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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, 2020
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 pursuant to section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	CYCC	The Nasdaq Stock Market LLC
Preferred Stock, $0.001 par value	CYCCP	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 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, every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

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	☒
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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate), as of June 30, 2020 (based upon the closing sale price of $4.65 of such shares on The NASDAQ Capital Market on June 30, 2020), the last business day of the registrant's most recently completed second fiscal quarter, was $22,609,904.

As of February 24, 2021, there were 7,103,650 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

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Summary of Principal Risk Factors

This summary briefly lists the principal risks and uncertainties facing our business, which are only a select portion of those risks. A more complete discussion of those risks and uncertainties is set forth in Part I, Item 1A of this Annual Report, entitled "Risk Factors". Additional risks not presently known to us or that we currently deem immaterial may also affect us. If any of these risks occur, our business, financial condition or results of operations could be materially and adversely affected.

Our business is subject to the following principal risks and uncertainties:

Risks Associated with Development and Commercialization of Our Drug Candidates

- The cost, time, and possibility of delays associated with clinical trials, which may be required to continue beyond our available funding. 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.
- We may suffer significant delays, setbacks or negative results in, or termination of, our clinical trials.
- 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 may be unable to directly control the timing, conduct and expense of our clinical trials, due to our reliance on contract research organizations and other third parties to conduct clinical trials,.
- 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.
- We have no manufacturing capacity and will rely on third party manufacturers for the late-stage clinical trials, development and commercialization of any drugs we may develop or sell.
- We may encounter difficulties in managing our growth and expanding our operations successfully as we evolve from a company primarily involved in discovery and development to one also involved in the commercialization of drugs and devices.
- 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.
- Even if we successfully complete the clinical trials for one or more of our product candidates, the product candidates may fail for other reasons.
- 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.
- We face intense competition and our competitors may develop drugs that are less expensive, safer, or more effective than our drug candidates.
- 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.

Risks Related to Our Business and Financial Condition

- We may face difficulty raising additional capital in the future which may not be available to us on reasonable terms, if at all, when or as we require additional funding.
- Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.
- The United Kingdom's withdrawal from the European Union could adversely impact our business, results of operations and financial condition.
- We have a history of operating losses and we may never become profitable. Our stock is a highly speculative 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.

- 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.
- Our business may be adversely affected by the ongoing coronavirus pandemic.

Risks Related to our Intellectual Property

- If we fail to enforce adequately or defend our intellectual property rights, our business may be harmed.
- We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

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.
- 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.
- 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.
- 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.
- 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.
- Our management team will have broad discretion over the use of the net proceeds from the recent sale of our securities.

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 developing innovative cancer medicines based on cell cycle, transcriptional regulation and mitosis control biology. 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 that can overcome resistance and ultimately increase a patient's overall survival.

The transcriptional regulation program is evaluating fadraciclib, a CDK2/9 inhibitor, in solid tumors and hematological malignancies. The anti-mitotic program is evaluating CYC140, a PLK1 inhibitor, in advanced cancers. Cyclacel's strategy is to build a diversified biopharmaceutical business based on a pipeline of novel drug candidates addressing oncology and hematology indications.

Our strategy is to build a diversified biopharmaceutical business based on a pipeline of novel drug candidates addressing oncology and hematology indications. 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, and Polo-like Kinases, or PLKs, are key regulators among the numerous genes and 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. Cyclacel's founder, Professor Sir David Lane, PhD, first identified CDK2/9 inhibition as the optimal target profile for transcriptionally active CDK inhibitors.

The lead drug in our transcriptional regulation program is fadraciclib (also known as CYC065), a CDK2/9 inhibitor.

