently evaluating the impact of the guidance on its consolidated financial statements.

In August 2014, the FASB issued guidance on management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and the provision of related footnote disclosures. This guidance is effective for the annual period ending after December 15, 2016 and for annual and interim periods thereafter. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

In June 2014, the FASB issued guidance on accounting for share based payments when the terms of an award provide that a performance target could be achieved after the requisite service period. The guidance requires that a performance target that affects vesting and that could be achieved after the requisite service period should be treated as a performance condition. This guidance is effective for annual periods, and interim periods within those annual periods, after December 15, 2015. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

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In May 2014, the FASB issued new guidance on accounting for revenue from contracts with customers. This new guidance will replace existing revenue guidelines with a new model, in which revenue is recognized upon transfer of control over goods or services to a customer. In August 2015, the FASB deferred the effective date of the guidance, which will now be effective for the Company on January 1, 2018, for both interim and annual periods. Early adoption is permitted for both interim and annual periods commencing on January 1, 2017. The guidance can be adopted using either a full retrospective (with certain practical expedients) or a modified retrospective method of transition. Under the modified retrospective approach, financial statements will be prepared for the year of adoption using the new standard, but prior periods will not be adjusted. Instead, companies will recognize a cumulative catch-up adjustment to the opening balance of retained earnings at the effective date for contracts that still require performance by the company, and disclose all line items in the year of adoption as if they were prepared under current revenue requirements. At this time, the Company has not decided on which method it will use to adopt the new standard, nor has it determined the effects of the new guidelines on its results of operations and financial position. For the foreseeable future, the Company's revenues will be limited to grants received from government agencies or nonprofit organizations and revenues from collaboration, supply and licensing agreements, and we are evaluating the effects of the new standard on these types of revenue streams.

3.

Significant Contracts

Distribution, Licensing and Research Agreements

The Company has entered into licensing agreements with academic and research organizations. Under the terms of these agreements, the Company has received licenses to technology and patent applications. The Company is required to pay royalties on future sales of products employing the technology or falling under claims of patent applications. Pursuant to the Daiichi Sankyo license under which the Company licenses certain patent rights for sapacitabine, its lead drug candidate, the Company is under an obligation to use reasonable endeavors to develop a product and obtain regulatory approval to sell a product and has 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. The up-front fee, Phase 3 entry milestone, and certain past reimbursements have been paid. A further $10.0 million in aggregate milestone payments could be payable subject to achievement of all the specific contractual milestones which are primarily related to regulatory approval in various territories, and the Company's decision to continue with these projects. 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 the Company or its 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 the Company wishes 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, with the right of first refusal ending sixty days after notification, to develop and/or commercialize in Japan. In general, the license may be terminated by the Company for technical, scientific, efficacy, safety, or commercial reasons on six months' notice, or twelve months' notice, if after a launch of a sapacitabine-based product, or by either party for material default. There were no milestones earned in 2014 or 2015 and there are no milestone payments that are expected to be applicable to the Company in 2016.

4.

Cash and Cash Equivalents

The following is a summary of cash and cash equivalents at December 31, 2014 and 2015 (in $000s):

	December 31,	
	2014	2015
Cash	$ 5,870	$ 8,487
Investments with original maturity of less than three months at the time of purchase	18,319	11,953

Total cash and cash equivalents	$ 24,189	$ 20,440

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Investments with original maturity of less than three months at time of purchase are made up of money market funds and commercial paper.

5.

Fair Value

Fair Value Measurements

As defined in ASC 820 “Fair Value Measurements and Disclosures” (“ASC 820”), fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, ASC 820 establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

- Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

- Level 2: Inputs other than quoted prices within Level 1 that are observable for the asset or liability, either directly or indirectly.

- Level 3: Unobservable inputs that are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considering counterparty credit risk in its measurement of fair value.

The fair value of the Company’s financial assets and liabilities that are measured on a recurring basis were determined using the following inputs as of December 31, 2014 (in $000s):

	Level 1	Level 2	Level 3	Total
ASSETS				
Cash equivalents	$ 18,319	$ —	$ —	$ 18,319
Financial instrument associated with stock purchase agreement	—	51	—	51
Total assets	$ 18,319	$ 51	$ —	$ 18,370

The fair value of the Company’s financial assets and liabilities that are measured on a recurring basis were determined using the following inputs as of December 31, 2015 (in $000s):

	Level 1	Level 2	Level 3	Total
ASSETS				
Cash equivalents	$ 11,953	$ —	$ —	$ 11,953
Total assets	$ 11,953	$ —	$ —	$ 11,953

Financial Instrument Associated with Stock Purchase Agreement

On November 14, 2013, the Company entered into a common stock purchase agreement with Aspire Capital Fund, LLC (“Aspire”) (the “Purchase Agreement”) under which Aspire purchased 511,509 shares of common stock for an aggregate purchase price of $2.0 million and committed to purchase up to an additional 3,042,038 shares from time to time as directed by the Company over the next two years at prices derived from the market prices on or near the date of each sale (see Note 10 — Stockholders’ Equity).

