Cyclacel Pharmaceuticals, Inc.
Form 10-K
March 28, 2019
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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, 2018
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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter):

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 29, 2018 (based upon the closing sale price of $1.42 of such shares on The NASDAQ Capital Market on June 29, 2018) was $15,117,872.

As of March 28, 2019, there were 17,199,974 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 29, 2019.

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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 clinical-stage biopharmaceutical company using its expertise in cell cycle, transcriptional regulation and DNA damage response biology in cancer cells to develop innovative, targeted medicines for cancer and other serious diseases. Cyclacel is a pioneer company in the field of cancer cell cycle biology with a vision to improve patient healthcare by translating insights in cancer biology into medicines.

Our strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a development pipeline of novel drug candidates. We have retained rights to commercialize our clinical development candidates and our business objective is to enter into selective partnership arrangements with these programs. 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.

Cell Cycle Control Biology

Loss of control of the cell cycle, the process by which cells grow and divide, lies at the heart of cancer. In normal cells, a complex set of interacting proteins tightly regulates progression through the phases of the cell cycle by which a cell grows, replicates its DNA and divides. This process also includes mechanisms known as cell cycle checkpoints, to ensure all necessary events of each cell cycle phase are completed before beginning the next phase. If the events are not completed correctly, the cells may commit suicide by a process of programmed cell death called apoptosis. Cyclin dependent kinases, or CDKs, are key regulators among the numerous proteins involved in cell cycle control processes. CDKs connect with proteins called cyclins to regulate cell cycle checkpoints and control transcription, DNA repair and metastatic spread. The discovery of CDKs and cyclins and their regulation of cell cycle checkpoint control were cited in the 2001 Nobel Prize in Physiology or Medicine.

Using our core strength in cancer cell cycle biology, we have evaluated several families of anticancer drugs that impact the cell cycle, including CYC065, sapacitabine, CYC140 and seliciclib. We believe that these drug candidates are differentiated from others in that they are orally-available and demonstrate unique target profiles and mechanisms and have the potential to treat multiple cancer indications.

Our development efforts focus on the following areas:

Transcriptional Regulation:

Cyclin Dependent Kinase (CDK) Inhibitors

CDKs are a family of enzymes first discovered as regulators of the cell cycle, but now understood to also provide pivotal functions in the regulation of transcription, DNA repair and metastatic spread. The precise selectivity of an individual CDK inhibitor molecule for certain specific CDKs is key to targeting particular tumor types and minimizing undesirable side effects through non-specific antiproliferative activity.

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In general, cell cycle regulation is less well controlled in cancer cells than in normal cells, which explains in part why cancer cells divide uncontrollably. Different CDKs are responsible for control of different aspects of proliferation, and when dysregulated, can be drivers of particular cancer sub-sets. Modulating CDK activity with targeted therapies is an attractive strategy to reinforce cell cycle control and decrease the rate of abnormal proliferation of cancer cells. The Food and Drug Administration, or FDA, approved CDK inhibitors, palbociclib, ribociclib and abemaciclib, are all being used with hormone therapy in the treatment of hormone receptor-positive, HER2-negative breast cancer. This has led to great interest in the development of this class of drugs as oncology therapeutics.

Cyclacel's founding scientist, Professor Sir David Lane, is an internationally recognized authority in cell cycle biology, who discovered p53, a key tumor suppressor that malfunctions in about two-thirds of human cancers. Under his guidance, Cyclacel's drug discovery and development programs concentrated on the CDK2/9 isoforms, which operate as key components of the p53 pathway. These efforts resulted in bringing two molecules into clinical trials: seliciclib, a first-generation CDK inhibitor, and CYC065, a second-generation CDK inhibitor, which has benefited from the Company's clinical experience with seliciclib.

CYC065 is being evaluated as a single agent in a Phase 1 trial in patients with advanced solid tumors and in a Phase 1 trial in combination with venetoclax (ABT-199, AbbVie), a Bcl-2 inhibitor, in relapsed or refractory chronic lymphocytic leukemia, or CLL. CYC065 may also be most useful as a therapy for liquid and solid tumor patients in combination with other anticancer agents, such as venetoclax, or HER2 inhibitors, such as trastuzumab.

Seliciclib, our first-generation CDK inhibitor, is being evaluated in an all-oral Phase 1/2 combination study with our sapacitabine in patients with BRCA mutations, and has been evaluated to date in over 500 patients.

DNA Damage Response, or DDR

Many cancers have defects in the way in which cells monitor and repair damaged DNA, collectively termed DNA damage response, or DDR. These deficiencies in DDR pathways render cells more susceptible to DNA damage. Many traditional cancer treatments, such as DNA-damaging chemotherapy and radiotherapy, are based on this finding. However, such treatments are often accompanied by significant and unwanted side effects. Developing treatments which target specific DDR deficiencies to preferentially kill cancer cells, while minimizing the impact on normal cells, has potential for more effective, better tolerated therapies to improve survival in multiple cancers.

We have focused on developing treatments targeting DNA damage pathways for several years. For example, our drug candidate sapacitabine is an oral nucleoside analogue prodrug whose metabolite, CNDAC, generates single-strand DNA breaks, or SSB, either leading to an arrest of the cell cycle at G2 phase or development of double-strand DNA breaks, or DSB. Repair of CNDAC-induced DSB is dependent on the homologous recombination, or HR repair pathway. BRCA mutations in cancer cells are a cause of HR deficiency, making such cancer cells more susceptible to cell death induced by sapacitabine.

We are evaluating sapacitabine in a Phase 1/2 combination study with seliciclib in patients with BRCA mutations and in an investigator-sponsored Phase 1/2 combination study with olaparib, an approved PARP inhibitor, in BRCA mutation positive patients with breast cancer. We believe that dual targeting of the DNA damage response pathway with the addition of sapacitabine to olaparib may enhance the efficacy of the current standard of care for such patients.

Sapacitabine in AML

We are also evaluating sapacitabine in SEAMLESS, a Phase 3 study in acute myeloid leukemia, or AML, in the elderly, in an alternating schedule with decitabine. On February 23, 2017 we announced that the trial did not meet its primary endpoint of demonstrating statistically significant improvement in overall survival for the experimental arm versus an active control arm of decitabine alone. However an improvement in complete remission rate was observed. In the stratified subgroup of patients with low baseline peripheral white blood cell count, comprising approximately two-thirds of the study's population, a trend towards improvement in overall survival was observed for the experimental arm. Data were reported

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at an oral presentation at the 59th American Society of Hematology Annual Meeting in December 2017. We have met with three European regulatory authorities to discuss a potential approval pathway for sapacitabine and received consistent guidance from them. The discussions followed submission of statistical and exploratory analyses demonstrating sapacitabine's potential clinical benefit in a subgroup of patients for whom the sapacitabine regimen may represent an improvement over low intensity treatment by decitabine alone.

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.

Polo-like Kinase, or PLK1, Inhibitor — CYC140

CYC140 is a novel, small molecule, selective, PLK1 inhibitor. It has demonstrated potent and selective target inhibition, impressive efficacy in human tumor xenografts at non-toxic doses. The pharmaceutical properties of CYC140 are improved over earlier clinical PLK inhibitors. Polo Kinase was first discovered in fruit flies in 1988 by Cyclacel's former Chief Scientist, Professor David Glover. PLK1 is a serine/threonine kinase with a central role in cell division, or mitosis, and is an important regulator of the DNA damage checkpoint. Cyclacel's translational biology program supports the development of CYC140 in acute leukemias and solid tumors, including esophageal cancer. A first-in-human, or FIH, study is underway.

Oncology Development Programs

We have generated several families of anticancer drugs that act on the cell cycle, including CDK inhibitors, nucleoside analogs and PLK inhibitors. In our development programs, we have intensively used 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 analytes, 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 have observed evidence of durable target engagement by CYC065 with prolonged suppression of the Mcl-1, or myeloid cell leukemia1, protein biomarker in peripheral blood cells in patient samples from our Phase 1 clinical study and 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 us to select patients who are more likely to respond to our drugs in clinical trials and to increase the benefit to such patients.

Although a number of pharmaceutical and biotechnology companies are currently attempting to develop CDK inhibitors, nucleoside analogs and PLK inhibitors we believe that our drug candidates are differentiated in that they are orally-available and demonstrate unique target profiles and mechanisms.

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Research and Development Pipeline

The following table summarizes our development pipeline:

PROGRAM	INDICATION	DEVELOPMENT STATUS	COMMERCIAL RIGHTS
Transcriptional Regulation			
CYC065 CDK inhibitor	Solid Tumors incl. Mcl-1, MYC family, Cyclin E amplification	Phase 1 part 2 (ongoing)	Worldwide
	CLL combination with venetoclax, Bcl-2 inhibitor	Phase 1 (ongoing)	Worldwide
DNA Damage Response			
Sapacitabine and seliciclib CDK inhibitor	BRCA mutation positive breast, ovarian, pancreatic cancer	Phase 1 part 3 (ongoing)	Worldwide (except Japan)
Sapacitabine and olaparib PARP inhibitor	BRCA mutation positive breast cancer	Phase 1 (ongoing investigator-sponsored study)	Worldwide (except Japan)
Sapacitabine in AML Phase 3 SEAMLESS study	AML ≥70 years unfit for or refused intensive chemotherapy	Phase 3 completed(subgroup analysis)	Worldwide(except Japan)
Mitosis Regulation			
CYC140 PLK inhibitor	Advanced leukemias	Phase 1 (ongoing)	Worldwide

Transcriptional Regulation Program

CYC065 — Cyclin Dependent Kinase Inhibitor

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. The best characterized CDK enzymes include CDK2, -4, -6 and -9. Different CDK inhibitor drugs selectively target different sets of CDKs. This CDK inhibitory profile is key for treating particular tumor types and avoiding undesirable side effects through nonspecific or off-target activity. Cyclacel's CDK inhibitors, CYC065 and seliciclib, target CDKs 2 and 9. CDK2/9 inhibition may also overcome aberrant cell cycle control in certain non-malignant diseases of proliferation.

The FDA approved CDK4/6 inhibitors, palbociclib, ribociclib and abemaciclib, represent an important therapeutic advance and are associated with very promising progression-free survival advantages with good tolerability when combined with hormone therapy versus hormone therapy alone in patients with hormone receptor-positive, HER2-negative breast cancer. CDK4/6 inhibitors, such as palbociclib, induce senescence or dormancy of cancer cells, which may be associated with the emergence of resistance. If clinical manifestation of resistance becomes common, the therapeutic utility of CDK4/6 inhibitors could be hampered.

Pharmacological inhibition of the CDK2/9 isoforms has been shown to have potent anticancer effects in certain cancer types, including some that are resistant to approved treatments. CDK2/9 inhibitors have been shown to induce apoptosis of cancer cells. It is hoped that treatment with CDK2/9 inhibitors will result in clinically relevant, tumor cell death in patients with selected cancer types. Similar to the approved CDK 4/6 inhibitors, CDK2/9 inhibitors will likely be given in combination with other available anticancer agents. For example, a potential use of CDK2/9 inhibitors may be to overcome cyclin E dependent resistance to CDK4/6 inhibitors and hormone therapy when given in combination with one or more of these agents.

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Different CDKs are responsible for controlling different aspects of proliferation which, when dysregulated, can be drivers of particular cancer sub-sets. Our CDK clinical candidates target:

- CDK2, which drives cell cycle transition and activates major DNA double-strand break pathways; and

- CDK9, which regulates transcription of certain genes, including cyclins, Mcl-1, MYC family and DNA double-strand break repair pathway components, through phosphorylation of RNA polymerase II.

Mcl-1 is overexpressed in many types of cancer acting as a survival and drug resistance mechanism. Multiple studies show that knockdown of Mcl-1 leads to cancer cell death and resensitization to drug treatment.

MYC proto-oncogenes encode MYC family proteins which ware overexpressed in over 50% of human cancers often via gene amplification. MYC proteins are transcriptional regulators which promote cancer cell growth and survival by increasing the expression of target genes involved in cell metabolism and growth. MYCN gene amplification is found in 45% of high-risk neuroblastomas, or NB, a childhood cancer with 10% long term survival.

CYC065 is a selective, second-generation inhibitor of CDK2/9 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 preclinical models with once a day oral dosing at well tolerated doses. CYC065 is mechanistically similar to seliciblib, Cyclacel's first-generation CDK2/9 inhibitor, but has much higher potency in vitro and in vivo, improved metabolic stability and longer patent protection. Translational biology data support development of CYC065 in Mcl-1 dependent cancers. In a Phase 1, first-in-human study of CYC065, prolonged reduction of Mcl-1 for at least 24 hours was achieved and preliminary anticancer activity observed. CYC065 has been shown to inhibit CDK9-dependent oncogenic and leukemogenic pathways, including MYCN and mixed lineage leukemia rearrangements, or MLL-r. CYC065 and seliciclib both suppress the Mcl-1-mediated survival pathway in cancer cells, leading to rapid induction of apoptosis in Mcl-1 dependent cancer cells and reversal of drug resistance associated with the addiction of cancer cells to cyclin E, a partner protein of CDK2.

Clinical development

CYC065 has completed part 1 of a first-in-human, single agent, ascending dose, Phase 1 trial to assess its safety, tolerability, pharmacokinetics and pharmacodynamics in patients with advanced solid tumors. The results of part 1 of the study were reported in an oral presentation at the 2018 Annual Meeting of the American Association of Cancer Research. 26 patients were treated with CYC065 as a 4-hour infusion once every 3 weeks and a recommended Phase 2 dose, or RP2D, established. Durable Mcl-1 suppression was observed in 11 of 13 patients treated at the RP2D. Stable disease lasting at least six cycles was observed in six patients of which three had molecular features associated with CYC065's mechanism, including Mcl-1, MYC or cyclin E. Dose limiting toxicities were reversible neutropenia, thrombocytopenia, febrile neutropenia, diarrhea, hypomagnesemia, white blood cell lysis syndrome and its associated electrolyte abnormalities and liver enzyme elevations. Part 2 of this Phase 1 translational study is evaluating additional dosing schedules in patients with advanced solid tumors, in particular those with amplification of Mcl-1, MYC family or cyclin E. We plan to open part 3 of the study to evaluate an oral form of CYC065.