Polo Kinases and other mitotic kinases were first discovered in fruit flies by Cyclacel's former Chief Scientist, Professor David Glover, PhD. PLK1 is a serine/threonine kinase playing a central role in cell division, or mitosis. In particular, PLK1 regulates mitotic entry, spindle formation, mitotic exit, cytokinesis and is an important regulator of the DNA damage checkpoint. Cancer cells are much more sensitive to PLK1 depletion than normal cells with intact checkpoints. Inhibiting PLK1 blocks proliferation by prolonged mitotic arrest followed by onset of cancer cell death.

The lead drug in our anti-mitotic program is CYC140, a PLK1 inhibitor.

In our DNA damage response, or DDR, program, we have also been developing sapacitabine, an orally available nucleoside analog.

Clinical Development Pipeline

The following table summarizes our development pipeline:

PROGRAM	INDICATION	PHASE
Transcriptional Regulation		
Fadraciclib CDK inhibitor (oral)	Solid tumors – multiple cohorts defined by cancer histology	Phase 1/2 to achieve proof of concept (in planning)
	Leukemias – multiple cohorts defined by cancer histology	Phase 1/2 to achieve proof of concept (in planning)
Fadraciclib CDK inhibitor (i.v.)	Solid Tumors incl. MCL1, MYC family, Cyclin E amplification	Phase 1 (ongoing) incl. part 3 oral bioequivalence study
	CLL combination with venetoclax, BCL2 inhibitor	Phase 1 (ongoing)
	AML/MDS combination with venetoclax, BCL2 inhibitor	Phase 1 (ongoing)
Mitosis Regulation		
CYC140 PLK inhibitor (oral)	Solid tumors – multiple cohorts defined by cancer histology	Phase 1/2 to achieve proof of concept (in planning)
CYC140 PLK inhibitor (i.v.)	Advanced leukemias	Phase 1 (ongoing)
DNA Damage Response		
Sapacitabine (oral)	BRCA mutated breast cancer combination with Olaparib, PARP inhibitor	Phase 1 (ongoing investigator-sponsored trial)
Sapacitabine (oral)	AML/MDS combination with venetoclax, BCL2 inhibitor	Phase 1/2 (ongoing)

Cyclacel currently retains all global marketing rights to the compounds associated with our clinical-stage drug programs with the exception of Japan in the case of sapacitabine.

Transcriptional Regulation Program

Fadraciclib — Cyclin Dependent Kinase (CDK) Inhibitor

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. Different CDK inhibitor drugs selectively target different sets of CDKs. 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 or off-target activity.

The best characterized CDK enzymes include CDK2, -4, -6 and -9. Cyclacel's CDK inhibitors, fadraciclib 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 clinically meaningful 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 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.

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 fadraciclib, a second-generation CDK inhibitor, which has benefited from the Company's clinical experience with seliciclib.

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.

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
- CDK9, which regulates transcription of certain genes, including cyclins, MCL1, MYC family and DNA double-strand break repair pathway components, through phosphorylation of RNA polymerase II.
    - MCL1 is overexpressed in many types of cancer acting as a survival and drug resistance mechanism. Multiple studies show that knockdown of MCL1 leads to cancer cell death and resensitization to drug treatment.
    - MYC proto-oncogenes encode MYC family proteins which are 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 poor long-term survival.

Fadraciclib 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. Fadraciclib is mechanistically similar to seliciclib, 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 fadraciclib in MCL1 dependent cancers. In a Phase 1, first-in-human study of fadraciclib, prolonged reduction of MCL1 for at least 24 hours was achieved and preliminary anticancer activity observed. Fadraciclib has been shown to inhibit CDK9-dependent oncogenic and leukemogenic pathways, including MYCN and mixed lineage leukemia rearrangements, or MLL-r. Fadraciclib and seliciclib both suppress the MCL1-mediated survival pathway in cancer cells, leading to rapid induction of apoptosis in MCL1 dependent cancer cells, and can reverse drug resistance associated with the addiction of cancer cells to cyclin E, a partner protein of CDK2.