The Company has accounted for the right to sell additional shares under the Purchase Agreement based on the guidance of ASC 815 “Derivative Financial Instruments” (“ASC 815”), which requires the instrument to be measured at fair value with changes in fair value reported in earnings each reporting period until the agreement is exhausted or expired. The primary inputs used to determine fair value are the price of the Company’s common stock, the remaining term, and aggregate share purchases on the measurement date. The instrument had a fair value of $0.5 million at the date of the transaction and a fair value of $0.1 million as of December 31, 2014.

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On July 8, 2015, the Company sold all remaining 314,424 shares of common stock that were subject to its agreement with Aspire and the Aspire Agreement has automatically terminated by its terms.

6.

Prepaid Expenses and Other Current Assets

The following is a summary of prepaid expenses and other current assets at December 31, 2014 and 2015 (in $000s):

	December 31,	
	2014	2015
Research and development tax credit receivable	$ 3,017	$ 2,093
Prepayments	902	893
Grant receivable	134	326
VAT receivable	309	607
Deposits	132	132
Other current assets	146	—
	$ 4,640	$ 4,051

7.

Property, Plant, and Equipment

Property, plant and equipment consisted of the following at December 31, 2014 and 2015 (in $000s):

	Useful lives in years from date of acquisition	December 31,	
		2014	2015
Leasehold improvements	5 to 15 years	$ 914	$ 885
Research and laboratory equipment	3 to 5 years	5,881	5,604
Office equipment and furniture	3 to 5 years	1,302	1,294
		8,097	7,783
Less: accumulated depreciation and amortization		(7,710)	(7,585)
		$ 387	$ 198

The depreciation and amortization of property, plant and equipment amounted to $0.2 million for each of the years ended December 31, 2014 and 2015.

8.

Accrued and Other Current Liabilities

Accrued and other current liabilities consisted of the following at December 31, 2014 and 2015 (in $000s):

	December 31,	
	2014	2015
Accrued research and development	$ 4,161	$ 3,284
Accrued legal and professional fees	303	291
Other current liabilities	162	163
	$ 4,626	$ 3,738

9.

Commitments and Contingencies

General
Please refer to Note 3 — Significant Contracts for further discussion of certain of the Company's commitments and contingencies.
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Leases

The following is a summary of the Company's contractual obligations and commitments relating to its facilities leases as at December 31, 2015 (in $000s):

	Operating Lease Obligations
2016	$ 537
2017	408
2018	381
2019	373
2020	373
Thereafter	1,795
Total	$ 3,867

Rent expense, which includes lease payments related to the Company's research and development facilities and corporate headquarters and other rent related expenses was $0.5 million for each of the years ended December 31, 2014 and 2015, respectively.

In October 2000, the Company entered into a twenty-five year lease for its research and development facility in Dundee, Scotland. In November 2013, the Company entered into a one year commitment to sublease part of the aforementioned research and development facility in Dundee, Scotland and recognized approximately $0.1 million for the year ended December 31, 2014. The commitment terminated in December 2014 and there was no sublease income in the year ended December 31, 2015. In May 2011, the Company extended its lease for office space at its headquarters in Berkeley Heights, New Jersey, through February 2017.

Preferred Dividends

The Company's Board of Directors considers numerous factors in determining whether to declare the quarterly dividend pursuant to the certificate of designations governing the terms of the Company's outstanding 6% Convertible Exchangeable ("Preferred Stock"), including the requisite financial analysis and determination of a surplus. Accrued and unpaid dividends in arrears on preferred stock were $0.6 million, or $1.90 per share, of preferred stock, as of December 31, 2014 and 2015.

10.

Stockholders' Equity

Preferred Stock

As of December 31, 2015, there were 335,273 shares of the Company's Preferred Stock issued and outstanding at an issue price of $10.00 per share. Dividends on the Preferred Stock are cumulative from the date of original issuance at the annual rate of 6% of the liquidation preference of the Preferred Stock, payable quarterly on the first day of February, May, August and November, commencing February 1, 2005. Any dividends must be declared by the Company's Board of Directors and must come from funds that are legally available for dividend payments. The Preferred Stock has a liquidation preference of $10.00 per share, plus accrued and unpaid dividends.

The Preferred Stock is convertible at the option of the holder at any time into the Company's shares of common stock at a conversion rate of approximately 0.06079 shares of common stock for each share of Preferred Stock based on a price of $164.50. The Company has reserved 20,381 shares of common stock for issuance upon conversion of the remaining shares of Preferred Stock outstanding at December 31, 2015. The shares of previously-converted Preferred Stock have been retired, cancelled and restored to the status of authorized but unissued shares of preferred stock, subject to reissuance by the Board of Directors as shares of Preferred Stock of one or more series.

The Company may automatically convert the Preferred Stock into common stock if the closing price of the Company's common stock has exceeded $246.75, which is 150% of the conversion price of the Preferred Stock, for at least 20 trading days during any 30-day trading period, ending within five trading days prior to notice of automatic conversion.

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The Certificate of Designations governing the Preferred Stock provides that if the Company fails to pay dividends on its Preferred Stock for six quarterly periods, holders of Preferred Stock are entitled to nominate and elect two directors to the Company's Board of Directors. This right accrued to the holders of Preferred Stock as of August 2, 2010 and two directors were nominated and elected at the annual meeting held on May 24, 2011.

The Preferred Stock has no maturity date and no voting rights prior to conversion into common stock, except under limited circumstances.