Supported by strong preclinical activity and the evidence of durable suppression of Mcl-1 from the Phase I FIH study we plan to evaluate CYC065 in hematologic malignancies as follows:

Mcl-1 dependent cancers

Chronic lymphocytic leukemia

We have opened enrollment of a Phase 1 study to evaluate CYC065 in combination with venetoclax in patients with relapsed or refractory CLL.

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CLL cell survival depends on the expression of anti-apoptotic proteins, including Mcl-1 and Bcl-2. In this context, targeting Mcl-1 or Bcl-1 releases pro-death signals and commits CLL cells to apoptosis. Venetoclax was recently approved as a second line treatment of relapsed/refractory CLL with or without 17p deletion after at least one prior therapy.

The pan-CDK inhibitors flavopiridol and dinaciclib have shown efficacy in CLL clinical trials, providing clinical proof-of-concept for the targeting of anti-apoptotic pathways in such leukemias. Mcl-1 expression can modulate resistance to Bcl-2 inhibition and is known to be upregulated in lymph node CLL cells, possibly leading to resistance to venetoclax.

Rapid cell death was induced in CLL and multiple myeloma cell lines after short exposure to CYC065, even in the presence of stromal cells which confer protection from standard treatments. Mcl-1 down-regulation was observed, consistent with the pro-apoptotic mechanism of CYC065. CYC065 synergizes with venetoclax in preclinical models at clinically achievable concentrations, supporting the clinical investigation of combination regimens of CYC065 and venetoclax.

Acute myeloid leukemia, or AML

Drug resistance in AML has been attributed among others to high levels of Mcl-1. AML cell lines are highly sensitive to CYC065 and 5 to 8 hours treatment is sufficient to achieve induction of cell death. CYC065 has single agent efficacy in AML xenografts and the potential to be combined with approved AML therapies. In leukemia cells harboring the rearranged Mixed Lineage Leukemia gene (MLLr) CYC065 reduced both Mcl-1 expression and CDK9 dependent transcription of MLL-regulated leukemogenic genes.

We anticipate opening for enrolment a Phase 1 study evaluating CYC065 in combination with venetoclax in patients with relapsed or refractory AML or myelodysplastic syndromes, or MDS.

Biospecimens will be collected from the clinical trials for assessment of biomarkers related to CYC065's mechanism of action.

Published preclinical data

Preclinical data supports the molecular rationale and therapeutic potential of CYC065 in both hematologic and solid tumors.

- Induces cancer cell death and can combine beneficially with other anti-cancer drugs

CYC065 targets key CDK9-dependent oncogenic and leukemogenic survival pathways. Data presented at the 2018 Annual Meeting of the American Association of Cancer Research demonstrated strong synergy between, CYC065, and the Bcl-2 inhibitor, venetoclax in primary chronic lymphocytic leukemia, or CLL, cells obtained from patients, including those with 17p deletions. In addition, the combination was active in two CLL samples which were resistant to either agent alone.

Data presented at the 2016 Annual Meeting of the American Association of Cancer Research demonstrated that CYC065 can induce cell death and combined beneficially with anti-cancer drugs from the Bcl-2 and BET (Bromodomain and Extra-Terminal domain) inhibitor classes, in in vitro models of B-cell lymphoma, including double-hit lymphomas. Combinations of CYC065 with the Bcl-2 inhibitor, venetoclax (ABT-199), or BET inhibitors were both synergistic. Short exposure to CYC065 was sufficient to downregulate MYC, an oncogene product aberrantly expressed in many cancers, and Mcl-1, an anti-apoptotic member of the Bcl-2 family, and to induce cell death. CYC065 treatment had no impact on Bcl-2 levels.

These findings support the hypothesis that dual targeting of the Mcl-1- and Bcl-2-dependent mechanisms could induce synergistic cell death by apoptosis and highlight an opportunity to rationally disrupt the pathways promoting the survival of CLL cells. Cyclacel has opened for enrolment a Phase 1 clinical study to evaluate CYC065 in combination with venetoclax in patients with relapsed/refractory CLL.

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Potent anticancer activity of CYC065 has been demonstrated in vivo in AML xenograft models resulting in over 90% inhibition of tumor growth.

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Prolonged survival and reduced tumor burden in MYCN-addicted neuroblastoma

The MYCN oncogene is over-expressed in a number of different types of cancer, most notably neuroblastoma, but also rhabdomyosarcoma, medulloblastoma, astrocytoma, Wilms' tumor and small cell lung cancer. Amplification of the MYCN oncogene is the most common genomic alteration in aggressive neuroblastomas, and is associated with poor clinical outcome. Preclinical data presented at the 2016 Childhood Cancer Meeting demonstrated that CYC065 prolonged survival in MYCN-addicted neuroblastoma models, and neuroblastoma cells with MYCN amplification and overexpression were found to be particularly sensitive. The mechanism of action of CYC065 included inhibition of MYCN transcription, downregulation of N-MYC protein, blocking neuroblastoma cell proliferation and inducing apoptosis. There are no approved drugs that directly target MYCN, prompting the investigation of indirect approaches such suppression of MYCN gene expression via CDK9 inhibition, or as exploitation of a synthetic lethal relationship between MYCN amplification/ overexpression and inhibition of CDK2.

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May reverse drug resistance associated with addiction of cancer cells to cyclin E, the partner protein of CDK2

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, while administration of CYC065 in combination with trastuzumab resulted in regression or sustained tumor growth inhibition.

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May have activity in triple-negative breast cancer

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's potent anticancer activity has been confirmed in. Like seliciclib, CYC065 combined effectively with sapacitabine in breast cancer cell lines.

We anticipate that CYC065 will likely be best used in combination with available anti-cancer agents, as is the case for recently approved CDK4/6 inhibitors. We have retained worldwide rights to commercialize CYC065.

Seliciclib, our first-generation CDK inhibitor, is a novel, orally-available, CDK2/7/9 inhibitor that has been evaluated in over 500 patients. As CYC065 has improved potency and pharmacological properties compared to seliciclib, we would expect to advance CYC065 in lieu of seliciclib.

DNA Damage Response program

Sapacitabine and CDK inhibitor

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, which can be repaired by the homologous recombination, or HR, repair pathway, or, if unrepaired, result in cell death.

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Sapacitabine has been evaluated in both hematological cancers and solid tumors. Over 1,000 patients have received sapacitabine in Phase 1, 2 and 3 studies.

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.

Phase 1/2 clinical trial of sapacitabine and seliciclib in patients with advanced cancers

In an ongoing Phase 1, single-arm, dose escalation study, sapacitabine and seliciclib are orally-administered sequentially in patients with incurable advanced solid tumors unresponsive to conventional treatment or for which no effective therapy exists. In Part 1 of the study 38 patients were treated with sapacitabine administered twice daily for 7 days sequentially followed by seliciclib twice daily for 3 days over a 21 day cycle, and in Part 2, 29 patients were dosed with sapacitabine each morning followed by seliciclib each evening, each once daily for 5 days per week for 2 weeks of a 28 day cycle. The primary objective of the trial is to determine the maximum tolerated dose with a secondary objective of antitumor activity of the combination. Sixty-seven patients have been treated in Parts 1 and 2 of the study, of which 44 were found to carry germline BRCA mutations and one a sporadic BRCA mutation.

The BRCA1 and BRCA2 gene mutations are the most common cause of homologous repair deficiency. In BRCA-mutated tumor cells, homologous recombination repair is defective and DNA double-strand break repair capacity is reduced and may via error-prone pathways, which can lead to genomic instability and cell death. Carriers of BRCA in their germline, have been reported to have a higher probability of developing breast, ovarian, prostate and pancreatic cancer than the general population.

Data from Part 1 and 2 of the study were presented at the 2016 American Society of Clinical Oncology Annual Meeting. Antitumor activity was observed in the subgroup of 45 patients with breast, ovarian and pancreatic cancers who tested positive for BRCA mutations (44 germline and 1 sporadic) with an overall disease control rate of over 30%. Best responses were as follows:

Best Responses

	PART 1		PART 2	
	BRCA carriers (n=16)	Others (n=22)	BRCA carriers (n=28)	Others (n=1)
CR	1	—	—	—
PR	3	—	2	—
SD	2	6	7	1*
ORR (CR/PR)	25%	0%	7%	0%
Disease Control (CR/PR/SD)	6 (37.5)%	6 (27.3)%	9 (32.1)%	1 (100.0)%

*

Patient with a sporadic BRCA mutation, i.e. not inherited. CR=complete response, PR=partial response, SD=stable disease, ORR=overall response rate.

One CR and five PR were observed in BRCA mutation carriers with breast, ovarian and pancreatic cancers. No CR or PR was observed in BRCA negative patients. Treatment durations for three breast/ ovarian cancer responders in Part 1 are 54, 93 and over 240 weeks and one breast cancer responder in Part 2 over 76 weeks respectively. Treatment durations for the two pancreatic cancer responders, one each in Parts 1 and 2, are 21 and 16 weeks, respectively. Responders included patients who underwent prior treatment with PARP inhibitors and PARP naïve patients. Stable disease was observed in nine BRCA mutation carriers and one sporadic BRCA positive patient, with treatment durations ranging from 16 to 88 weeks. The overall response rate, or ORR, is 11% (Part 1 ORR 25% and Part 2 7%). The difference in Part 1 and Part 2 ORRs may suggest that the seliciclib dose in the Part 2 schedule may be too low for enhancing the activity of sapacitabine. Dose limiting toxicities were reversible elevations in transaminase and bilirubin, neutropenia or febrile neutropenia and pneumonia. Adverse events were mild to moderate in intensity.

Pharmacodynamic effects of the seliciclib and sapacitabine combination were observed in skin biopsies. Part 1 biopsies following 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.

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Approved treatment for advanced ovarian cancer, including but not limited to BRCA-mutated (germline and/or somatic) associated advanced ovarian cancer, include the poly ADP-ribose polymerase, or PARP, inhibitors, olaparib, niraparib and rucaparib. We believe that sapacitabine, possibly administered alongside a PARP or CDK inhibitor, may offer an alternative or complementary approach to PARP inhibitors in this area of unmet medical need. Once mature data become available from a completed extension study of an additional 20 BRCA mutation positive patients with metastatic breast cancer and an ongoing Part 3 evaluating alternative dosing schedules, we will consider further development plans. In parallel, an investigator-sponsored study is enrolling at Dana Faber Cancer Centre evaluating sapacitabine with olaparib in patients with BRCA positive breast cancer.

Sapacitabine in AML

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

On February 23, 2017, we announced that the trial did not meet its primary endpoint of demonstrating statistically significant improvement in overall survival, or OS, for the experimental arm versus an active control arm. An improved rate of complete remission, or CR, a secondary endpoint, was observed in patients who had discontinued therapy at the time of analysis. Other endpoints and safety were similar between the arms. In the stratified subgroup of patients with low baseline peripheral white blood cell count, comprising approximately two-thirds of the study's population, a trend toward improvement in OS was observed for the experimental arm. The opposite was true for patients with high white blood cell count. Full results from the SEAMLESS study were presented at the 59th American Society of Hematology, or ASH Annual Meeting in December 2017.

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. Stratification factors at randomization were antecedent hematological disorders, baseline peripheral white blood cells and baseline bone marrow blasts. SEAMLESS completed enrollment in December 2014 with approximately 110 centers participating in the United States and Europe.

In December 2014, the study's independent 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 had 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.

In accordance with the DSMB's recommendations, we followed-up patients as per the study protocol until the prespecified 424 events had been observed.

Stratified and exploratory subgroup analyses have been completed and have defined a patient population who may benefit from treatment with the experimental arm. We have met and received consistent guidance from three European regulatory authorities regarding a potential approval pathway for sapacitabine. The discussions followed submission of statistical and exploratory analyses demonstrating sapacitabine's potential clinical benefit in a subgroup of patients for whom the sapacitabine regimen may represent an improvement over low intensity treatment by decitabine alone. We previously submitted, and have received validation of, a Pediatric Investigation Plan, or PIP, to the EMA, or European Medicines Agency.

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

We have evaluated sapacitabine in an open-label, multi-center, randomized Phase 2 trial in patients aged 60 or older with intermediate-2 or high-risk myelodysplastic syndromes, or MDS, after treatment

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failure of front-line hypomethylating agents, such as azacitidine and/or decitabine. The study randomized 63 patients 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 in 3 dosing schedules.

At the 2013 ASH Meeting and Exposition, we announced one-year survival data, the study's primary endpoint. The median overall survival for each arm was approximately 9.7 months for Arm G, 9.7 months for Arm H, and 7.6 months for Arm I. The median overall survival for all three arms was approximately 8.6 months. One-year survival was 38% for Arm G, 24% for Arm H, and 33% for Arm I. Nine patients had responded (2 CRs, 2 CRp, and 5 major HIs): 19% for Arm G, 10% for Arm H and 14% for Arm I and the time to response was one to four cycles. Median number of cycles was three with a range of one to over 23 and 30 patients received four or more cycles. Additionally, 23 patients achieved stable disease lasting longer than 16 weeks. The 30 day mortality from all causes was 5% in each of the three arms and ten patients, or approximately 16%, were still alive.

Median 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

In 2008, sapacitabine received orphan drug designation for the treatment of both AML and MDS from the EMA, which confers a range of benefits to sponsor companies, including market exclusivity for a period of 10 years following a product's approval for either of these indications in Europe. In 2010, the FDA granted orphan drug designation to sapacitabine for the treatment of AML and MDS, which confers a range of benefits to sponsor companies, including market exclusivity for a period of seven years from the date of drug approval.

Polo-Like-Kinase inhibitor — CYC140

In our polo-like kinase, or 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. Polo kinase was discovered by Professor David Glover, our former Chief Scientist. We have opened a Phase I FIH study for enrollment evaluating CYC140 in patients with advanced leukemias. We have retained worldwide rights to commercialize CYC140.

Preclinical data presented at the 2016 28th EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics Symposium demonstrated the therapeutic potential of CYC140 as a targeted anti-cancer agent. The data demonstrated that CYC140 is a selective PLK1 inhibitor which preferentially induces growth inhibition and cell death in malignant versus non-malignant cells.