Clinical development

Solid tumors

Fadraciclib has been evaluated in 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 (065-01, NCT02552953). 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 fadraciclib as a 4-hour infusion once every 3 weeks and a recommended Phase 2 dose, or RP2D, established. Durable MCL1 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 fadraciclib's mechanism, including MCL1, 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 study tested a more intensive dosing regimen with 24 patients treated with fadraciclib as a 1-hour infusion or orally on days 1, 2, 8 and 9 every 3 weeks. One patient with MCL1 amplified endometrial cancer has experienced a confirmed partial response after 4 cycles and remains on fadraciblib monotherapy for 18 months with 96% reduction in target tumor lesions. Another patient with cyclin E amplified ovarian cancer has achieved cancer shrinkage of target tumor lesions of 29%. In part 3 of the trial high bioequivalence of an oral formulation of fadraciblib was observed. These data were reported at the Plenary Session of the 32nd EORTC-NCI-AACR (ENA) Symposium in October 2020.

Supported by strong preclinical activity, the observation of durable suppression of MCL1 in patients and preliminary evidence of anticancer activity from the ongoing Phase 1 first-in-human (FIH) study we are preparing to commence a streamlined Phase 1/2 clinical studies in a broad range of solid tumors and leukemias. The study will evaluate oral fadraciclib in multiple cohorts defined by cancer histology and biospecimens will be collected for translational analysis. The aim of these streamlined studies is to identify clinical activity which may lead to registration-enabling outcomes.

Leukemias

Chronic lymphocytic leukemia (fadraciclib-02, NCT03739554)

We are enrolling a Phase 1 study to evaluate fadraciclib in combination with venetoclax in patients with relapsed or refractory CLL. The study design and preliminary data from the study were presented at a poster presentation during the 61st American Society of Hematology 2019 Annual Meeting and Exposition. fadraciclib is being administered intravenously via four-hour infusion on days 1 and 15 in combination with daily oral venetoclax. Initial dose escalation is 33% and upon occurrence of the first dose limiting toxicity, or DLT, 25%. The primary objective is determination of a recommended Phase 2 dose, or RP2D, defined as the highest dose level at which less than one-third of at least six patients experience a DLT during the first treatment cycle. Treatment will continue until progression of disease, unacceptable toxicity or changes in patient condition that renders patients ineligible for further treatment. Laboratory tests and CT scans will be performed regularly to assess response according to standard criteria.

Of the five R/R CLL patients enrolled in CYC065-02 all had failed ibrutinib and one had also failed CAR-T cell treatment. Patients remained minimal residual disease, or MRD, positive after treatment ramp with single agent venetoclax for up to 5 weeks. Continuing shrinkage of enlarged lymph nodes was observed by CT scan on the combination of venetoclax and fadraciclib dosed once every two weeks. The patient who failed CAR-T cell therapy and two additional patients achieved MRD negative status on the combination.

CLL cell survival depends on the expression of anti-apoptotic proteins, including MCL1 and BCL2. In this context, targeting MCL1 or BCL2 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. MCL1 expression can modulate resistance to BCL2 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 fadraciclib, even in the presence of stromal cells which confer protection from standard treatments. MCL1 down-regulation was observed, consistent with the pro-apoptotic mechanism of fadraciclib. fadraciclib synergizes with venetoclax in preclinical models at clinically achievable concentrations, supporting the clinical investigation of combination regimens of fadraciclib and venetoclax.

Acute myeloid leukemia, or AML (CYC065-03, NCT04017546)

Drug resistance in AML has been attributed among others to high levels of MCL1. AML cell lines are highly sensitive to fadraciclib and 5 to 8 hours of treatment is sufficient to achieve induction of cell death. Fadraciclib 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), fadraciclib reduced both MCL1 expression and CDK9 dependent transcription of MLL-regulated leukemogenic genes.