The Company may, at its option, redeem the Preferred Stock in whole or in part, out of funds legally available at the redemption price of $10.00 per share.

The Preferred Stock is exchangeable, in whole but not in part, at the option of the Company on any dividend payment date beginning on November 1, 2005 (the "Exchange Date") for the Company's 6% Convertible Subordinated Debentures ("Debentures") at the rate of $10.00 principal amount of Debentures for each share of Preferred Stock. The Debentures, if issued, will mature 25 years after the Exchange Date and have terms substantially similar to those of the Preferred Stock. No such exchanges have taken place as of December 31, 2015.

For the year ended December 31, 2014, the company declared dividends of $0.15 per share quarterly on its Preferred Stock. These dividends were paid on February 1, May 1, August 1 and November 3, 2014, respectively.

On February 18, 2015, the Board of Directors of the Company declared a quarterly cash dividend in the amount of $0.15 per share on the Company's Preferred Stock. The cash dividend was paid on May 1, 2015 to the holders of record of the Preferred Stock as of the close of business on April 17, 2015.

On May 22, 2015, the Board of Directors of the Company declared a quarterly cash dividend in the amount of $0.15 per share on the Company's Preferred Stock. The cash dividend was paid on August 1, 2015 to the holders of record of the Preferred Stock as of the close of business on July 17, 2015.

On October 14, 2015, the Board of Directors declared a quarterly cash dividend in the amount of $0.15 per share on the Company's Preferred Stock. The cash dividend was paid on November 2, 2015 to the holders of record of the Preferred Stock as of the close of business on October 23, 2015.

On December 24, 2015, the Board of Directors declared a quarterly cash dividend in the amount of $0.15 per share on the Company's Preferred Stock. The cash dividend was paid on February 1, 2016 to the holders of record of the Preferred Stock as of the close of business on January 21, 2016.

Common Stock

July 2015 Controlled Equity OfferingSM

On July 10, 2015, the Company entered into a Controlled Equity OfferingSM Sales Agreement (the "Agreement") with Cantor under which the Company may, from time to time, sell shares of its common stock having an aggregate offering price of up to $8.35 million through Cantor. Under the Agreement, Cantor may sell the Shares by methods deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the "Securities Act"). The Company will pay Cantor a commission of up to 3.0% of the gross sales price per share sold. Cyclacel is not obligated to make any sales under the Agreement. During the year ended December 31, 2015, the Company issued 879,583 shares of its common stock for proceeds, net of certain fees and expenses, of approximately $0.5 million.

March 2015 Public Offering

On March 9, 2015, the Company completed a public offering of 10,000,000 shares of its common stock at a price to the public of $1.00 per share for proceeds, net of certain fees and expenses, of approximately $9.2 million.

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April 2014 Underwriting Agreement

On April 3, 2014, the Company entered into an underwriting agreement relating to the public offering and sale of 2,857,143 shares of the Company's common stock, par value $0.001 per share, at a price to the public of $3.50 per share, for proceeds, net of certain fees and expenses, of approximately $9.3 million.

November 2013 Stock Purchase Agreement

On November 14, 2013, the Company entered into a common stock Purchase Agreement with Aspire (the "Purchase Agreement"). Upon execution of the Purchase Agreement, Aspire purchased 511,509 shares of common stock for an aggregate purchase price of $2.0 million. Under the terms of the Purchase Agreement, Aspire has committed to purchase up to an additional 3,042,038 shares from time to time as directed by the Company or, in certain instances, as agreed to by both parties, over the next two years at prices derived from the market prices on or near the date of each sale. However, such commitment is limited to an additional $18.0 million of share purchases. In consideration for entering into the Purchase Agreement, concurrent with the execution of the Purchase Agreement, the Company issued 166,105 shares of the Company's common stock to Aspire in lieu of a commitment fee. The fair value of these shares has been recorded as a component of other assets and will continue to be remeasured each reporting period, until the agreement is exhausted or expired, with gains or losses reported in the consolidated statements of operations. During the year ended December 31, 2014, the Company sold 950,000 shares to Aspire under the Purchase Agreement for proceeds of $3.1 million.

During the year ended December 31, 2015, the Company sold all remaining 1,414,424 shares of common stock that were subject to the Purchase Agreement for net proceeds of approximately $1.4 million. All of the available shares under the Aspire Agreement have now been sold and the Aspire Agreement has automatically terminated by its terms.

Summary of Outstanding Warrants

The following table summarizes information about warrants outstanding at December 31, 2015:

Issued in Connection With	Expiration Date	Common Shares Issuable	Weighted Average Exercise Price
July 2011 stock issuance	2016	544,117	$ 9.52
Total		544,117	$ 9.52

There were no exercises of warrants during the years ended December 31, 2014 and 2015. Warrants for 202,499 shares of common stock, issued in connection with the January 2010 stock issuance and warrants for 594,513 shares of common stock, issued in connection with the October 2010 stock issuance, expired during the year ended December 31, 2015.

Exercise of Stock Options

No stock options were exercised during the years ended December 31, 2014 and 2015.

11.

Stock-Based Compensation Arrangements

ASC 718 requires compensation expense associated with share-based awards to be recognized over the requisite service period, which for the Company is the period between the grant date and the date the award vests or becomes exercisable. Most of the awards granted by the Company (and still outstanding), vest ratably over three or four years, however, certain awards granted to members of the Company's Board of Directors vest in their entirety on the one-year anniversary following the date of grant.