Treatment of proliferating cells with CYC140 resulted in reduced phosphorylation of the PLK1 substrate phospho-nucleophosmin, accumulation of cells in mitosis and an increase in the proportion of mitotic cells with monopolar spindles, which are all features consistent with PLK1 inhibition. In a cell line panel derived from esophageal cancer and various non-malignant solid tissues, CYC140 was preferentially cytotoxic to malignant cells. Its differential cytotoxicity is further increased through pulse treatment. Malignant cells which are sensitive to CYC140 undergo complete growth inhibition and induction of cell death in response to treatment. In contrast, non-malignant cells are only temporarily arrested and normal cell cycle transit is restored.

Potent anti-tumor activity of CYC140 has been demonstrated in preclinical xenograft models of acute leukemia and solid tumors, including esophageal cancer, with tumor growth delay, tumor regression and cures being observed. Identification of several pharmacodynamic markers and demonstration of activity in a majority of malignant cell lines derived from AML, acute lymphoblastic leukemia, or ALL, and esophageal cancer support prospective clinical development of CYC140, alone and in several potential combinations with targeted agents.

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MD Anderson Cancer Center

In October 2018 we entered into a three-year strategic alliance agreement with The University of Texas MD Anderson Cancer Center that will enable clinical evaluation for safety and efficacy of three of our medicines in patients with hematological malignancies, including CLL, AML, MDS and other advanced leukemias.

MD Anderson will conduct four clinical studies with a total projected enrollment of up to 170 patients, which will investigate CYC065, CYC140 and sapacitabine either as single agents or in combination with approved drugs. The collaboration leverages MD Anderson's expertise in clinical development of drugs for hematological malignancies and our novel drug portfolio that is based on our knowledge of cell cycle biology and mechanisms of cancer cell resistance to medicines.

Under the agreement, MD Anderson will assume the patient costs for all studies and we, as the sponsor, will provide investigational drugs and other limited support. Upon first commercial sale in specific indications studied in the alliance, we will make certain payments to MD Anderson.

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, 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 ongoing investigator sponsored trials, or ISTs, evaluating oral seliciclib capsules in endocrinologic and inflammatory indications in patients who have failed prior treatments. In an IST at Cedars-Sinai, Los Angeles, supported in part by a grant from The National Institute of Diabetes and Digestive and Kidney Diseases, patients are being treated in an ongoing Phase 2 trial to evaluate seliciclib as a potential therapy for Cushing's disease. Cushing's disease is characterized by abnormally high levels of cortisol, a stress hormone, associated with pituitary tumors, which are highly sensitive to cell cycle disruptions. In a European IST, oral seliciclib capsules are being evaluated as a potential treatment for rheumatoid arthritis, or RA. Investigators are evaluating whether seliciclib can benefit patients with RA by targeting proliferating fibroblasts. If confirmed, this would be a novel approach compared to approved 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, Cyclacel entered into a collaboration, licensing and supply agreement with ManRos Therapeutics SA, or ManRos, for the exclusive development and commercialization by ManRos of our oral seliciclib capsules 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. We have received upfront payments and may 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

We plan to continue to build a diversified biopharmaceutical business focused in hematology and oncology based on a pipeline of novel drug candidates and utilizing our area of historical expertise in cancer cell cycle and mitosis biological mechanisms. Our clinical development strategy is focused on two ongoing programs in transcriptional regulation and DNA damage response.

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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 team 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.

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 clinical-stage drug programs. To optimize our commercial return, we intend to enter into selected partnering arrangements and to retain 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.

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.

In-license Agreement with Daiichi Sankyo

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 sapacitabine. Daiichi Sankyo filed patent applications claiming sapacitabine, certain crystalline forms and methods for its preparation and use which encompass our chosen commercial development form, as well as related know-how and materials. The license grants us the exclusive right to exploit and sublicense sapacitabine and any other products covered by the patents and patent applications owned by Daiichi Sankyo. The license was originally subject to certain third-party rights related to certain territories but the license has since been expanded to a worldwide territory. The license agreement also grants to us nonexclusive, sublicensed rights to CNDAC, which is 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. 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

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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.

Patents and Proprietary Technology

Patents and Proprietary Rights

We own 19 patents granted in the United States, 13 granted by the European Patent Office, or EPO, and 53 granted in other countries worldwide. In addition, we have a license to 37 patents granted in the US, by the EPO or worldwide. We have 4 patent applications pending in the United States, 1 before the EPO, 10 pending patent applications in other countries and two pending PCT applications still in the international application phase. No assurances can be given that any 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 2 pending patent applications worldwide to which we have a license.

Intellectual Property Strategy

We consider intellectual property rights to be vital and use a variety of methods to secure, protect and evaluate these rights. These methods include ownership and enforcement of patent rights, patent applications, license agreements with third parties, invention assignment, confidentiality and non-compete agreements with key employees and consultants, material transfer agreements, and trademark protection.

We give priority to obtaining substance of matter claims in the United States, the EPO, Japan and other important markets if such protection is available. We prefer substance of matter claims because they provide us with 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.

Since publications in the scientific or patent literature often lag behind actual discoveries, we are not certain of being first to make the inventions covered by each of our pending patent applications or the first to file those patent applications. Generally, patent applications in the United States are maintained in secrecy for a period of 18 months or more, which increases the uncertainty we face. Moreover, the patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. As a result, we cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. To date, there has been no consistent policy regarding the 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

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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 drug candidates, sapacitabine, seliciclib, CYC065 or other therapeutic candidates, or 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 potential uses of sapacitabine, seliciclib and CYC065 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. For example, in one case we opposed a European patent relating to human aurora kinase and the patent has been finally revoked (no appeal was filed). Litigation would create substantial costs. 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.

CYC065

Issued patents for the CYC065 compound cover the United States, EPO and ten other countries.

Sapacitabine

Issued patents for the sapacitabine compound expired in the United States in 2014 and elsewhere in 2012. Patents for the crystalline forms issued in the United States, EPO, Japan and thirteen other countries. 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. There is no assurance that we will be able to obtain any such extension.

Separately, we own an issued United States patent with granted claims to a specified method of administration of sapacitabine, adding to the existing composition of matter patents and supporting market exclusivity out to 2030. We also own patents issued in the United States or in Europe which claim methods of use of sapacitabine with hypomethylating agents, including decitabine which has been tested in the SEAMLESS Phase 3 trial, and with other anticancer drugs.

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, EMA and comparable regulatory agencies in state and local jurisdictions 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.

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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;

- 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

- 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

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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 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:

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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.

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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.

When appropriate, we and our collaborators, as applicable, 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

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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 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, AstraZeneca, Onconova, Boehringer Ingelheim, BMS/Innate, Celgene, CTI Biopharma, Daiichi Sankyo, Eisai, Jazz, GlaxoSmithKline, Johnson & Johnson, Lilly, MEI Pharma, Otsuka, Pfizer, Sanofi, Sunesis and Teva. Several pharmaceutical and biotechnology companies have CDK inhibitors in clinical trials including Bayer, Dainippon Sumitomo, G1 Therapeutics, Lilly, Merck, MetaMax, MEI Pharma, Nerviano Medical Sciences/Tiziana Life Sciences, Novartis, Otsuka/Astex, Pfizer, Piramal, Astra Zeneca and Tragara. Several companies are pursuing discovery and research activities in each of the other areas that are the subject of our research and drug development programs. We believe that Amgen, AstraZeneca, CASI Pharmaceuticals, Nerviano Medical Sciences, Nemucore, Otsuka/Taiho Oncology and Takeda are conducting clinical development of Aurora kinase inhibitors for hemato-oncology indications. We believe that Arbutus Biopharma, Boehringer Ingelheim, GlaxoSmithKline, Merck, Nerviano Medical Sciences/Trovagene and Takeda have commenced clinical trials with PLK1 inhibitor candidates for hemato-oncology indications.

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Legal Proceedings

From time to time, we may be involved in routine litigation incidental to the conduct of our business. As of December 31, 2018 we were not party to any material legal proceedings.

Employees

As of March 28, 2019, we had 14 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

We were incorporated in Delaware in August 1997. 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 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.

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Item 1A. Risk Factors

In analyzing our company, you should consider carefully the following risk factors. Factors that could cause or contribute to differences in our actual results include those discussed in the following subsection, as well as those discussed below 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

Our SEAMLESS Phase 3 study failed to meet its primary endpoint of demonstrating statistically significant improvement in overall survival for the experimental arm versus an active control. While we may discuss the data from the SEAMLESS Phase 3 study with regulatory authorities, we may be unable to identify a viable path forward for continued development for, or be able to obtain regulatory approval for, or commercialize, this product indication.

To date, we have devoted significant research, development and clinical efforts and financial resources toward the development of sapacitabine. On February 23, 2017, we announced top-line results from the pivotal Phase 3 SEAMLESS study in elderly patients aged 70 years or older with newly diagnosed AML, who are not candidates for or have refused intensive induction chemotherapy. The trial did not meet its primary endpoint of demonstrating statistically significant improvement in overall survival for the experimental arm versus an active control. Our clinical development strategy in oncology will henceforth concentrate on our two ongoing, clinical programs in DNA damage response and transcriptional regulation, which include our area of historical expertise in CDK inhibitors. These programs target biomarker-selected patients, such as those with BRCA mutations or resistance to existing cancer therapies.

An improved rate of complete remission, a secondary endpoint, was observed in patients who had discontinued therapy at the time of analysis. While we plan to discuss the data from the SEAMLESS Phase 3 study with European and U.S. regulatory authorities, we may be unable to salvage any value from the Phase 3 trial and may be unable to identify a viable plan for continued clinical development of this product indication. Even if we are able to design further trials and identify a path forward toward potential regulatory approval, such development will likely require significant financial and personnel resources, and no assurance can be given that additional capital would be available or that such capital would be available at acceptable terms. Our continuing analyses of data from the topline Phase 3 trial may also produce negative or inconclusive results.

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, and/or may no longer be binding on the FDA. Thus, our Special Protocol Assessment ("SPA") regarding our SEAMLESS trial does not guarantee marketing approval of our sapacitabine oral capsules for the treatment of AML. 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.

As the SEAMLESS trial did not achieve the primary basis for an efficacy claim, the SPA agreement with the FDA is no longer binding on the FDA.

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 may also 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

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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 Institutional Review Board, or 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, as demonstrated by our announcement on February 24, 2017 that our SEAMLESS Phase 3 study failed to reach its primary endpoint;

- 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 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.

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 a decrease in potassium levels has been observed in patients receiving seliciclib. In addition, we have or may pursue clinical trials for CYC065, 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

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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 that they may 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, research institutions or other industry participants to advance our programs and enable us to maintain our financial and operational capacity.

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.

We expect to continue to be dependent upon collaborative arrangements or strategic alliances to complete the development and commercialization of some of our drug candidates, including but not limited

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to 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 risks 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 as 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 its 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 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 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 additional or 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 innovations. 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.

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.

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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: Phases 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 the 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. As the trial did not meet its primary endpoint of
demonstrating statistically significant improvement in overall survival for the experimental arm versus an active control, 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 and 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 FDA or EMA officials may find that our or our third party manufacturer’s processes or facilities are not in compliance with cGMP; or

- the fact that new regulations may be enacted by the FDA or EMA pursuant to which they 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

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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 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 if a regulatory agency 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 the imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose other administrative or judicial civil or criminal penalties;
- withdraw regulatory approval;
- refuse to approve pending applications or supplements to approved applications filed by us or our potential future collaborators;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products.

Even if we successfully complete the clinical trials for 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, without limitation, the possibilities 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;

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- have adverse side effects that make their use less desirable; or

- fail to compete effectively 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 are approved by the FDA or EMA, together with another agent such as decitabine, 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;

- 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.

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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, and 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.

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 pairs to contain or reduce the cost of healthcare through various means

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.

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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 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

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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.

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

One of our primary strategies for product candidates under development 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.

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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;
- 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

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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

Our ability to raise 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, 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 plan, we expect our existing resources to be sufficient to fund our planned operations through at least the second quarter of 2020, although our estimates may prove to be incorrect and we could spend our available financial resources faster than we currently expect. 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.

The United Kingdom’s proposed exit from the European Union could adversely impact our business, results of operations and financial condition

In 2016, the United Kingdom held a referendum in which voters approved an exit from the European Union, commonly referred to as “Brexit.” As a result of the referendum, the United Kingdom parliament voted in March 2017 to commence the United Kingdom’s official withdrawal process from the European

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Union. Negotiations between the United Kingdom and the European Union remain ongoing and are complex, and there can be no assurance regarding the terms, timing or consummation of any resulting agreements. The United Kingdom is due to leave the European Union automatically at the earliest on April 12, 2019 or the latest on May 22, 2019 depending on the voting of the United Kingdom parliament, unless the negotiations are extended by unanimous consent of the European Council.

The effects of Brexit will depend on any agreements the United Kingdom makes to retain access to European Union markets either during a transitional period or more permanently. The measures could potentially disrupt the markets and tax jurisdictions in which we operate, including our wholly owned subsidiary Cyclacel Limited, which was organized under the laws of England and Wales, and our research facility in Dundee, Scotland, which is also the center of our translational work and development programs, and adversely change tax benefits or liabilities in these or other jurisdictions, and may cause us to lose potential customers, suppliers, and employees. In addition, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which European Union laws to replace or replicate.

The implementation of Brexit may also create global economic uncertainty, which may cause partners, suppliers and potential customers to closely monitor their costs and reduce their spending budget.

Since Scottish voters were overwhelming in favor of the United Kingdom remaining in the European Union, Scotland may in the future seek independence from the United Kingdom, as it unsuccessfully sought to do by referendum in September 2014. Any such efforts by Scotland to separate from the United Kingdom, even if unsuccessful, could lead to uncertainty and further disrupt the markets and tax jurisdictions in which we operate, and may cause us to lose potential customers, suppliers, and employees.

Any of these effects of Brexit, among others, could materially adversely affect our business, business opportunities, results of operations, financial condition and cash flows.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the “Tax Cuts and Jobs Act,” or TCJA, that significantly reforms the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest and net operating loss carryforwards, allows for the expensing of capital expenditures, and puts into effect the migration from a “worldwide” system of taxation to a territorial system. Our net deferred tax assets and liabilities have been revalued at December 31, 2017 using the newly enacted U.S. corporate rate. This reduced our net deferred tax asset by $4.1 million, which was offset by a corresponding decrease in the valuation allowance. We continue to examine the impact this tax reform legislation may have on our business. The impact of this tax reform is uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged

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government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon completion of this offering and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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 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.