We are enrolling a Phase 1 study evaluating fadraciclib in combination with venetoclax in patients with relapsed or refractory AML or MDS. The study design and preliminary data from the study was presented at a poster presentation during the 61st American Society of Hematology 2019 Annual Meeting and Exposition. fadraciclib is being administered intravenously via four-hour infusion on days 1 and 15 in combination with daily venetoclax on days 1 to 15. Initial dose escalation is 33% and 25% upon occurrence of the DLT. The primary objective is determination of RP2D defined as the highest dose level at which less than one-third of at least six patients experience a DLT during the first treatment cycle. Treatment will continue until progression of disease, unacceptable toxicity or changes in patient condition that renders patients ineligible for further treatment. Laboratory tests and bone marrow aspirate/biopsy will be performed to assess response according to standard criteria.

Four of twelve patients in CYC065-03 achieved decreases in leukemia blast cells in their peripheral blood as reported by investigators.

Similar to our clinical development strategy for fadraciclib in solid tumors we plan to commence a streamlined Phase 1/2 clinical studies in a broad range of leukemias. The study will evaluate **oral** fadraciclib in multiple cohorts defined by cancer histology and collection of biospecimens for translational analysis. The aim of these studies is to identify clinical activity which may lead to registration-enabling studies.

Published preclinical data

Preclinical data suggest that fadraciclib may benefit adults and children with hematological malignancies, including AML, acute lymphocytic leukemias, or ALL, and in particular leukemias with rearrangement of the Mixed Lineage Leukemia gene (MLL-r), CLL, B-cell lymphomas, multiple myelomas, and patients with certain solid tumors, including breast and uterine cancers, and neuroblastomas. Published preclinical data with respect to fadraciclib has yielded the following results:

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

Fadraciclib 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, fadraciclib, and the BCL2 inhibitor, venetoclax in primary 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 fadraciclib can induce cell death and combined beneficially with anti-cancer drugs from the BCL2 and BET (Bromodomain and Extra-Terminal domain) inhibitor classes, in *in vitro* models of B-cell lymphoma, including double-hit lymphomas. Combinations of fadraciclib with the BCL2 inhibitor, venetoclax (ABT-199), or BET inhibitors were both synergistic. Short exposure to fadraciclib was sufficient to downregulate MYC, an oncogene product aberrantly expressed in many cancers, and MCL1, an anti-apoptotic member of the BCL2 family, and to induce cell death. Fadraciclib treatment had no impact on BCL2 levels.

These findings support the hypothesis that dual targeting of the MCL1- and BCL2-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 fadraciclib in combination with venetoclax in patients with relapsed/refractory CLL.

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

- *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 fadraciclib 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 fadraciclib included inhibition of MYCN transcription, downregulation of MYCN protein, blocking neuroblastoma cell proliferation and inducing apoptosis. There are no approved drugs that directly target MYCN, prompting the investigation of indirect approaches such as suppression of MYCN gene expression via CDK9 inhibition, or exploitation of a synthetic lethal relationship between MYCN amplification/ overexpression and inhibition of CDK2.

- *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 fadraciclib 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 fadraciclib in combination with trastuzumab resulted in regression or sustained tumor growth inhibition.

- *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 fadraciclib 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. Fadraciclib directs a pro-apoptotic mechanism in breast cancer cell lines, which includes transcriptional down regulation of key pro-survival and oncogenic regulators, including MCL1 and MYC. Like seliciclib, fadraciclib combined effectively with sapacitabine in breast cancer cell lines.

We anticipate that fadraciclib 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 fadraciclib.

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

Mitosis Regulation Program

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.

CYC140 is a novel, small molecule, selective, PLK1 inhibitor It has demonstrated potent and selective target inhibition (PLK1 IC_{50} ~ 3 nM) and impressive efficacy in human tumor xenografts at non-toxic doses. The pharmaceutical properties of CYC140 are improved over earlier clinical stage PLK inhibitors. 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. PLK1 over-expressing tumors with levels correlating with patient prognosis include esophageal, gastric, leukemia, NSCLC, ovarian and squamous cell cancers as well as MYC amplified cancers. Recent data with another PLK1 inhibitor in clinical development, suggest that PLK1 inhibition may be effective in KRAS-mutated metastatic colorectal cancer.