The Company recognizes all share-based awards under the straight-line attribution method. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company evaluates its forfeiture assumptions quarterly and the expected forfeiture rate is adjusted when necessary. Ultimately, the actual expense recognized over the vesting period is based on only those shares that vest.

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Stock based compensation has been reported within expense line items on the consolidated statement of operations for 2014 and 2015 as shown in the following table (in $000s):

	Year Ended December 31, 2014	Year Ended December 31, 2015
Research and development	$ 392	$ 240
General and administrative	831	505
Stock-based compensation costs before income taxes	$ 1,223	$ 745

2015 Plan

On May 22, 2015, the Company's stockholders approved the 2015 Plan, under which Cyclacel may make equity incentive grants to its officers, employees, directors and consultants. The Company has reserved 3,500,000 shares of its common stock under the 2015 Plan. The 2015 Plan replaces the 2006 Plan, under which there were no remaining reserved shares available for issuance as of September 30, 2015. Stock option awards granted under the Company's equity incentive plans have a maximum life of 10 years and generally vest over a one to four-year period from the date of grant.

During 2015, the Company granted approximately 1,470,000 options to employees and directors with a grant date fair value of approximately $0.8 million. During 2014, the Company granted approximately 63,000 options to employees and directors with a grant date fair value of approximately $0.2 million. The weighted average grant-date fair values of options granted during the years ended December 31, 2014 and 2015 were $2.48 and $0.51, respectively.

As of December 31, 2015, the total remaining unrecognized compensation cost related to the non-vested stock options amounted to approximately $1.0 million, which will be amortized over the weighted-average remaining requisite service period of 2.19 years.

During the years ended December 31, 2014 and 2015, the Company did not settle any equity instruments with cash. There were no stock option exercises during the years ended 2014 and 2015. No income tax benefits were recorded for the years ended December 2014 and 2015 because ASC 718 prohibits recognition of tax benefits for exercised stock options until such benefits are realized. The Company was not able to benefit from the deduction for exercised stock options for the years ended December 31, 2014 and 2015 because the Company incurred tax losses in each of those years.

Outstanding Options

A summary of the share option activity and related information is as follows:

	Number of Options Outstanding	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value ($000s)
Options outstanding at December 31, 2013	949,685	$ 15.02	7.38	$ 152
Granted	63,000	$ 3.11		
Exercised	—			
Cancelled/forfeited	(2,387)	$ 31.08		
Options outstanding at December 31, 2014	1,010,298	$ 14.24	6.58	$ —
Granted	1,470,281	$ 0.63		
Exercised	—			
Cancelled/forfeited	(5,000)	$ 67.82		
Options outstanding at December 31, 2015	2,475,579	$ 6.05	8.09	—
Unvested at December 31, 2015	1,577,211	$ 1.01	9.61	$ —

Vested and exercisable at December 31, 2015	898,368	$ 14.91	5.42	$ —

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The fair value of the stock options granted is calculated using the Black-Scholes option-pricing model as prescribed by ASC 718 using the following assumptions:

	Year ended December 31, 2014	Year ended December 31, 2015
Expected term (years)	6	5-6
Risk free interest rate	1.835% – 2.005%	1.520% – 1.845%
Volatility	101%	96% – 108%
Expected dividend yield over expected term	0.00%	0.00%
Resulting weighted average grant date fair value	$2.48	$0.51

The expected term assumption was estimated using past history of early exercise behavior and expectations about future behaviors. The Company relied exclusively on its historical volatility as an input to the option pricing model as management believes that this rate will be representative of future volatility over the expected term of the options. Estimates of pre-vesting option forfeitures are based on the Company's experience. Currently the Company uses a forfeiture rate of 0 – 30% depending on when and to whom the options are granted. The Company adjusts its estimate of forfeitures over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures are recognized through a cumulative adjustment in the period of change and may impact the amount of compensation expense to be recognized in future periods.

The Company considers many factors when estimating expected forfeitures, including types of awards, employee class, and historical experience. During the years ended December 31, 2014 and 2015, the Company recognized an expense of approximately $0.5 million and $0.1 million, respectively, as a result of revised forfeiture rates.

The weighted average risk-free interest rate represents interest rate for treasury constant maturities published by the Federal Reserve Board. If the term of available treasury constant maturity instruments is not equal to the expected term of an employee option, Cyclacel uses the weighted average of the two Federal Reserve securities closest to the expected term of the employee option.