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 such 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. As our Phase 3 study for AML did not meet its primary endpoint of demonstrating statistically significant improvement in overall survival for the experimental arm versus an active control our clinical development programs are now all at an early stage of testing in Phase 1⁄2. CYC065 is in a first-in-human Phase 1 study and a combination of sapacitabine and seliciclib, is currently in a Phase 1⁄2 clinical trial. 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.

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, 2017 and December 31, 2018, our accumulated deficit was $342.5 million and $349.8 million, respectively. Our net loss was $7.5 million and $7.3 million for the years ended December 31, 2017 and 2018, respectively. In addition to the SEAMLESS study, which we announced on February 23, 2017 failed to reach its primary endpoint, our drug candidates are in the early- to 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

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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 January 8, 2019, we received a letter from the Listing Qualifications Staff (the "Staff") of The NASDAQ Stock Market LLC 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). Pursuant to the NASDAQ Listing Rule 5810(c)(3)(A), the Company was granted a 180-calendar day compliance period, or until July 7, 2019, to regain compliance with the minimum bid price requirement. During the compliance period, the Company's shares of common stock will continue to be listed and traded on The NASDAQ Capital Market. To regain compliance, the closing bid price of the Company's shares of common stock must meet or exceed $1.00 per share for at least ten consecutive business days during this 180-day grace period. If the Company is not in compliance by July 7, 2019, we may be eligible for an additional 180-calendar day compliance period. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The NASDAQ Capital Market, except for the minimum bid price. In addition, we would be required to notify NASDAQ of our intent to cure the minimum bid price deficiency by effecting a reverse stock split, if necessary. If we do not regain compliance within the allotted compliance period(s), including any extensions that may be granted by NASDAQ, NASDAQ will provide notice that our shares of common stock will be subject to delisting, and we would then be entitled to appeal NASDAQ's determination to a NASDAQ Hearings Panel and request a hearing.

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, 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

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distribution capabilities. The development and commercialization of our drug candidates is very expensive. 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, including our discussions with European and United States regulatory authorities concerning the top-line data from our pivotal Phase 3 SEAMLESS study;
- 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;
- the effect of competing technological and market developments; and
- 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.

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

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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, since announcing that our SEAMLESS trial failed to meet its primary endpoint, we have decided to focus our clinical development strategy in oncology on our two ongoing, clinical programs in transcriptional regulation and DNA damage response, which include our area of historical expertise in 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.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation. Our business and operations would suffer in the event of system failures.

In the ordinary course of our business, we collect and store sensitive data, intellectual property and proprietary business information owned or controlled by ourselves or our customers. This data encompasses a wide variety of business-critical information including research and development information, commercial information, and business and financial information. We face four primary risks relative to protecting this critical information: loss of access; inappropriate disclosure; inappropriate modification; and inadequate monitoring of our controls over the first three risks.

We utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. The secure processing, storage, maintenance, and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. As use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our systems and networks and the confidentiality, availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from such cyber-attacks, including computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such an event could cause interruption of our operations. For example, the loss of data from ongoing or completed clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs. In addition, there can be no assurance that we will promptly detect any such disruption or security breach, if at all. To the extent that any disruption or security breach were to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could suffer reputational harm or face litigation or adverse regulatory action and the development of our product candidates could be delayed.

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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 in 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. Seliciclib is protected by granted patents claiming 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 2033. 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.

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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.

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 on 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

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uses of our drug candidates sapacitabine, seliciclib, CYC065 or other therapeutic candidates, or 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, seliciclib and CYC065 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 in the area of kinases, including CDK and PLK 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).

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.

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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 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. 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 Inter Partes Review (IPR) or 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 do not grant patent claims directed to methods of treating humans and, in these countries, patent protection may take the form of alternative claim constructions or 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

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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.

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.

Section 404 of the Sarbanes-Oxley Act of 2002 requires that we maintain internal control over financial reporting that meets applicable standards. As with many smaller companies with small staff, material weaknesses in our financial controls and procedures may be discovered. 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 NASDAQ 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, 2018, 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, 2018 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

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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:

- 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.

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 the members of our Board of Directors. Under Section 141 of the Delaware General Corporation Law, our

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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, and most recently renewed as of January 1, 2019), 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, 2018, 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 securities-related litigation, including securities class action litigation or securities-related investigations, which could 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:

- 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;

- additions to or departures of our key personnel;

- 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 stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for publicly traded securities. 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 and derivative litigation, and as a public company, we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities. 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.

As a result of our recent announcement of top-line results from the pivotal Phase 3 SEAMLESS study, our stock price declined substantially. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities.

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 convertible 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 convertible 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 140,373 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 convertible 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 convertible preferred stock into common stock if the closing price of our common stock exceeds $2,961 per share. 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.

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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 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 risks 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 recent sale of our securities.

On October 4, 2018, the Company entered into a Common Stock Sales Agreement, or the Sales Agreement, with H.C. Wainwright & Co., LLC, or Wainwright, as sales agent, pursuant to which Wainwright may sell shares of our common stock, par value $0.001 per share, having an aggregate offering price of up to $5,000,000, by any method that is deemed to be an “at the market offering” as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. Shares sold under the Sales Agreement will be offered and sold pursuant to the Company’s previously filed and effective Registration Statement on Form S-3 and a prospectus supplement and accompanying base prospectus. The Company will pay Wainwright a commission of 3.0% of the gross sales price per share sold. During 2018, the Company sold 500,000 shares under the Sales Agreement for gross proceeds of approximately $0.7 million. During the first quarter of 2019, the Company sold a further 4.7 million shares under the Sales Agreement for gross proceeds of approximately $4.3 million. The Company has now reached the maximum aggregate offering price and there will be no further sale of shares under the Sales Agreement.

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

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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.

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Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

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

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, 2018, 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 Capital Market, or NASDAQ, under the symbol "CYCC". Our preferred stock currently trades on NASDAQ under the symbol "CYCCP".

Holders of Common Stock

On March 26, 2019, we had approximately 30 registered holders of record of our 17,199,974 shares of common stock outstanding. On March 26 2019, the closing sale price of our common stock as reported by NASDAQ was $0.92 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 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, 2018 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 2018, our primary focus has been on our transcriptional regulation program where we are evaluating CYC065, our cyclin dependent kinase, or CDK, inhibitor and our DNA damage response, or DDR, program where we are evaluating sapacitabine in combination with our CDK inhibitor seliciclib in Phase 1/2 studies in patients with solid tumors. Additionally in our SEAMLESS study of sapacitabine in

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Acute Myeloid Leukemia, or AML, stratified and exploratory subgroup analyses have been completed and have defined a patient population who may benefit from treatment with the experimental arm. We have begun discussing the SEAMLESS data with certain regulatory authorities.

Transcriptional Regulation Program

CDKs are a family of enzymes first discovered as regulators of the cell cycle, but that are now understood to also provide pivotal functions in the regulation of transcription, DNA repair and metastatic spread. The precise selectivity of an individual CDK inhibitor molecule for certain specific CDKs is key to targeting particular tumor types and minimizing undesirable side effects through non-specific antiproliferative activity.

In general, cell cycle regulation is less well controlled in cancer cells than in normal cells, which explains in part why cancer cells divide uncontrollably. Different CDKs are responsible for control of different aspects of proliferation, and when dysregulated, can be drivers of particular cancer sub-sets. Modulating CDK activity with targeted therapies is an attractive strategy to reinforce cell cycle control and decrease the rate of abnormal proliferation of cancer cells. The first FDA approval in March 2015 of a CDK inhibitor for palbociclib, and more recently in 2017, ribociclib and abemaciclib, for a type of breast cancer, has led to great interest in the development of this class of drugs as oncology therapeutics.

Cyclacel's founding scientist, Professor Sir David Lane, is a globally recognized authority in cell cycle biology, who discovered p53, a key tumor suppressor that malfunctions in about two-thirds of human cancers. Under his guidance, Cyclacel's drug discovery and development programs concentrated on the CDK2/9 isoforms, which operate as key components of the p53 pathway. These efforts resulted in bringing two molecules into clinical trials: seliciclib, a first-generation CDK inhibitor, and CYC065, a second-generation CDK inhibitor, which has benefited from the Company's clinical experience with seliciclib.

CYC065 has been evaluated in a first-in-human, Phase 1 trial in patients with advanced solid tumors and a recommended Phase 2 dose established. The study demonstrated that CYC065 durably suppresses Mcl-1, a member of the Bcl-2 family of survival proteins. CYC065 is under investigation in combination with other anticancer drugs, including Bcl-2 inhibitors such as venetoclax. Preclinical data suggests that CYC065 may benefit adults and children with hematological malignancies, including acute myeloid leukemias (AML), acute lymphocytic leukemias (ALL), and in particular leukemias with rearrangement of the Mixed Lineage Leukemia gene (MLL-r), chronic lymphocytic leukemias (CLL), B-cell lymphomas, multiple myelomas, and patients with certain solid tumors, including breast and uterine cancers, and neuroblastomas.

DNA Damage Response, or DDR, Program

Many cancers have defects in the way in which cells monitor and repair damaged DNA, collectively termed DNA damage response, or DDR. These deficiencies in DDR pathways render cells more susceptible to DNA damage. Many traditional cancer treatments, such as DNA-damaging chemotherapy and radiotherapy, are based on this finding. However, such treatments are often accompanied by significant and unwanted side effects. Developing treatments which target specific DDR deficiencies to preferentially kill cancer cells, while minimizing the impact on normal cells, has potential for more selective, better tolerated therapies to improve survival in multiple cancers.

We have focused on developing treatments targeting DNA damage pathways for several years. For example, sapacitabine is an oral nucleoside analogue prodrug whose metabolite, CNDAC, generates single-strand DNA breaks, or SSB, either leading to arrest of the cell cycle at G2 phase or development of double-strand DNA breaks, or DSB. Repair of CNDAC-induced DSB is dependent on the homologous recombination, or HR repair pathway. BRCA mutations in cancer cells are a cause of HR deficiency, making such cancer cells more susceptible to cell death induced by sapacitabine.

We are evaluating sapacitabine in a Phase 1/2 combination study with seliciclib in patients with BRCA mutations. A Phase 1b/2 investigator-sponsored clinical trial is underway to evaluate the safety and effectiveness of sapacitabine in combination with olaparib in patients with BRCA mutant breast cancer. The trial is being conducted at the Dana-Farber Cancer Institute with collaborators Cyclacel and AstraZeneca providing sapacitabine investigational drug and the approved PARP-inhibitor olaparib, respectively.

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CYC140

CYC140 is a novel, small molecule, selective polo-like-kinase 1 (PLK1) inhibitor which is open for enrollment in a FIH study in patients with advanced leukemias and MDS. CYC140 is differentiated from previous clinical PLK1 inhibitors, demonstrating potent and selective target inhibition and high activity in xenograft models of human cancers when dosed orally at non-toxic doses and is the subject of a translational biology program focused on acute leukemias and esophageal cancer.

MD Anderson Clinical Collaboration

On October 1, 2018, the Company entered into a three-year Clinical Collaboration Agreement, or CCA with The University of Texas MD Anderson Cancer Center, or MD Anderson. The main objective of the CCA is to clinically evaluate the safety and efficacy of three Cyclacel medicines in patients with hematological malignancies, including chronic lymphocytic leukemias, acute myeloid leukemias, myelodysplastic syndromes and other advanced leukemias. Under the terms of the CCA, MD Anderson will conduct four clinical studies with a total projected enrollment of up to 170 patients. Under the risk-sharing agreement MD Anderson will assume the patient costs for all studies and Cyclacel, who is the sponsor, will provide investigational drugs and other limited support. Upon first commercial sale in specific indications studied in the alliance, Cyclacel will make certain payments to MD Anderson.

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

Corporate Developments

On October 4, 2018, the Company entered into a Common Stock Sales Agreement, or the Sales Agreement, with H.C. Wainwright & Co., LLC, or Wainwright, as sales agent, pursuant to which Wainwright may sell shares of our common stock, par value $0.001 per share, having an aggregate offering price of up to $5,000,000, by any method that is deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. Shares sold under the Sales Agreement will be offered and sold pursuant to the Company's previously filed and effective Registration Statement on Form S-3 and a prospectus supplement and accompanying base prospectus. The Company will pay Wainwright a commission of 3.0% of the gross sales price per share sold.

Dividend on Preferred Stock

On December 11, 2018, 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, 2019 to the holders of record of the Preferred Stock as of the close of business on January 14, 2019.

Results of Operations

Years Ended December 31, 2017 and 2018

Results of Continuing Operations

Revenues

On January 1, 2018, we adopted ASC Topic 606, Revenue from Contracts with Customers ("ASC 606"). Under this new guidance, we recognize revenue when we transfer control of promised goods or services to customers, in amounts that reflects the consideration to which we expect to be entitled. We adopted ASC 606 on a modified retrospective basis, meaning that we did not restate the results of the 2017 comparative period. However, the adoption of ASC 606 did not have a material effect on our reported revenues, net loss, assets, or shareholders' equity.

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The following table summarizes the components of our revenues for the years ended December 31, 2017 and 2018 (in thousands except percentages):

	Year ended December 31,		Difference	
	2017	2018	$	%
Grant revenue	$ —	$ —	$ —	—
Collaboration and research and development revenue	—	150	150	100
Total Revenue	$ —	$ 150	$ 150	100

Collaboration and research and development revenue represents a milestone payment in respect to a collaboration, licensing and supply agreement with ManRos Therapeutics SA or ManRos, entered into in June 2015. We had no revenue in 2017 relating to this agreement.

The future

Recognition of any further revenue from milestones under a collaboration, licensing and supply agreement with ManRos Therapeutics SA 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 organizations;
- Preclinical studies and laboratory supplies and materials;
- Technology license costs;
- Stock-based compensation; and
- Rent and facility expenses for our office and laboratories.