Cyclacel's translational biology program supports the development of CYC140 in acute leukemias and solid tumors.

Clinical development

CYC140 is undergoing safety/tolerability evaluation in a Phase 1 first-in-human trial (NCT03884829) in patients with advanced leukemias. Seven patients with advanced leukemias have been recruited so far to this first-in-human, single agent, dose escalation study of CYC140 given intravenously. No dose-limiting toxicities have been observed thus far.

Supported by strong preclinical activity we plan to commence a streamlined Phase 1/2 clinical studies in a broad range of solid tumors. The study will evaluate **oral** CYC140 in multiple cohorts defined by cancer histology and collection of biospecimens for translational analysis. This will be followed by a similar study to evaluate oral CYC140 in hematological malignancies. The aim of these studies is to identify clinical activity which may lead to registration-enabling studies.

Published preclinical data

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. 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.

We have retained worldwide rights to commercialize CYC140.

DNA Damage Response program

Sapacitabine

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 via intravenous administration. 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.

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.

Clinical development

Sapacitabine and venetoclax

We have dosed 12 patients in a Phase 1/2 study (NCT01211457) evaluating the safety and effectiveness of sapacitabine, in an oral regimen in combination with venetoclax in patients with relapsed or refractory AML or MDS. The Phase 1/2 study is intended to enroll patients with relapsed or refractory AML or MDS with the objective of determining the safety and efficacy of the combination. Secondary objectives include duration of response, CR, CRp, PR, or major HI, transfusion requirements, number of hospitalized days and overall survival.

Phase 1/2 clinical trial of sapacitabine and olaparib in patients BRCA mutant breast cancer (investigator sponsored)

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. As a result of findings in a Phase 1/2 of sapacitabine and an expansion cohort in patients with metastatic breast cancer, a combination regimen of sapacitabine and olaparib, a PARP inhibitor, is now being evaluated in an investigator-sponsored trial with sponsor Dana-Farber Cancer Institute and supported by the Company and Astra Zeneca in approximately 64 patients with PARP inhibitor-naïve, metastatic HER2-negative breast cancer with germline BRCA1/2 mutation (NCT03641755). Seven patients have been enrolled to date with two partial responses and prolonged stable diseases observed.

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 482 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 European Medicines Agency, or EMA.

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.

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 fadraciclib, 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 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 Medical Center, Los Angeles, supported in part by grants from The National Institute of Diabetes, Digestive and Kidney Diseases and the FDA, 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. . A preclinical collaboration with the MRC Centre for Inflammation Research at the University of Edinburgh is comparing fadraciclib to seliciclib as a potential treatment for COVID-19 pneumonia, acute lung injury or Acute Respiratory Distress Syndrome. The study is based on extensive research carried out in Professor Adriano Rossi's laboratory which demonstrated that MCL1 downregulation by seliciclib induced anti-inflammatory effects and promoted resolution of inflammation in relevant models. Initial results from the comparative program confirmed the hypothesis that fadraciclib enabled overactive neutrophil apoptosis is more active in this setting than seliciclib in line with its higher dose potency. The investigators consider that further research is merited to evaluate the potential therapeutic use of fadraciclib in COVID-19 pneumonia and other pulmonary diseases.

Business Strategy

We plan to continue to build a diversified biopharmaceutical business focused on 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 mitosis control biology.

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. Generally we plan 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 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, 9 granted by the European Patent Office, or EPO, and 51 granted in other countries worldwide. In addition, we have a license to 39 patents granted in the US, by the EPO or worldwide.