Restricted Stock Units

The Company issued 85,097 restricted stock units to employees during the year ended December 31, 2013, the vesting of which is dependent upon the fulfillment of certain clinical and financial conditions. The Company determined that the satisfaction of the clinical and financial conditions was probable at December 31, 2014 and, as a result, recorded an expense of $0.5 million related to 80,969 restricted stock units, net of forfeitures, for the year ended December 31, 2014. The restricted stock units were valued based on the fair value at the date of grant, which is equivalent to the market price of a share of the Company's common stock. The expense was recognized entirely in the fourth quarter of 2014 as the awards became probable of vesting in that quarter. Summarized information for restricted stock unit activity for the years ended December 31, 2014 and 2015 is as follows:

	Restricted Stock Units	Weighted Average Grant Date Value Per Share
Non-vested at December 31, 2013	119,248	$ 5.62
Granted	—	$ —
Vested	(29,999)	$ 5.81
Forfeited	(233)	$ 5.39
Non-vested at December 31, 2014	89,016	$ 5.56
Vested	(89,016)	$ 5.56
Non-vested at December 31, 2015	—	—

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12.
Employee Benefit Plans

Pension Plan
The Company operates a defined contribution group personal pension plan for all of its UK based employees. Company contributions to the plan totaled approximately $63,000 and $65,000 for the years ended December 31, 2014 and 2015, respectively.

401(k) Plan
The 401(k) Plan provides for matching contributions by the Company in an amount equal to the lesser of 100% of the employee's deferral or 6% of the U.S. employee's qualifying compensation. The 401(k) Plan is intended to qualify under Section 401(k) of the Internal Revenue Code, so that contributions to the 401(k) Plan by employees or by the Company, and the investment earnings thereon, are not taxable to the employees until withdrawn. Company matching contributions are tax deductible by the Company when made. Company employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit of $18,000 if under 50 years old and $24,000 if over 50 years old and to have those funds contributed to the 401(k) Plan. The Company made contributions of approximately $46,000 and $47,000 to the 401(k) Plan for the years ended December 31, 2014 and 2015, respectively.

13.
Discontinued Operations

On August 10, 2012, the Company entered into an agreement with Sinclair Pharmaceuticals Limited ("Sinclair") to terminate, effective September 30, 2012, the distribution agreements relating to the promotion and sale of Xclair®, Numoisyn® Lozenges and Numoisyn® Liquid (collectively, the "ALIGN products").

Product revenue, cost of goods sold and selling, general and administrative costs related to the promotion and sale of the ALIGN products have been reclassified from operating results from continuing operations to income from discontinued operations in the consolidated statement of operations for all periods presented as follows (in $000s):

	Year ended December 31, 2014	Year ended December 31, 2015
Interest income	$ 29	$ —
Income tax on discontinued operations	(10)	—
Net income from discontinued operations, net of tax	$ 19	$ —

The assets and liabilities associated with product promotion and sales have been classified within assets and liabilities of discontinued operations in the accompanying consolidated balance sheets (in $000s):

	December 31, 2014	December 31, 2015
Current assets of discontinued operations:		
Short term portion of minimum royalty arrangement receivable, net	$ 96	$ —
Returns indemnification receivable	75	75
Total current assets of discontinued operations	171	75
Long-term assets of discontinued operations:		
Long-term portion of minimum royalty arrangement receivable, net	—	—
Total assets of discontinued operations	$ 171	$ 75
Current liabilities of discontinued operations:		
Returns provision	$ 75	$ 75
Total current liabilities of discontinued operations	$ 75	$ 75

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14.
Taxes

(Loss) income from continuing operations before taxes is comprised of the following components for the years ended December 31, 2014 and 2015 (in $000s):

	Year Ended December 31, 2014	Year Ended December 31, 2015
Domestic	$ (2,898)	$ (2,520)
Foreign	(19,751)	(13,966)
Loss from continuing operations before taxes	$ (22,649)	$ (16,486)

The benefit (provision) for income taxes from continuing operations consists of the following (in $000s):

	Year Ended December 31, 2014	Year Ended December 31, 2015
Current – domestic	$ 34	$ —
Current – foreign	3,209	2,144
Current – total	3,243	2,144
Deferred – domestic	—	—
Income tax benefit	$ 3,243	$ 2,144

The Company has incurred a taxable loss in each of the operating periods since incorporation. The income tax credits of $3.2 million and $2.1 million for the years ended December 31, 2014 and 2015, respectively, represent UK research and development (“R&D”) tax credits for expenditures in the United Kingdom that are refundable.

A reconciliation of the (benefit) provision for income taxes from continuing operations with the amount computed by applying the statutory federal tax rate to loss from continuing operations before income taxes is as follows (in $000s):

	Year Ended December 31, 2014	Year Ended December 31, 2015
Loss from continuing operations before taxes	$ (22,649)	$ (16,486)
Income tax expense computed at statutory federal tax rate	(7,701)	(5,605)
Disallowed expenses and non-taxable income	406	27
Loss surrendered to generate R&D credit	7,294	2,479
Additional research and development tax relief	(7,262)	(3,402)
Change in valuation allowance	(4,963)	(4,189)
Research and development credit – prior years	—	—
Foreign items, including change in tax rates, and other	3,555	6,882
Other foreign items	5,428	1,664
	$ (3,243)	$ (2,144)

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Significant components of the Company's deferred tax assets are shown below (in $000s):

	December 31,	
	2014	2015
Net operating loss carryforwards	$ 45,060	$ 41,003
Depreciation, amortization and impairment of property and equipment	81	101
Stock options	1,815	2,193
Accrued expenses	179	—
Research and development credits	4,332	4,021
Other	78	38
Translation adjustment	—	—
Deferred tax assets	51,545	47,356
Valuation allowance for deferred tax assets	(51,545)	(47,356)
Net deferred taxes	$ —	$ —

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting and tax purposes.