The following table provides information with respect to our research and development expenditures for the years ended December 31, 2017 and 2018 (in thousands except percentages):

	Year ended December 31,		Difference	
	2017	2018	$	%
Transcriptional Regulation (CYC065)	$ 1,057	$ 2,522	$ 1,465	139
DNA Damage Response (sapacitabine and seliciblib)	364	43	(321)	(88)
Sapacitabine (SEAMLESS and manufacturing)	2,504	814	(1,690)	(67)
Other research and development programs and expenses	312	948	636	204
Total research and development	$ 4,237	$ 4,327	$ 90	2

Research and development expenses represented 45% of our operating expenses for each of the years ended December 31, 2017 and 2018.

Research and development expenses remained relatively flat at $4.2 million and $4.3 million for the years ended December 31, 2017 and 2018 respectively. Research and development expenses relating to transcriptional regulation increased by $1.5 million from $1.1 million for the year ended December 31, 2017 to $2.5 million for the year ended December 31, 2018, as the clinical evaluation of CYC065 progresses. Research and development expenses relating to sapacitabine decreased by $1.7 million from $2.5 million for the year ended December 31, 2017 to $0.8 million for the year ended December 31, 2018, primarily as a result of a reduction in expenditures associated with the SEAMLESS Phase 3 trial and related costs.

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The future

We anticipate that overall research and development expenses for the year ended December 31, 2019 will increase compared to the year ended December 31, 2018, as we progress the clinical development of CYC065. The timing and extent of any future SEAMLESS expenditure, including the possibility of registration submissions to regulatory authorities in Europe and the U.S., are dependent upon the outcome of discussions with regulatory authorities.

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, 2017 and 2018 (in thousands except percentages):

	Year ended December 31,		Difference	
	2017	2018	$	%
General and administrative	$ 5,254	$ 5,371	$ 117	2
Total General and administrative	$ 5,254	$ 5,371	$ 117	2

Total general and administrative expenses represented 55% of our operating expenses for each of the years ended December 31, 2017 and 2018.

Our general and administrative expenditures increased by 2% from $5.3 million for the year ended December 31, 2017 compared to $5.4 million for the year ended December 31, 2018.

The future

We expect general and administrative expenditures for the year ended December 31, 2019 to decrease as compared to our expenditures for the year ended December 31, 2018 due to reduced recruitment and professional consultancy costs

Other income (expense), net

The following table summarizes the other income (expense) for years ended December 31, 2017 and 2018 (in thousands except percentages):

	Year ended December 31,		Difference	
	2017	2018	$	%
Foreign exchange losses	$ (39)	$ (90)	$ (51)	(131)
Interest income	118	331	213	181
Other income, net	949	682	(267)	(28)
Total other income, net	$ 1,028	$ 923	$ (105)	(10)

Total other income, net, decreased by approximately $0.1 million from approximately $1.0 million for the year ended December 31, 2017 to approximately $0.9 million for the year ended 31 December, 2018. The decrease in other income is primarily related to lower royalties receivable under a December 2005 Asset Purchase Agreement, or APA, whereby Xcyte Therapies, Inc., or Xcyte (a business acquired by the Company in March 2006) sold certain assets and intellectual property to ThermoFisher Scientific Company, or TSC (formerly Life Technologies Corporation) through an APA and other related agreements. The assets and technology were not part of the Company’s product development plan following the transaction between Xcyte and Cyclacel in March 2006. Accordingly, the company recognized $949,000 and $682,000 of other income arising from sales related to this transaction during the years ended 31 December 31, 2017 and 2018, respectively. We have no knowledge of TSC’s activities and cannot predict when we may receive income under the APA, if any. Partially offsetting the decline in other income from the TSC APA was an increase in interest income, resulting from higher yields on cash held on deposit in 2018.

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Foreign exchange gains (losses)

Foreign exchange losses increased by $51,000 to a loss of approximately $90,000 for the year ended December 31, 2018 compared to a loss of approximately $39,000 for the year ended December 31, 2017. The announcement in June 2017 of the referendum of the United Kingdom's Membership of the European Union, or Brexit, advising for the exit of the United Kingdom from the European Union caused significant volatility in currency exchange rate fluctuations that resulted in the strengthening of the U.S. dollar against foreign currencies in which we conduct business, primarily the Euro and British Pound. The significant currency exchange rate fluctuations of the U.S. dollar relative to other currencies may adversely affect our results of operations.

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 resulted in a loss of $9.3 million for the year ended December 31, 2018 and a favorable unrealized foreign exchange movement resulted in a gain of $14.6 million for the year ended December 31, 2017.

The future

Other income (expense), net will continue to be impacted by changes in foreign exchange rates and the receipt of income under the APA. As we are not in control of sales made by TSC, we are unable to estimate the level and timing of income under the APA, if any.

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 (loss) until repayment of the intercompany loan becomes foreseeable.

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, 2017 and 2018 (in thousands except percentages):

	Year ended December 31,		Difference	
	2017	2018	$	%
Income tax benefit	$ 993	$ 1,337	$ 344	35
Total Income tax benefit	$ 993	$ 1,337	$ 344	35

The income tax benefit increased by approximately $0.3 million to $1.3 million for the year ended December 31, 2018 from $1.0 million for the year ended December 31, 2017. 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 continue to elect to receive payment of the tax credit. 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 higher in the fiscal year ended December 31, 2019, the level of tax credits recoverable is anticipated to be higher in 2019 compared to the fiscal year ended December 31, 2018. The US Tax Cuts and Jobs Act enacted in December 2017 has not had a material effect on the company's results of operations or financial position.

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Liquidity and Capital Resources

The following is a summary of our key liquidity measures as of December 31, 2017 and 2018 (in thousands):

	Year ended December 31,	
	2017	2018
Cash and cash equivalents	$ 23,910	$ 17,504
Working capital:		
Current assets	25,974	19,787
Current liabilities	(4,113)	(4,450)
Total working capital	$ 21,861	$ 15,337

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, royalty income, and a limited amount of product revenue from operations discontinued in September 2012. We have incurred significant loses since our inception. As of December 31, 2018, we had an accumulated deficit of $349.8 million.

Cash Flows

Cash provided by (used in operating, investing and financing activities for the years ended December 31, 2017 and 2018 is summarized as follows (in thousands):

	Year Ended December 31,	
	2017	2018
Net cash used in operating activities	$ (7,480)	$ (6,701)
Net cash used in investing activities	(13)	(39)
Net cash provided by financing activities	14,748	429

Operating activities

Net cash used in operating activities decreased by $0.8 million, from $7.5 million for the year ended December 31, 2017 to $6.7 million for the year ended December 31, 2018. The decrease in cash used by operating activities was primarily the result of a change in working capital of $0.5 million and a reduction in net loss of $0.2 million.

Investing activities

Net cash used in investing activities increased by approximately $26,000 for the year ended December 31, 2018 due to additional capital expenditure on IT equipment in 2018.

Financing activities

Net cash provided by financing activities was $0.4 million for the year ended December 31, 2018, primarily as a result of approximately $0.6 million in net proceeds from the issuance of common stock under the Sales Agreement with Wainright, offset by dividend payments of approximately $0.2 million to the holders of our 6% Preferred Stock.

Net cash provided by financing activities was $14.8 million for the year ended December 31, 2017, primarily as a result of the approximately $13.7 million in net proceeds from the July 2017 underwritten public offering and approximately $1.1 million in net proceeds from the issuance of common stock under the FBR Sales Agreement entered into in June 2016 offset by dividend payments of approximately $0.2 million to the holders of our 6% Preferred Stock.

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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, including the R&D tax credit, and recent financing activities, are sufficient to satisfy our planned working capital, capital expenditures and other financial commitments through the second quarter of 2020. 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.

Contractual Obligations

The following table summarizes our long-term contractual obligations as of December 31, 2018 (in thousands):

Payments Due by Period

	Total	Less than 1 year	1 – 3 years	3 – 5 years	More than 5 years
Operating Lease Obligation(1)	$ 2,201	$ 325	$ 650	$ 645	$ 581

(1)
Operating lease obligations relate primarily to leasing of office and laboratory space at 1 James Lindsay Place, Dundee, UK. The lease, which was entered into in October 2000, expires in October 2025.

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Off-Balance Sheet Arrangements

Since our inception, we have not had any off-balance sheet arrangements or relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or variable interest entities, which are typically established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

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 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.

Our significant accounting policies are more fully described in Note 2 to our consolidated financial statements included elsewhere in this report. We believe the following critical accounting policies reflect our more significant estimates and assumptions used 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.

Stock-based Compensation

We grant stock options, restricted stock units and restricted stock to officers, employees, directors and consultants under the Company’s 2018 Equity Incentive Plan, or the 2018 Plan. The 2018 Plan replaced the 2015 Equity Incentive Plan, or the 2015 Plan. We measure compensation cost for all stock-based awards at fair value on date of grant and recognize compensation over the requisite service period. 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 significant adjustments to the expense recognized for share-based payments.

We grant certain stock compensation awards that vest only upon achievement of certain performance conditions. If, in our judgment, achievement of those performance conditions is not probable, we do not recognize any compensation cost for those awards. As of December 31, 2018, we have outstanding approximately 518,000 stock option awards that contain one or more performance conditions. Approximately 76,000 of these awards have vested during the year, and we have recognized approximately $103,000 of compensation cost related to these specific awards during the year ended December 31, 2018. Had we determined that the performance conditions for all of the stock compensation awards were probable of being met, we would have recognized significantly more compensation cost in our December 31, 2018 consolidated statement of operations (loss).

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Recent Accounting Pronouncements Not Yet Effective

In July 2017, the FASB issued Accounting Standards Update ("ASU") No. 2017-11, Accounting for Certain Financial Instruments with Down Round Features ("ASU 2017-11), which simplifies the accounting for certain financial instruments with down-round features. A down round feature is a provision in a financial instrument that reduces the strike price of an issued financial instrument if the issuer sells shares of its stock for an amount less than the currently stated strike price of the issued financial instrument or issues an equity-linked financial instrument with a strike price below the currently stated strike price of the issued financial instrument. ASU 2017-11 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted, including adoption in an interim period. ASU 2017-11 should be adopted retrospectively for each prior reporting period presented or retrospectively as of the beginning of the year of adoption. The Company anticipates this standard will not have a material impact on its consolidated financial statements.

In February 2016, the FASB issued guidance on accounting for leases in ASU No, 2016-02. The guidance requires that lessees recognize a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term at the commencement date. The guidance is effective for fiscal years beginning after December 15, 2018. The Company plans to initially apply the new leases standard at the adoption date by recognizing any necessary cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. That is, the Company will not recast prior period financial statements for the effects of this new standard. The Company is still finalizing its evaluation of the new standard, but expects that it will initially recognize an operating lease liability, and a corresponding right-of-use asset, of approximately $1.6 million on transition to the new guidance.

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

INDEX TO CYCLACEL PHARMACEUTICALS, INC. FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Cyclacel Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Cyclacel Pharmaceuticals, Inc. and its subsidiaries (the Company) as of December 31, 2017 and 2018, the related consolidated statements of operations (loss), comprehensive loss, changes in stockholders' equity and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2018, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ RSM US LLP

We have served as the Company's auditor since 2013.

New York, New York

March 28, 2019

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CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31, 2017	2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,910	$ 17,504
Prepaid expenses and other current assets	2,064	2,283
Total current assets	25,974	19,787
Property and equipment, net	29	36
Total assets	$ 26,003	$ 19,823
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,558	$ 2,719
Accrued and other current liabilities	2,555	1,732
Total current liabilities	4,113	4,451
Other liabilities	124	100
Total liabilities	4,237	4,551
Commitments and contingencies (Notes 3 and 9)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2017 and December 31, 2018		
6% Convertible Exchangeable preferred stock; 335,273 shares issued and outstanding at December 31, 2017 and December 31, 2018. Aggregate preference in liquidation of $4,006,512 at December 31, 2017 and December 31, 2018	—	—
Series A convertible preferred stock; 264 shares issued and outstanding at December 31, 2017 and December 31, 2018	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2017 and December 31, 2018; 11,997,447 and 12,497,447 shares issued and outstanding at December 31, 2017 and December 31, 2018, respectively	12	12
Additional paid-in capital	365,057	365,817
Accumulated other comprehensive loss	(794)	(760)
Accumulated deficit	(342,509)	(349,797)
Total stockholders' equity	21,766	15,272
Total liabilities and stockholders' equity	$ 26,003	$ 19,823

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

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CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS (LOSS)
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2017	2018
Revenues:		
Collaboration and research and development revenue	$ —	$ 150
Operating expenses:		
Research and development	4,237	4,327
General and administrative	5,254	5,371
Total operating expenses	9,491	9,698
Operating loss	(9,491)	(9,548)
Other income (expense):		
Foreign exchange losses	(39)	(90)
Interest income	118	331
Other income, net	949	682
Total other income (expense), net	1,028	923
Loss from continuing operations before taxes	(8,463)	(8,625)
Income tax benefit	993	1,337
Net loss	(7,470)	(7,288)
Dividend on convertible exchangeable preferred shares	(201)	(201)
Beneficial conversion feature of Series A convertible stock	(3,638)	—
Conversion of Series A convertible preferred stock	(3,537)	—
Net loss applicable to common shareholders	$ (14,846)	$ (7,489)
Basic and diluted earnings per common share:		
Net loss per share – basic and diluted	$ (1.95)	$ (0.62)
Weighted average common shares outstanding	7,631,152	12,094,131

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 thousands)

	Year Ended December 31,	
	2017	2018
Net loss	$ (7,470)	$ (7,288)
Translation adjustment	(14,687)	9,370
Unrealized foreign exchange gain (loss) on intercompany loans	14,636	(9,336)
Comprehensive loss	$ (7,521)	$ (7,254)

The accompanying notes are an integral part of these consolidated financial statements.
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CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share amounts)