We have 1 patent application pending in the United States, 1 before the EPO, 11 pending patent applications in other countries and 4 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.

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 composition of matter claims because they provide us with rights to the compounds themselves, and not merely a particular use. In addition to composition 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 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. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire, or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent and the commercial opportunity of the product.

If patents are issued to others containing valid claims that cover our compounds or their manufacture or use or screening assays related thereto, we may be required to obtain licenses to these patents or to develop or obtain alternative technology. We are aware of several published patent applications, and understand that others may exist, that could support claims that, if granted and held valid, would cover various aspects of our developmental programs, including in some cases particular uses of our drug candidates fadraciclib, CYC140 and sapacitabine, 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 fadraciclib, CYC140 and sapacitabine and 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.

Issued patents for the fadraciclib compound cover the United States, EPO and eleven other countries. Issued patents for CYC140 cover the United States, EPO and six other countries. 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. 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.

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.

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 cGMP, 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 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:

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

- *Accelerated Approval.* Under the FDA's accelerated approval regulations, the FDA is authorized to approve drug candidates that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses, and that provide meaningful therapeutic benefit to patients over existing treatments based upon either a surrogate endpoint that is expected to predict a clinical benefit or on the basis of an effect on a clinical endpoint other than patient survival. In clinical trials, surrogate endpoints are alternative measurements of the symptoms of a disease or condition that are substituted for measurements of observable clinical symptoms. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to validate the surrogate endpoint or confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to validate a surrogate endpoint or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA. In rare instances the FDA may grant accelerated approval of an NDA based on Phase 2 data and require confirmatory Phase 3 studies to be conducted after approval and/or as a condition of maintaining approval. We can give no assurance that any of our drugs will be reviewed under such procedures.

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

The FDA or EMA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. A company can make only those claims relating to safety and efficacy that are approved by the FDA or EMA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe approved drugs for uses that are not described in the drug's labeling and that differ from those tested by us and approved by the FDA or EMA. Such off-label 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. Some of these factors can delay completion of recruitment into our clinical trials.

A large number of drug candidates are in development for the treatment of leukemia and lymphomas, MDS, gastrointestinal, genitourinary, gynecological and thoracic cancers and other advanced solid tumors. Several biopharmaceutical companies have CDK or MCL1 inhibitors in clinical trials including Adastra, Amgen, AstraZeneca, Dainippon Sumitomo, Eli Lilly, G1 Therapeutics, Kronos Bio, MEI Pharma, Merck, Novartis, Otsuka, Pfizer, Prelude, Servier, Syros, Tiziana and Vincera. Cardiff Oncology (formerly Trovagene) has a PLK1 inhibitor in clinical trials and we believe that Arbutus, Boehringer Ingelheim, GlaxoSmithKline, Merck, Onconova, and Takeda have been and may continue to be evaluating PLK inhibitors for hemato-oncology indications. Several biopharmaceutical companies have nucleoside analogs on the market or in trials which may be competitive to sapacitabine in hemato-oncology indications including AbbVie, AstraZeneca, BMS, CTI Biopharma, Daiichi Sankyo, Jazz, GlaxoSmithKline, Johnson & Johnson, Eli Lilly, MEI Pharma, Otsuka, Pfizer, Sanofi and Teva. 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.

Legal Proceedings

From time to time, we may be involved in routine litigation incidental to the conduct of our business. As of December 31, 2020 we were not party to any material legal proceedings.

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, UK 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.

Item 1A. Risk Factors

In analyzing our company, you should carefully consider 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.

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 as a result, concentrate more 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 have discussed the data from the SEAMLESS Phase 3 study with European and U.S. regulatory authorities and have received consistent guidance from them, 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 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 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 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 incompletely explored 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 less attractive;
- 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 fadraciblib, CYC140, sapacitabine and/or seliciclib in more than one indication. There is a risk that unacceptable toxicity or adverse events observed in a trial for one indication could result in the delay or suspension of all trials involving the same drug candidate. Even if we believe that the data collected from clinical trials of our drug candidates are promising with respect to safety and efficacy, such data may not be deemed sufficient by regulatory authorities to warrant product approval. 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 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 clinical trials, 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 trials and 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.