A valuation allowance has been established, as realization of such assets is uncertain. The Company's management evaluated the positive and negative evidence bearing upon the realizability of its deferred assets, and has determined that, at present, the Company may not be able to recognize the benefits of the deferred tax assets under the more likely than not criteria. Accordingly, a valuation allowance of approximately $47.3 million has been established at December 31, 2015. The valuation allowance has decreased by approximately $4.2 million in 2015.

In certain circumstances, as specified in the Tax Reform Act of 1986, due to ownership changes, the Company's ability to utilize its net operating loss ("NOL") carryforwards may be limited. The benefit of deductions from the exercise of stock options is included in the NOL carryforwards. The benefit from these deductions will be recorded as a credit to additional paid-in capital if and when realized through a reduction of cash taxes. As of December 31, 2014 and 2015, the Company had federal NOLs of $23.9 million and $26.7 million and foreign NOLs of $173.0 million and $171.7 million, respectively. The Company's federal NOLs will start to expire in 2026, and the state NOLs totaling $17.0 million will start expiring in 2023. The Company's foreign NOL's do not expire under UK tax law.

Utilization of the NOLs may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company completed a Section 382 study as of June 30, 2014 noting there was no ownership change since the Company's formation. Management has evaluated all significant tax positions at December 31, 2014 and 2015 and concluded that there are no material uncertain tax positions. The Company would recognize both interest and penalties related to unrecognized benefits in income tax expense. The Company has not recorded any interest and penalties on any unrecognized tax benefits since its inception.

Tax years 2012, 2013 and 2014 remain open to examination by major taxing jurisdictions to which the Company is subject, which are primarily in the United Kingdom and the United States, as carryforward attributes generated in years past may still be adjusted upon examination by the United Kingdom's H.M. Revenue & Customs, the Internal Revenue Service ("IRS") or state tax authorities. The Company is currently not under examination by the IRS or any other jurisdictions for any tax years.

We have not provided a deferred tax liability on the cumulative amount of unremitted foreign earnings of international subsidiaries because it is our intent to permanently reinvest such earnings outside of the United States. We would recognize this deferred tax liability if we were to experience a change in circumstances producing a change in that intention. The United States foreign tax credits which would arise upon such a distribution have also not been recognized.

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15.
Geographic Information

Geographic information for the years ended December 31, 2014 and 2015 is as follows (in $000s):

	Year Ended December 31, 2014	Year Ended December 31, 2015
Revenue		
United Kingdom	$ 1,734	$ 1,944
Total Revenue	1,734	1,944
Net loss		
United States:		
Continuing operations	(2,865)	(2,520)
Discontinued operations	19	—
Total United States	(2,846)	(2,520)
United Kingdom	(16,541)	(11,822)
Total Net Loss	$ (19,387)	$ (14,342)

	December 31, 2014	2015
Total Assets		
United States:		
Continuing operations	$ 18,923	$ 17,124
Discontinued operations	171	75
Total United States	19,094	17,199
United Kingdom	10,293	7,565
Total Assets	29,387	24,764
Long Lived Assets, net		
United States:		
Continuing operations	6	4
Discontinued operations	—	—
Total United States	6	
United Kingdom	381	194
Total Long Lived Assets, net	$ 387	$ 198

16.
Subsequent Events

Deficiency and Compliance Notice from The NASDAQ Stock Market
On February 2, 2016, the Company received a letter from the Listing Qualifications Staff (the “Staff”) of The NASDAQ Stock Market LLC (“NASDAQ”) indicating that the Company had not regained compliance with the $1.00 minimum bid price requirement for continued listing on The NASDAQ Capital Market, as set forth in NASDAQ Listing Rule 5450(a)(1), by the end of the previously granted compliance period that expired on February 2, 2016. As a result, the

Staff indicated that the Company would be subject to delisting unless it timely requests a hearing before a NASDAQ Listing Qualifications Panel (the “Panel”).

The Company has scheduled a hearing before the Panel on March 31, 2016, at which it will present its plan to regain compliance with the minimum bid price requirement, and request a further extension of time to do so. The Panel has the discretion to grant the Company up to an additional 180 calendar days from the date of the Staff’s notice, or until August 1, 2016, to regain compliance with the minimum bid price requirement. The hearing will automatically stay any delisting action pending the issuance of a final decision and the expiration of any further extension granted by the Panel. There can be no assurance that the Panel will grant the Company’s request for continued listing.

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Item 9.
Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A.
Controls and Procedures

(a) Disclosure Controls:

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. An evaluation was performed under the supervision and with the participation of the Company's management, including the Chief Executive Officer and Chief Financial Officer, on the effectiveness of the Company's disclosure controls and procedures as of December 31, 2015.

Pursuant to this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2015, the end of the period covered by this report, our disclosure controls and procedures were effective.

We have concluded that the consolidated financial statements in this Annual Report on Form 10-K fairly present, in all material respects, our financial position, results of operations and cash flows as of the dates, and for the periods, presented, in conformity with U.S. GAAP.

(b) Management's Annual Report on Internal Control Over Financial Reporting:

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

(1)
Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;

(2)
Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and

(3)
Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process, and it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of

the effectiveness of our internal control over financial reporting based on the framework in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 2013.