	P Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balances at December 31, 2016	335,273	$ —	4,256,829	$ 4	$ 350,051	$ (743)	$ (335,039)	$ 14,273
Issue of common stock, preferred stock and associated warrants on underwritten offering, net of expenses	8,872	—	3,154,000	3	13,681	—	—	13,684
Series A Preferred stock conversions	(8,608)	—	4,304,000	4	(4)	—	—	—
Warrant exercise	—	—	99,500	—	199	—	—	199
Issue of common stock on At Market Issuance sales agreement	—	—	183,118	—	1,066	—	—	1,066
Stock-based compensation	—	—	—	—	266	—	—	266
Preferred stock dividends	—	—	—	—	(201)	—	—	(201)
Unrealized foreign exchange on intercompany loans	—	—	—	—	—	14,636	—	14,636
Translation adjustment	—	—	—	—	—	(14,687)	—	(14,687)
Loss for the period	—	—	—	—	—	—	(7,470)	(7,470)
Balances at December 31,	335,537	$ —	11,997,447	$ 12	$ 365,057	$ (794)	$ (342,509)	$ 21,766

2017								
Issue of common stock on At Market Issuance sales agreement	—	—	500,000	—	630	—	—	630
Stock-based compensation	—	—	—	—	331	—	—	331
Preferred stock dividends	—	—	—	—	(201)	—	—	(201)
Unrealized foreign exchange on intercompany loans	—	—	—	—	—	(9,336)	—	(9,336)
Translation adjustment	—	—	—	—	—	9,370	—	9,370
Loss for the period	—	—	—	—	—	—	(7,288)	(7,288)
Balances at December 31, 2018	335,537	$ —	12,497,447	$ 12	$ 365,817	$ (760)	$ (349,797)	$ 15,272

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 thousands)

	Year Ended December 31,	
	2017	2018
Cash flows from operating activities:		
Net loss	$ (7,470)	$ (7,288)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	32	29
Stock-based compensation expense	266	331
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,232	(327)
Accounts payable and other current liabilities	(1,540)	554
Net cash used in operating activities	(7,480)	(6,701)
Cash flows from investing activities:		
Purchases of property and equipment	(13)	(39)
Net cash used in investing activities	(13)	(39)
Cash flows from financing activities:		
Proceeds from issuance of equity securities, net of issuance costs	14,749	630
Proceeds from the exercise of stock options and warrants, net of issuance costs	200	—
Payment of preferred stock dividend	(201)	(201)
Net cash provided by financing activities	14,748	429
Effect of exchange rate changes on cash and cash equivalents	135	(95)
Net increase/(decrease) in cash and cash equivalents	7,390	(6,406)
Cash and cash equivalents at beginning of period	16,520	23,910
Cash and cash equivalents at end of period	$ 23,910	$ 17,504
Supplemental cash flow information:		
Cash received during the period for:		
Interest	118	331
Taxes	1,815	1,158
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 and Basis of Presentation

Cyclacel Pharmaceuticals Inc., ("Cyclacel" or "the Company") is a clinical-stage biopharmaceutical company using its expertise in cell cycle, transcriptional regulation and DNA damage response biology in cancer cells to develop innovative medicines. The transcriptional regulation program is evaluating CYC065, a CDK inhibitor, in patients with advanced solid cancers and in combination with venetoclax in patients with advanced hematological malignancies, including CLL and AML. The DNA damage response program is evaluating a sequential regimen of sapacitabine and seliciclib, a CDK inhibitor, in BRCA positive patients with advanced solid cancers and a concomitant regimen of sapacitabine and olaparib, a PARP inhibitor, in BRCA positive patients with breast cancer. CYC140, a PLK inhibitor, is in a Phase 1 first-in-human study in patients with advanced leukemias. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a pipeline of novel drug candidates.
As of December 31, 2018, 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.
The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, 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.
Through December 31, 2018, the Company has funded all of its operations and capital expenditures with proceeds from the issuance of public equity securities, private placements of securities, government grants, research and development tax credits, interest on investments, royalty income, product revenue and licensing revenue. The Company has incurred recurring losses since its inception, including net losses of $7.5 million and $7.3 million for the years ended December 31, 2017 and 2018, respectively. As of December 31, 2018, the Company had an accumulated deficit of $349.8 million. The Company expects to continue to generate operating losses for the foreseeable future due to, among other things, costs related to the clinical development of its drug candidates, its preclinical programs and its administrative organization.
Going Concern
Management considers that there are no conditions or events, in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern for a period of at least one year from the date the financial statements are issued. The Company expects that its cash of $17.5 million as of December 31, 2018 will be sufficient to fund its operating expenses and capital expenditure requirements through the second quarter of 2020.
This evaluation is based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued, including:
a.
The Company's current financial condition, including its liquidity sources

b.
The Company's conditional and unconditional obligations due or anticipated within one year

c.
The funds necessary to maintain the Company's operations considering its current financial condition, obligations, and other expected cash flows, and

d.

Other conditions and events, when considered in conjunction with the above that may adversely affect the Company's ability to meet its obligations.

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The future viability of the Company beyond the second quarter of 2020 is dependent on its ability to raise additional capital to finance its operations. The Company will need to raise substantial additional capital to pursue the transcriptional regulation program, evaluating CYC065, a CDK inhibitor, in patients with advanced cancers or the DNA damage response program, evaluating a sequential regimen of sapacitabine and seliciclib, a CDK inhibitor, in patients with BRCA positive, advanced solid cancers Additional funding may not be available to the Company on favorable terms, or at all. If the Company is unable to obtain additional funds, it will need to reduce operating expenses, enter into a collaboration or other similar arrangement with respect to development and/or commercialization rights to sapacitabine or its CDK inhibitors, if available, or be forced to delay or reduce the scope of its CDK inhibitors and sapacitabine development programs, including any potential regulatory filings related to the SEAMLESS study, and/or limit or cease its operations. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies.

Reverse Stock Split

On May 27, 2016, the Company completed a one-for-twelve reverse stock split (the "Reverse Stock Split"), which reduced the number of shares of the Company's common stock that were issued and outstanding immediately prior to the effectiveness of the Reverse Stock Split. The number of shares of the Company's authorized common stock was not affected by the Reverse Stock Split and the par value of Cyclacel's common stock remained unchanged at $0.001 per share. The Reverse Stock Split reduced the number of shares of the Company's common stock that were outstanding at May 27, 2016 from 36,075,730 to 3,006,311 after the cancellation of fractional shares. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who otherwise held fractional shares of the Company's common stock as a result of the Reverse Stock Split received a cash payment in lieu of such fractional shares.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and include the financial statements of Cyclacel Pharmaceuticals, Inc. and all of the Company's wholly owned subsidiaries. All intercompany accounts 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, 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.

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

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exchange are used to translate any equity transactions. 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.

Cash and Cash Equivalents

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. 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. 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 deposits its cash in financial institutions that it believes have high credit quality and has not experienced any losses on such accounts and does not believe it is exposed to any significant credit risk on cash and cash equivalents.

The Company's cash and cash equivalents balance at December 31, 2018 was $17.5 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 ("FDIC") up to $250,000 per account. The Company has cash balances exceeding the balance insured by the FDIC that totaled approximately $16.8 million at December 31, 2018. 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 $0.2 million at December 31, 2018.

Property and Equipment

The components of property 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.

Impairment of Long-lived Assets

The Company reviews property 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.

Fair Value of Financial Instruments

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Assets and liabilities measured at fair value are classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.

- Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

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- Level 3 — Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying values of cash and cash equivalents, other receivables, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Segments

The Company is managed and operated as one business which is focused on using cell cycle, transcriptional regulation and DNA damage response biology to develop innovative, targeted medicines for cancer and other proliferative diseases .The entire business is managed by a single management team that reports to the Chief Executive Officer. The Company does not operate separate lines of business with respect to any of its products or product candidates and the Company does not prepare discrete financial information with respect to separate products or product candidates or by location. Accordingly, the Company views its business as one reportable operating segment with development operations in two geographic areas, namely the United States and the United Kingdom.

Revenue Recognition

On January 1, 2018, the Company adopted new guidance on revenue recognition, which has been codified within Accounting Standards Codification (ASC) 606, Revenue from Contracts with Customers (“ASC 606”). The comparative financial information for the year ended December 31, 2017 has not been restated and is prepared in accordance with the accounting policies that are described below in the section entitled “Revenue Recognition Prior to the Adoption of ASC 606”.

With effect from January 1, 2018, the Company recognizes revenue using the five step model provided in ASC 606, which involves:

(1)
identifying the contract with a customer;

(2)
identifying the performance obligations in the contract;

(3)
determining the transaction price;

(4)
allocating the transaction price to the performance obligations in the contract; and

(5)
recognizing revenue when, or as, the Company satisfies a performance obligation.

The transaction price includes fixed payments and an estimate of variable consideration, including milestone payments. The Company determines the variable consideration to be included in the transaction price by estimating the most likely amount that will be received and then applies a constraint to reduce the consideration to the amount which is probable of being received. When applying the constraint, the Company considers:

- Whether achievement of a development milestone is highly susceptible to factors outside the entity’s influence, such as milestones involving the judgment or actions of third parties, including regulatory bodies;

- Whether the uncertainty about the achievement of a milestone is not expected to be resolved for a long period of time;

-

Whether the Company can reasonably predict that a milestone will be achieved based on previous experience; and

- The complexity and inherent uncertainty underlying the achievement of a milestone.

The transaction price is allocated to each performance obligation based on the relative standalone selling price of each performance obligation. The best estimate of the standalone selling price is determined after considering all reasonably available information, including market data and conditions, entity-specific factors such as the cost structure of the deliverable and internal profit and pricing objectives.

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The revenue allocated to each performance obligation is recognized as or when the Company satisfies the performance obligation, which could be at a point in time, or over time, depending on the nature of the performance obligation. During 2018, the Company recognized $150,000 from a milestone payment in respect to a collaboration, licensing and supply agreement with ManRos Therapeutics SA or ManRos, entered into in June 2015. The Company had no revenue in 2017 relating to this agreement. The 2018 revenue recognized related to a license, and related know-how, that was transferred to ManRos in 2015. As discussed in the following section, prior to the adoption of ASC 606, the Company recognized revenues from milestone payments in the period where the milestone was achieved. As the events triggering the $150,000 milestone payment did not occur until 2018, no revenue had been recognized for this contingent payment prior to the adoption of ASC 606. Similarly, under ASC 606, the Company will typically wait to include any potential milestone payments in the transaction price until satisfaction of the milestone becomes probable, consistent with the notion of the constraint discussed previously.

Revenue Recognition Prior to the Adoption of ASC 606

Prior to the adoption of ASC 606, the Company recognized revenue in accordance with ASC Topic 605, Revenue Recognition ("ASC 605"). Under ASC 605, 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. The best estimate of the selling price is determined after considering all reasonably available information, including market data and conditions, entity-specific factors such as the cost structure of the deliverable and internal profit and pricing objectives. 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.

In regards to the ManRos agreement, upfront and non-contingent milestone payments have been allocated to the separate deliverables within the arrangement and recognized over the period in which the deliverables were transferred to ManRos, which occurred in 2015. The consideration allocated to the main deliverable — the transfer of the Company's know-how — was determined based on its estimated standalone selling price, using a market approach that identified similar license deals for a Phase 1/2 asset. The Company reviewed various licensing transactions in the public domain in the CF area and similar stage of asset development.

Milestone payments which are non-refundable, non-creditable and contingent on achieving clinical milestones are recognized as revenues either on achievement of such milestones if the milestones are considered substantive or over the period the Company has continuing performance obligations, if the milestones are not considered substantive. When determining if a milestone is substantive, the Company considers the following factors:

- The degree of certainty in achieving the milestone
- The frequency of milestone payments
- The Company's efforts, which result in achievement of the milestone
- The amount of the milestone payment relative to the other deliverables and payment terms, and
- Whether the milestone payment is related to future performance or deliverables

In the year ended December 31, 2017, the Company recognized no revenue from milestone payments. However, the Company records as deferred revenue any amounts received prior to satisfying the revenue recognition criteria. Deferred revenue not expected to be recognized within the next twelve months is reported as non-current deferred

revenue. The Company recognized $0 and $0.2 million deferred revenue as of December 31, 2017 and 2018 respectively. The deferred revenue reported as of December 31, 2017 relates to a prepayment received from ManRos Therapeutics SA for a development milestone that is not expected to be achieved until mid-2018 (see Note 3 for additional details).

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

Other Income

Other income is primarily related to royalty income received under a historical Asset Purchase Agreement for activities which are not part of the Company's ongoing operations and activities.

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.

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.

Patent Costs

Patent prosecution costs are charged to general and administrative expenses 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. Operating leases relate primarily to the Company's research and development facilities and corporate headquarters.

Stock-based Compensation

The Company measures all stock options and other stock-based awards granted to employees and directors based on the fair value on the date of the grant and recognizes compensation expense of those awards 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. Generally, the Company issues stock options and restricted stock awards to employees with only service-based vesting conditions and records the expense for these awards using the straight-line method. However, in certain years, the Company granted restricted stock units to employees that were dependent upon the fulfillment of certain clinical and financial conditions. In such instances where the performance condition must be met for the award to vest, the company only recognizes compensation expense when the award is probable of vesting (See Note 11 — Stock-Based Compensation).

The Company classifies stock-based compensation expense in its statement of operations in the same manner in which the award recipient's payroll costs are classified. The Company accounts for forfeitures as they occur.

The fair value of restricted stock and restricted stock units is determined based on the number of shares granted 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, expected term of the award, interest rates, and dividend yields.

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The Company relies 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.

The expected term assumption is estimated using past history of early exercise behavior and expectations about future behaviors.

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.

The expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Income Taxes

The Company accounts for income taxes using 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 accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

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.

In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2017 and 2018.

Comprehensive Income (Loss)

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 as applicable, to arrive at comprehensive income (loss). No taxes were recorded on items of other comprehensive income (loss). There were no reclassifications out of other comprehensive income (loss) during the years ended December 31, 2017 and 2018.

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Recently Issued Accounting Pronouncements

In July 2017, the FASB issued Accounting Standards Update ("ASU") No. 2017-11, Accounting for Certain Financial Instruments with Down Round Features ("ASU 2017-11"), which simplifies the accounting for certain financial instruments with down-round features. A down round feature is a provision in a financial instrument that reduces the strike price of an issued financial instrument if the issuer sells shares of its stock for an amount less than the currently stated strike price of the issued financial instrument or issues an equity-linked financial instrument with a strike price below the currently stated strike price of the issued financial instrument. ASU 2017-11 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted, including adoption in an interim period. ASU 2017-11 should be adopted retrospectively for each prior reporting period presented or retrospectively as of the beginning of the year of adoption. The Company anticipates this standard will not have a material impact on its consolidated financial statements.

In October 2016, the FASB issued ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfer of Assets Other than Inventory ("ASU 2016-16"), which requires the recognition of the income tax consequences of an intra-entity transfer of an asset, other than inventory, when the transfer occurs. The standard is effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. This standard did not have a material impact on the company's consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments ("ASU 2016-15"), to address diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The standard is effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. This standard did not have a material impact on the company's consolidated financial statements.

In February 2016, the FASB issued guidance on accounting for leases in ASU No, 2016-02. The guidance requires that lessees recognize a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term at the commencement date. The guidance is effective for fiscal years beginning after December 15, 2018. The Company plans to initially apply the new leases standard at the adoption date by recognizing any necessary cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. That is, the Company will not recast prior period financial statements for the effects of this new standard. The Company is still finalizing its evaluation of the new standard, but expects that it will initially recognize an operating lease liability, and a corresponding right-of-use asset, of approximately $1.6 million on transition to the new guidance.

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. The most significant licensing agreement is with Daiichi Sankyo. Pursuant to the Daiichi Sankyo license under which the Company licenses certain patent rights for sapacitabine 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

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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 2017 or 2018.

On October 1, 2018, the Company entered into a three-year Clinical Collaboration Agreement, or CCA with The University of Texas MD Anderson Cancer Center, or MD Anderson. The main objective of the CCA is to clinically evaluate the safety and efficacy of three Cyclacel medicines in patients with hematological malignancies, including chronic lymphocytic leukemias, acute myeloid leukemias, myelodysplastic syndromes and other advanced leukemias. Under the terms of the CCA, MD Anderson will conduct four clinical studies with a total projected enrollment of up to 170 patients. Under the risk-sharing agreement MD Anderson will assume the patient costs for all studies and Cyclacel, who is the sponsor, will provide investigational drugs and other limited support. Upon first commercial sale in specific indications studied in the alliance, Cyclacel will make certain payments to MD Anderson.

Collaboration, Supply and Licensing Agreements

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. Another milestone was achieved in the first quarter of 2018. The Company will receive further milestone payments, as well as tiered royalties if seliciclib is commercialized for the treatment of CF.

4.

Cash and Cash Equivalents

The following is a summary of cash and cash equivalents at December 31, 2017 and 2018 (in thousands):

	December 31,	
	2017	2018
Cash	$ 1,103	$ 816
Investments with original maturity of less than three months at the time of purchase	22,807	16,688
Total cash and cash equivalents	$ 23,910	$ 17,504

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

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5.
Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	Fair Value Measurements as of December 31, 2017 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 22,807	$ —	$ —	$ 22,807
Total Assets	$ 22,807	$ —	$ —	$ 22,807

	Fair Value Measurements as of December 31, 2018 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 16,688	$ —	$ —	$ 16,688
Total Assets	$ 16,688	$ —	$ —	$ 16,688

6.
Prepaid Expenses and Other Current Assets

The following is a summary of prepaid expenses and other current assets at December 31, 2017 and 2018 (in thousands):

	December 31,	
	2017	2018
Research and development tax credit receivable	$ 1,054	$ 1,148
Prepayments	363	543
VAT receivable	409	356
Deposits	132	66
Other current assets	106	170
Prepaid expenses and other current assets	$ 2,064	$ 2,283

7.
Property and Equipment

Property and equipment consisted of the following at December 31, 2017 and 2018 (in thousands):

	Lives in years	December 31,	
		2017	2018
Leasehold improvements	5 to 15	$ 835	$ 807
Research and laboratory equipment	3 to 5	4,854	4,209
Office equipment and furniture	3 to 5	1,236	1,140

	6,925	6,156
Less: accumulated depreciation and amortization	(6,896)	(6,120)
	$ 29	$ 36

Depreciation and amortization expense for property and equipment was $32,000 and $29,000 for the years ended December 31, 2017 and 2018, respectively. The Company sold fully depreciated assets for proceeds of $0 and $16,000 during the years ended December 31, 2017 and 2018 respectively.

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8.
Accrued and Other Current Liabilities

Accrued and other current liabilities consisted of the following at December 31, 2017 and 2018 (in thousands):

	December 31,	
	2017	2018
Accrued research and development	$ 1,645	$ 1,110
Accrued legal and professional fees	248	259
Other current liabilities	662	363
	$ 2,555	$ 1,732

Other current liabilities in 2017 include $150,000 deferred income in respect of payment received in advance of achieving a milestone under the ManRos agreement (see Note 3 — Significant Contracts).

9.
Commitments and Contingencies

General

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

Leases

In October 2000, the Company entered into a twenty-five year lease for its research and development facility in Dundee, Scotland. 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 and $0.4 million for each of the years ended December 31, 2017 and 2018, respectively.

The following is a summary of the Company's future contractual obligations and commitments relating to its facilities leases as at December 31, 2018 (in thousands):

	Operating Lease Obligation
2019	$ 321
2020	321
2021	321
2022	321
2023	321
thereafter	581
Total future minimum lease obligations	$ 2,186

10.
Stockholders' Equity

The Company has completed the following equity issuances during the periods presented in the consolidated financial statements.

October 2018 At Market Issuance

On October 4, 2018, the Company entered into a Common Stock Sales Agreement, or the Sales Agreement, with H.C. Wainwright & Co., LLC, or Wainwright, as sales agent, pursuant to which Wainwright may sell shares of our common stock, par value $0.001 per share, having an aggregate offering price of up to $5,000,000, by any method that

is deemed to be an “at the market offering” as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. Shares sold under the Sales Agreement will be offered and sold pursuant to the Company’s previously filed and effective Registration

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Statement on Form S-3 and a prospectus supplement and accompanying base prospectus. The Company will pay Wainwright a commission of 3.0% of the gross sales price per share sold. During 2018, the Company sold 500,000 shares under the Sales Agreement for gross proceeds of approximately $0.7 million.

July 2017 Underwritten Public Offering

On July 21, 2017, the Company issued (i) 3,154,000 Class A Units for $2 per unit, each consisting of one share of the Company's common stock, and a warrant to purchase one share of common stock (the "Class A Warrants"), and (ii) 8,872 Class B Units, each consisting of one share of the Company's Series A Convertible Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock"), convertible into 500 shares of Common Stock at the initial conversion price, and a warrant to purchase a number of shares of common stock equal to $1,000.00 divided by the conversion price (the "Class B Warrants") for $1,000 per unit. The net proceeds to the Company after the underwriters' exercise in full of the over-allotment option were approximately $13.7 million, after deducting underwriting discounts, commissions and other estimated offering expenses. The Class A Units and Class B Units have no stand-alone rights and the shares of common stock, Series A Preferred Stock and the Class A and Class B Warrants comprising those units were immediately separable.

The common stock, Class A Warrants and Class B Warrants (together the "Warrants") and Series A Preferred Stock are freestanding financial instruments. The Warrants are classified within equity (as a component of additional paid-in capital) in the consolidated balance sheet and are not remeasured on a recurring basis. The Series A Preferred Stock is classified within permanent equity in the consolidated balance sheet.

The proceeds from the Class A Units were allocated to common stock and Class A Warrants on a relative fair value basis. Similarly, the proceeds from the Class B Units were allocated to the Series A Preferred Stock and the Class B Warrants based on their relative fair values. Following the allocation of the offering proceeds associated with the Class B units, the Company determined that the Series A Preferred Stock had a beneficial conversion feature with an aggregate intrinsic value of approximately $3,638,000. As the Series A Preferred Stock contained no stated redemption date, and the conversion feature could be exercised at any time, the discount associated with the beneficial conversion feature was immediately charged against additional paid-in capital and treated as a deemed dividend for both financial reporting and earnings per share purposes.

The following is a description of the Company's outstanding equity instruments.

Warrants

As of December 31, 2018, there were 7,490,500 warrants outstanding, each with an exercise price of $2.00. All such warrants were issued in connection with the July 2017 Underwritten Public Offering and are immediately exercisable. The Warrants expire in 2024. Subject to limited exceptions, a holder of warrants will not have the right to exercise any portion of its warrants if the holder (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of common stock in excess of 4.99% (or, at the election of the purchaser, 9.99%) of the shares of our Common Stock then outstanding after giving effect to such exercise.

The exercise price and the number of shares issuable upon exercise of the warrants is subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting the Company's common stock. The warrant holders must pay the exercise price in cash upon exercise of the warrants, unless such warrant holders are utilizing the cashless exercise provision of the warrants. On the expiration date, unexercised warrants will automatically be exercised via the "cashless" exercise provision.

Prior to the exercise of any warrants to purchase common stock, holders of the warrants will not have any of the rights of holders of the common stock purchasable upon exercise, including the right to vote, except as set forth therein.

Warrants exercised during the years ended December 31, 2017 and 2018 were 99,500 and 0, respectively.

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Series A Preferred Stock

8,872 shares of the Company's Series A Preferred Stock were issued in the July 2017 Underwritten Public Offering. Each share of Series A Preferred Stock is convertible at any time at the option of the holder thereof, into a number of shares of common stock determined by dividing $1,000 by the initial conversion price of $2.00 per share, subject to a 4.99% blocker provision, or, upon election by a holder prior to the issuance of shares of Series A Preferred Stock, 9.99%, and is subject to adjustment for stock splits, stock dividends, distributions, subdivisions and combinations. During the year ended December 31, 2017, 8,608 shares of the Series A Preferred Stock were converted into 4,304,000 shares of common stock. As of December 31, 2018, 264 shares of the Series A Preferred Stock remain issued and outstanding. The 264 shares of Series A Preferred Stock issued and outstanding at December 31, 2018, are convertible into 132,000 shares of common stock.

In the event of a liquidation, the holders of shares of the Series A Preferred Stock may participate on an as-converted-to-common-stock basis in any distribution of assets of the Company. The Company shall not pay any dividends on shares of common stock (other than dividends in the form of common stock) unless and until such time as dividends on each share of Series A Preferred Stock are paid on an as-converted basis. There is no restriction on the Company's ability to repurchase shares of Series A Preferred Stock while there is any arrearage in the payment of dividends on such shares, and there are no sinking fund provisions applicable to the Series A Preferred Stock.

Subject to certain conditions, at any time following the issuance of the Series A Preferred Stock, the Company has the right to cause each holder of the Series A Preferred Stock to convert all or part of such holder's Series A Preferred Stock in the event that (i) the volume weighted average price of our common stock for 30 consecutive trading days (the "Measurement Period") exceeds 300% of the initial conversion price of the Series A Preferred Stock (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends and similar transactions), (ii) the daily trading volume on each Trading Day during such Measurement Period exceeds $500,000 per trading day and (iii) the holder is not in possession of any information that constitutes or might constitute, material non-public information which was provided by the Company. The right to cause each holder of the Series A Preferred Stock to convert all or part of such holder's Series A Preferred Stock shall be exercised ratably among the holders of the then outstanding preferred stock.

The Series A Preferred Stock has no maturity date, will carry the same dividend rights as the common stock, and with certain exceptions contains no voting rights. In the event of any liquidation or dissolution of the Company, the Series A Preferred Stock ranks senior to the common stock in the distribution of assets, to the extent legally available for distribution.

6% Convertible Exchangeable Preferred Stock

As of December 31, 2018, there were 335,273 shares of the Company's 6% Convertible Exchangeable ("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 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 Preferred Stock, including the requisite financial analysis and determination of a surplus. Accrued and unpaid dividends in arrears on preferred stock were $0.7 million, or $1.95 per share, of preferred stock, as of December 31, 2017 and 2018.

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 0.00507 shares of common stock for each share of Preferred Stock based on a price of $1,974. The Company has reserved 1,698 shares of common stock for

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issuance upon conversion of the remaining shares of Preferred Stock outstanding at December 31, 2017. 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 $2,961, 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.

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, 2018.

For the year ended December 31, 2018, the company declared dividends of $0.15 per share quarterly on its Preferred Stock. These dividends were paid on May 1, August 1 and November 1, 2018, and February 1, 2019, respectively.

Common Stock

Exercise of Stock Options

No stock options were exercised during the years ended December 31, 2017 and 2018.

11.

Stock-Based Compensation

Stock based compensation has been reported within expense line items on the consolidated statement of operations for the years ended 2017 and 2018 as shown in the following table (in thousands):

	Year Ended December 31, 2017	Year Ended December 31, 2018
Research and development	$ 72	$ 88
General and administrative	194	243
Stock-based compensation costs before income taxes	$ 266	$ 331

2018 Plan

In May 2018, the Company's stockholders approved the 2018 Equity Incentive Plan (the "2018 Plan"), under which Cyclacel may make equity incentive grants to its officers, employees, directors and consultants. The 2018 Plan replaces the 2015 Equity Incentive Plan (the "2015 Plan").

The 2018 Plan allows for the issuance of up to 1,500,000 shares of the Company's common stock pursuant to various types of award grants, including stock options and restricted stock units. In addition, the 2018 Plan allows up to 709,889 additional shares to be issued if awards outstanding under the 2018 Plan are cancelled or expire on or after the date of the Company's 2018 annual meeting of stockholders.

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As of December 31, 2018, the Company has reserved 1,662,739 shares of the Company's common stock under the 2018 Plan, including shares that were available under the 2015 Plan and carried forward to the 2018 Plan. 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.

There were 170,853 options granted during the year ended December 31, 2017. Exactly 158,853 of these options are performance based, which will vest upon the fulfillment of certain clinical conditions. The Company determined that the satisfaction of one criterion, the commencement of the HEM study by December 31, 2018 occurred as of December 31, 2018, but that the other vesting criteria related to these awards were not probable as of December 31, 2018. As such, the Company recognized compensation cost for these grants under the expectation that 25% of these awards (the portion associated with the HEM study) will vest.

There were 306,304 options granted during the year ended December 31, 2018. Exactly 174,272 of these options are performance based, which will vest upon the fulfillment of certain clinical conditions. The Company determined that the satisfaction of one criterion, the commencement of the HEM study by December 31, 2018, occurred as of December 31, 2018, but that the other vesting criteria related to these awards were not probable as of December 31, 2018. As such, the Company recognized compensation cost for these grants under the expectation that 25% of these awards (the portion associated with the HEM study) will vest.