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Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2015. Management based this assessment on criteria for effective internal control over financial reporting described in "Internal Control-Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Management's assessment included an evaluation of the design of the Company's internal control over financial reporting and testing of the operational effectiveness of its internal control over financial reporting. Management reviewed the results of its assessment with the Audit Committee.

Based on this assessment, management determined that, as of December 31, 2015, the Company's internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

This annual report does not include an attestation report of the Company's registered independent public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

(c) Changes in Internal Control Over Financial Reporting

There have not been any changes in the Company's internal control over financial reporting (as defined in Rule 13a-15(f)) during the fiscal quarter ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B.

Other information

Not applicable.

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PART III

Item 10.

Directors, Executive Officers and Corporate Governance

The information required by item 10 is incorporated herein by reference from the Company's Proxy Statement, which will be filed with the SEC within 120 days after the end of the Company's 2015 fiscal year pursuant to Regulation 14A for its 2016 Annual Meeting of Stockholders.

Item 11.

Executive Compensation

The information required by item 11 is incorporated herein by reference from the Company's Proxy Statement, which will be filed with the SEC within 120 days after the end of the Company's 2015 fiscal year pursuant to Regulation 14A for its 2016 Annual Meeting of Stockholders.

Item 12.

Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by item 12 is incorporated herein by reference from the Company's Proxy Statement, which will be filed with the SEC within 120 days after the end of the Company's 2015 fiscal year pursuant to Regulation 14A for its 2016 Annual Meeting of Stockholders.

Item 13.

Certain Relationships and Related Transactions, and Director Independence

The information required by item 13 is incorporated herein by reference from the Company's Proxy Statement, which will be filed with the SEC within 120 days after the end of the Company's 2015 fiscal year pursuant to Regulation 14A for its 2016 Annual Meeting of Stockholders.

Item 14.

Principal Accountant Fees and Services

The information required by item 14 is incorporated herein by reference from the Company's Proxy Statement, which will be filed with the SEC within 120 days after the end of the Company's 2015 fiscal year pursuant to Regulation 14A for its 2016 Annual Meeting of Stockholders.

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PART IV

Item 15.

Exhibits and Financial Statement Schedules

(a)

Documents filed as part of this report are as follows:

(1)

See “Index to Consolidated Financial Statements and Financial Statement Schedules” at Item 8 of this Annual Report on Form 10-K.

(2)

Other financial statement schedules have not been included because they are not applicable or the information is included in the financial statements or notes thereto.

(3)

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

(b)

Exhibits:

EXHIBIT NUMBER	DESCRIPTION
1.1	Engagement Letter, dated March 3, 2015, by and between Cyclacel Pharmaceuticals, Inc. and H.C. Wainwright & Co., LLC (previously filed Exhibit 1.1 to the Registrant’s Current Report on Form 8-K, originally filed with the SEC on March 4, 2015, and incorporated herein by reference).
1.2	Controlled Equity Offering Sales Agreement, dated July 10, 2015, by and among the Company and Cantor Fitzgerald & Co. (previously filed as Exhibit 10.1 to the Registrant’s Current Report on Form 8-K, originally field with the SEC on July 10, 2015, and incorporated herein by reference).
3.2	Amended and Restated Bylaws of Cyclacel Pharmaceuticals, Inc. (Previously filed as Exhibit 3.2 to the Registrant’s Annual Report on Form 10-K, File No. 000-50626, originally filed with the SEC on March 31, 2011 and incorporated herein by reference).
3.3	Preferred Stock Certificate of Designations (previously filed as Exhibit 3.2 to the Registrant’s Current Report on Form 8-K, originally filed with the SEC on November 5, 2004, and incorporated herein by reference).
4.1	Specimen of Common Stock Certificate (previously filed as Exhibit 4.1 to Registrant’s Registration Statement on Form S-1, File No. 333-109653, originally filed with the SEC on October 10, 2003, as subsequently amended, and incorporated herein by reference).
4.2	Specimen of Preferred Stock Certificate of Designation (previously filed as Exhibit 3.2 to Registrant’s Registration Statement on Form S-1, File No. 333-119585, originally filed with the SEC on October 7, 2004, as subsequently amended, and incorporated herein by reference).
4.3	Form of Warrant to purchase shares of Cyclacel Pharmaceuticals, Inc. Common Stock (previously filed as Exhibit 4.1 to the Registrant’s Current Report on Form 8-K, originally filed with the SEC on July 1, 2011, and incorporated herein by reference).
4.4	Registration Rights Agreement, dated as of December 14, 2012, by and between the Company and Aspire Capital Fund, LLC (previously filed as Exhibit 4.1 to the Registrant’s Current Report on Form 8-K, originally filed with the SEC on December 17, 2012, and incorporated herein by reference).

4.5	Registration Rights Agreement, dated November 14, 2013, by and between the Company and Aspire Capital Fund, LLC (previously filed as Exhibit 4.1 to the Registrant's Quarterly Report on Form 10-Q, originally filed with the SEC on November 14, 2013, and incorporated herein by reference).
10.1	Stock Purchase Agreement, dated December 15, 2005, between Xcyte Therapies, Inc., and Cyclacel Group plc (previously filed as Exhibit 2.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on December 20, 2005, and incorporated herein by reference).