The weighted average grant-date fair values of options granted during the years ended December 31, 2017 and 2018 were $1.59 and $1.25, respectively.

As of December 31, 2018, the total remaining unrecognized compensation cost related to the non-vested, non-performance related stock options with service conditions amounted to approximately $0.1 million, which will be amortized over the weighted-average remaining requisite service period of 2.05 years.

During the years ended December 31, 2017 and 2018, the Company did not settle any equity instruments with cash. There were no stock option exercises during the years ended 2017 and 2018. No income tax benefits were recorded for the years ended December 31, 2017 and 2018 because the Company has accumulated net operating losses for tax purposes and is not likely to benefit from any deductions associated with exercises of granted option awards.

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, 2016	389,379	$ 25.80	5.83	$ 121
Granted	170,853	$ 1.93		
Exercised	—			
Cancelled/forfeited	(24,615)	$ 179.92		
Options outstanding at December 31, 2017	535,617	$ 11.10	8.23	$ —
Granted	306,304	$ 1.51		
Exercised	—			
Cancelled/forfeited	(10,310)	$ 82.38		
Options outstanding at December 31, 2018	831,611	$ 6.68	8.13	$ —
Unvested at December 31, 2018	573,830	$ 2.57	8.59	$ —
Vested and exercisable at December 31, 2018	257,781	$ 15.84	7.10	$ —

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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, 2017	Year ended December 31, 2018
Expected term (years)	6	6
Risk free interest rate	1.890% – 2.265%	2.730% – 2.855%
Volatility	108%	105% – 107%
Expected dividend yield over expected term	0.00%	0.00%
Resulting weighted average grant date fair value	$1.59	$1.25

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 $54,000 and $55,000 for the years ended December 31, 2017 and 2018, 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 $18,500 if under 50 years old and $24,500 if over 50 years old and to have those funds contributed to the 401(k) Plan. The Company made contributions of approximately $28,000 and $36,000 to the 401(k) Plan for the years ended December 31, 2017 and 2018, respectively.

13.
Taxes

(Loss) income from continuing operations before taxes is comprised of the following components for the years ended December 31, 2017 and 2018 (in thousands):

	Year Ended December 31,	
	2017	2018
Domestic	$ (127)	$ 20
Foreign	(8,336)	(8,645)
Loss from continuing operations before taxes	$ (8,463)	$ (8,625)

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

	Year Ended December 31,	
	2017	2018
Current – domesti	$ —	$ (5)
Current – foreign	993	1,342
Current – total	993	1,337
Deferred – domestic	—	—

Income tax benefit	$ 993	$ 1,337

The Company has incurred a taxable loss in each of the operating periods since incorporation. The income tax credits of $1.0 million and $1.3 million for the years ended December 31, 2017 and 2018, respectively, represent UK research and development ("R&D") tax credits for expenditures in the United Kingdom that are refundable.

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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 thousands):

	Year Ended December 31,	
	2017	2018
Loss from continuing operations before taxes	$ (8,463)	$ (8,625)
Income tax expense computed at statutory federal tax rate	(2,877)	(1,811)
Disallowed expenses and non-taxable income	3	310
Loss surrendered to generate R&D credit	856	1,519
Additional research and development tax relief	(1,262)	(1,342)
Change in valuation allowance	(4,487)	(7,440)
Foreign items, including change in tax rates, and other	1,901	(1,700)
Change in US Tax Rate	4,112	—
Section 382 Limitation	—	9,985
Other foreign items	761	(858)
	$ (993)	$ (1,337)

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act (“Tax Act”), which made significant changes to U.S. federal income tax law. The Company expects that certain aspects of the Tax Act will positively impact the Company’s future after-tax earnings in the U.S., primarily due to the lower federal statutory tax rate. Set forth below is a discussion of certain provisions of the Tax Act and our preliminary assessment of the effect of such provisions on the Company’s results of operations, cash flows and consolidated financial statements.

The Tax Act will affect 2018 and forward, including but not limited to a reduction in the federal corporate rate from 35.0% to 21.0%, elimination of the corporate alternative minimum tax, a new limitation on the deductibility of certain executive compensation, limitations on net operating losses generated after December 31, 2017 and various other items. These changes did not have a material impact on our financial statements due to the accumulated net operating losses in the U.S.

The Tax Act provides for a one-time “deemed repatriation” of accumulated unrepatriated foreign earnings determined as of November 2, 2017 or December 31, 2017, whichever is greater. We were not subject to this provision due to the accumulated deficit in our foreign earnings for tax purposes. The Tax Act also created a new requirement that certain income earned by controlled foreign corporations must be included currently in the gross income of the U.S. shareholder under the Global Intangible Low-Taxed Income (GILTI) provision. Our foreign earnings are not subject to GILTI due to our current deficit in the UK.

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118 (“SAB 118”), which addresses how a company recognizes provisional amounts when a company does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete its accounting for the effect of the changes in the Act. SAB 118 provides for a measurement period that should not extend beyond one year from the Act enactment date for companies to complete the accounting under Accounting Standards Codification Topic 740, Income Taxes (“ASC 740”). In accordance with SAB 118, a company must reflect the income tax effects of those aspects of the Act for which the accounting under ASC 740 is complete. To the extent that a company’s accounting for certain income tax effects of the Tax Act is incomplete but it is able to determine a reasonable estimate, it must record a provisional estimate to be included in the financial statements. If a company cannot determine a provisional estimate to be included in the financial statements, it should continue to apply ASC 740 on the basis of the provision of the tax laws that were in effect immediately before the enactment of the Act. Based on our analysis of the Tax Act, the Company made reasonable estimates of its 2017 impact. As a result of the federal corporate

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tax rate reduction from 35% to 21%, we re-measured certain deferred tax assets and liabilities, which resulted in a reduction in our DTA of approximately $4.4 million that was offset by a decrease in our valuation allowance. No adjustments were made as a result of the Tax Act for the year ended December 31, 2018.

The primary difference between the income tax benefit at the statutory rate and the Company's effective income tax expense for the year ended December 31, 2018 was primarily attributable to the change in our valuation allowance and foreign operations.

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

	Year Ended December 31,	
	2017	2018
Net operating loss and tax credit carryforwards	$ 38,948	$ 33,835
Depreciation, amortization and impairment of property and equipment	111	109
Stock options	1,807	1,482
Research and development credits	4,021	—
Other	—	—
Deferred tax assets	44,887	35,426
Valuation allowance for deferred tax assets	(44,887)	(35,426)
Net deferred tax assets	$ —	$ —

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 $35.4 million has been established at December 31, 2018. The valuation allowance has decreased by approximately $9.4 million in 2018.

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. 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 and has concluded that an ownership changed occured on March 4, 2015 and July 21, 2017. As a result of the ownership changes, the NOLs are limited.

As of December 31, 2017 and 2018, the Company had federal NOLs of $28.4 million and $0.0 million, respectively. The Company has state NOLs of $18.7 million which will begin to expire in 2028. As of December 31, 2017 and 2018, the Company had foreign NOLs of $186.2 million and $191.2 million, respectively. The Company's foreign NOL's do not expire under UK tax law however the use of these NOLs is restricted to an annual £5 million allowance in each standalone company or group and above this allowance, there will be a 50% restriction in the profits that can be covered by losses brought forward.

Management has evaluated all significant tax positions at December 31, 2017 and 2018 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 2015, 2016 and 2017 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.

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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.

The Company has an aggregate deficit in foreign earnings and therefore has not provided any deferred tax liability on its outside book-tax basis difference in its foreign subsidiaries and because it is also our intent to permanently reinvest any 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. As a result of the repeal of the Section 902 foreign tax credit under the Tax Act, future distributions would not be offset by a foreign tax credit.

14.

Net Loss Per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Years ended December 31,	
	2017	2018
Numerator:		
Net loss	$ (7,470)	$ (7,288)
Dividend on convertible exchangeable preferred shares	$ (201)	$ (201)
Beneficial conversion feature of Series A convertible stock	$ (3,638)	$ —
Conversion of Series A convertible preferred stock	$ (3,537)	$ —
Net loss attributable to common shareholders	$ (14,846)	$ (7,489)
Denominator:		
Weighted-average number of common shares used in loss per share – basic and diluted	7,631,152	12,094,131
Loss per share – basic and diluted	$ (1.95)	$ (0.62)

Potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Year ended December 31,	
	2017	2018
Stock options	535,616	831,611
Convertible preferred stock	1,698	1,698
Series A preferred stock	132,000	132,000
Common stock warrants	7,490,500	7,490,500
Total shares excluded from calculation	8,159,814	8,455,809

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15.
Geographic Information

Geographic information for the years ended December 31, 2017 and 2018 is as follows (in thousands):

	Year Ended December 31,	
	2017	2018
Revenue		
United Kingdom	$ —	$ 150
Total Revenue	$ —	$ 150
Net loss		
United States	$ (127)	$ 15
United Kingdom	(7,343)	(7,303)
Total Net Loss	$ (7,470)	$ (7,288)

	December 31,	
	2017	2018
Total Assets		
United States	$ 23,522	$ 17,384
United Kingdom	2,481	2,439
Total Assets	$ 26,003	$ 19,823
Long Lived Assets, net		
United States	$ 0	$ 3
United Kingdom	29	33
Total Long Lived Assets, net	$ 29	$ 36

16.
Subsequent Events

During the first quarter of 2019, the Company sold a further 4.7 million shares under the Sales Agreement with Wainwright for gross proceeds of approximately $4.3 million. The Company has now reached the maximum aggregate offering price and there will be no further sale of shares under the Sales Agreement.

On March 7, 2019, 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 is due to be paid on May 1, 2019 to the holders of record of the Preferred Stock as of the close of business on April 15, 2019.

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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, 2018.

Pursuant to this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2018, 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, 2018. 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, 2018, 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 year ended December 31, 2018 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 2018 fiscal year pursuant to Regulation 14A for its 2018 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 2018 fiscal year pursuant to Regulation 14A for its 2018 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 2018 fiscal year pursuant to Regulation 14A for its 2018 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 2018 fiscal year pursuant to Regulation 14A for its 2018 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 2018 fiscal year pursuant to Regulation 14A for its 2019 Annual Meeting of Stockholders.

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	Description

Number	
3.1	Amended and Restated Certificate of Incorporation of Cyclacel Pharmaceuticals, Inc. (previously filed as Exhibit 3.1 to the Registrant's Annual Report on Form 10-K, originally filed with the SEC on April 1, 2013, and incorporated herein by reference).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cyclacel Pharmaceuticals, Inc. (previously filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on May 27, 2016, and incorporated herein by reference).

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Exhibit Number	Description
3.3	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).
3.4	Certificate of Designation of 6% Convertible Exchangeable Preferred Stock (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).
3.5	Certificate of Designation of Series A Preferred Stock (previously filed as Exhibit 3.5 to the Registrant's Registration Statement on Form S-1 (No. 333-218305), originally filed with the SEC on July 17, 2017, 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 February 17, 2004, 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 21, 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).
4.6	Form of Warrant to purchase shares of Cyclacel Pharmaceuticals, Inc.'s Common Stock (previously filed as Exhibit 4.3 to the Registrant's Registration Statement on Form S-1 (No. 333-218305), originally filed with the SEC on July 17, 2017, and incorporated herein by reference).
10.1†	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).
10.2†	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).
10.3†	Equity Incentive Plan (previously filed as Exhibit 10.1 to Registrant's Current Report on Form 8-K originally filed with the SEC on June 1, 2018).
10.4†	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).
10.5†	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).

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Exhibit Number	Description
10.6†	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).
10.7#	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).
10.8#	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).
10.9†	Employment Extension Agreement, by and between Cyclacel Pharmaceuticals, Inc. and Spiro Rombotis, dated as of December 22, 2016 (previously filed as Exhibit 10.14 to the Registrant's Annual Report on Form 10-K, originally filed with the SEC on March 1, 2017, and incorporated by reference).
10.10†	Employment Extension Agreement, by and between Cyclacel Pharmaceuticals, Inc. and Paul McBarron, dated as of December 22, 2016 (previously filed as Exhibit 10.15 to the Registrant's Annual Report on Form 10-K, originally filed with the SEC on March 1, 2017, and incorporated by reference).
10.11†	Employment Extension Agreement, by and between Cyclacel Pharmaceuticals, Inc. and Spiro Rombotis, dated as of June 27, 2017 (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on June 27, 2017, and incorporated by reference)..
10.12†	Employment Extension Agreement, by and between Cyclacel Pharmaceuticals, Inc. and Paul McBarron, dated as of June 27, 2017 (previously filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on June 27, 2017, and incorporated by reference).
10.13†	Employment Agreement, by and between Cyclacel Pharmaceuticals, Inc. and Spiro Rombotis, dated as of December 6, 2017 (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on December 12, 2017, and incorporated by reference).
10.14†	Employment Agreement, by and between Cyclacel Pharmaceuticals, Inc. and Paul McBarron, dated as of December 6, 2017 (previously filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on December 12, 2017, and incorporated by reference).
10.15#	Clinical Collaboration Agreement by and between Cyclacel Pharmaceuticals, Inc. and the University of Texas M.D. Anderson Cancer Center dated as of August 21, 2018 (previously filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2018).
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.
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.

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Exhibit Number	Description
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, 2017, 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.

Exhibits:

†
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.

By:
/s/ Paul McBarron

Date: March 28, 2019

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 28, 2019
/s/ Paul McBarron Paul McBarron	Chief Operating Officer, Chief Financial Officer & Executive Vice President, Finance (Principal Financial and Accounting Officer) and Director	March 28, 2019
/s/ Dr. David U'Prichard Dr. David U'Prichard	Chairman	March 28, 2019
/s/ Dr. Christopher Henney Dr. Christopher Henney	Vice Chairman	March 28, 2019
/s/ Sir John Banham Sir John Banham	Director	March 28, 2019
/s/ Samuel L. Barker Samuel L. Barker	Director	March 28, 2019
/s/ Gregory Hradsky Gregory Hradsky	Director	March 28, 2019
/s/ Lloyd Sems Lloyd Sems	Director	March 28, 2019
/s/ Robert Spiegel Robert Spiegel	Director	March 28, 2019