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EXHIBIT NUMBER	DESCRIPTION
10.2	Amendment No. 1 to the Stock Purchase Agreement, dated January 13, 2006, between Xcyte Therapies Inc., and Cyclacel Group plc (previously filed as exhibit 2.1 to the Registrant's current report on Form 8-K filed with the Commission on January 19, 2006, and incorporated herein by reference).
10.3†	Amended and Restated Equity Incentive Plan (previously filed as Exhibit 10.1 to Registrant's Current Report on Form 8-K, originally filed with the SEC on May 24, 2012, and incorporated by reference).
10.4†	Equity Incentive Plan (previously filed as Exhibit 10.1 to Registrant's Current Report on Form 8-K, originally filed with the SEC on May 22, 2015, and incorporated by reference).
10.5†	Employment Agreement by and between Cyclacel Pharmaceuticals, Inc. and Spiro Rombotis, dated as of January 1, 2014 (previously filed as Exhibit 10.4 to the Registrant's Annual Report on Form 10-K, originally filed with the SEC on March 24, 2014, and incorporated by reference).
10.6†	Employment Agreement by and between Cyclacel Pharmaceuticals, Inc. and Paul McBarron, dated as of January 1, 2014 (previously filed as Exhibit 10.5 to the Registrant's Annual Report on Form 10-K, originally filed with the SEC on March 24, 2014, and incorporated by reference).
10.7†	Form of Change in Control Agreement by and between Cyclacel Pharmaceuticals, Inc. and Dr. Judy Chiao, dated as of December 10, 2010 (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on December 14, 2010, and incorporated herein by reference).
10.8	Agreement between the Company and Scottish Enterprise dated March 27, 2006 (previously filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, for the quarterly period ended June 30, 2009, originally filed with the SEC on August 13, 2009, and incorporated herein by reference).
10.9	Addendum to Agreement between the Company and Scottish Enterprise dated June 22, 2009 (previously filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, for the quarterly period ended June 30, 2009, originally filed with the SEC on August 13, 2009, and incorporated herein by reference).
10.10#	License Agreement by and between Sankyo Co., Ltd. and Cyclacel Limited, dated September 10, 2003, and letter amendments dated April 1, 2004 and April 28, 2004 (previously filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, for the quarterly period ended June 30, 2011, originally filed with the SEC on August 12, 2011, and incorporated herein by reference).
10.11#	Amendment No. 4 to License Agreement between Daiichi Sankyo Company, Limited and Cyclacel Limited, dated July 11, 2011(previously filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, for the quarterly period ended June 30, 2011, originally filed with the SEC on August 12, 2011, and incorporated herein by reference).
10.12	Common Stock Purchase Agreement, dated November 14, 2013, by and between Cyclacel Pharmaceuticals, Inc. and Aspire Capital Fund, LLC (previously filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, originally filed with the SEC on November 14, 2013, and incorporated herein by reference).
10.13	Form of Securities Purchase Agreement, by and between Cyclacel Pharmaceuticals, Inc. and certain investors (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on March 4, 2015, and incorporated herein by reference).
21	Subsidiaries of Cyclacel Pharmaceuticals, Inc. (previously filed as Exhibit 21 to the Registrant's Annual Report on Form 10-K, originally filed with the SEC on March 26, 2014, and incorporated herein by reference).
23.1*	Consent of Independent Registered Public Accounting Firm.

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EXHIBIT NUMBER	DESCRIPTION
31.1*	Certification of Spiro Rombotis, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Paul McBarron, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Spiro Rombotis, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code).
32.2**	Certification of Paul McBarron, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code).
101	The following materials from Cyclacel Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2015, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Statements of Income, (ii) the Condensed Consolidated Balance Sheets, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) Notes to Condensed Consolidated Financial Statements.

†
Indicates management compensatory plan, contract or arrangement.

#
Confidential treatment has been granted with respect to certain portions of this exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission as part of an application for confidential treatment pursuant to the Securities and Exchange Act of 1934, as amended.

*
Filed herewith.

**
Furnished herewith.

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SIGNATURES

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

CYCLACEL PHARMACEUTICALS, INC.

/s/ Paul McBarron

Date: March 29, 2016 By: Paul McBarron
Chief Operating Officer, Chief Financial Officer &
Executive Vice President, Finance
(Principal Financial and Accounting Officer)

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

Signature	Title	Date
/s/ Spiro Rombotis Spiro Rombotis	President & Chief Executive Officer (Principal Executive Officer) and Director	March 29 , 2016
/s/ Paul McBarron Paul McBarron	Chief Operating Officer, Chief Financial Officer & Executive Vice President, Finance (Principal Financial and Accounting Officer) and Director	March 29, 2016
/s/ Dr. David U'Prichard Dr. David U'Prichard	Chairman	March 29, 2016
/s/ Dr. Christopher Henney Dr. Christopher Henney	Vice Chairman	March 29, 2016
/s/ Dr. Nicholas Bacopoulos Dr. Nicholas Bacopoulos	Director	March 29, 2016
/s/ Sir John Banham Sir John Banham	Director	March 29, 2016
/s/ Samuel L. Barker Samuel L. Barker	Director	March 29, 2016
/s/ Gregory Hradsky Gregory Hradsky	Director	March 29, 2016
/s/ Lloyd Sems Lloyd Sems	Director	March 29, 2016

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