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 or Europe 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.

Additionally, the United Kingdom’s determination to leave the European Union, or Brexit has resulted in a decision to move the EMA from the United Kingdom to the Netherlands, which was completed in December 2020. This transition may cause disruption in the administrative and medical scientific links, including delays in granting clinical trial authorization or marketing authorization.

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

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

Even if our product candidates receive regulatory approval, we may still face future development and regulatory difficulties.

Our product candidates, if approved, will also be subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information. In addition, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA and EMA regulatory requirements and requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to the FDA's or EMA's 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, among other things:

- 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;
- 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, solid tumors including breast, endometrial/uterine and ovarian cancers and lymphomas. Several pharmaceutical and biotechnology companies have CDK inhibitors, PLK1 inhibitors or other products on the market or in clinical trials which may be competitive to our drugs 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.

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. Discussions continue at the federal level regarding policies that would require manufacturers to pay higher rebates in Medicare Part D, give states more flexibility on drugs that are covered under the Medicaid program, and other policy proposals that could impact reimbursement for our products. 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.

Several states, including Florida, Colorado, and Maine, have enacted laws or proposed legislation designed to facilitate the importation of prescription drugs from Canada and other foreign countries. Other states could adopt similar approaches or could pursue different policy changes in a continuing effort to reduce healthcare costs. Additionally, proposals have been introduced in Congress that aim to overhaul provisions of the Patient Protection and Affordable Care Act, to allow re-importation of prescription drugs from foreign countries and enable Medicare to negotiate drug prices with biopharmaceutical manufacturers.

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.

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 always 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 cGMP. Similar requirements exist in the European Union through the EMA. Failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on them or us, including fines, injunctions, civil penalties, disgorgement, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, before any product batch produced by our manufacturers can be shipped, it must conform to release specifications for the content of the pharmaceutical product. If the operations of one or more of our manufacturers were to become unavailable for any reason, any required FDA or EMA review and approval of the operations of an alternative supplier could cause a delay in the manufacture of our products.

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.

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 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 2022, 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. Changes to United Kingdom tax legislation related to research and development tax credits may reduce or eliminate the cash flow benefit we receive from these tax credits. 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 fadraciclib and CYC140.

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 withdrawal from the European Union could adversely impact our business, results of operations and financial condition.

Following recent European Parliament elections and the general election in the United Kingdom, the United Kingdom left the European Union on January 31, 2020, entering into a transition period ending December 31, 2020.

The impact of Brexit and the resulting turmoil on the political and economic future of the United Kingdom and the European Union is uncertain, and we may be adversely affected in ways we cannot currently anticipate. 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. We may find it more difficult to conduct business in the United Kingdom and the European Union as a result of increased regulatory complexity and possible new restrictions on the movement of goods, capital, and personnel, as well as possible tariffs on imports to and exports from the United Kingdom.

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.

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

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 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 marketplace, 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. Fadraciblib and CYC140 are in Phase 1 studies and a combination of sapacitabine and venetoclax, 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, 2019 and December 31, 2020, our accumulated deficit was $357.6 million and $366.1 million, respectively. Our net loss was $7.8 million and $8.5 million for the years ended December 31, 2019 and 2020, 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 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.

As previously reported, on January 11, 2019, we received a letter from the Listing Qualifications Staff, or 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), or Bid Price Rule. Pursuant to the Nasdaq Listing Rule 5810(c)(3)(A), the Company was granted a second compliance period until January 6, 2020, to regain compliance with the Bid Price Rule since the Company notified Nasdaq of its intent to cure the deficiency by effecting a reverse stock split in order to regain compliance therewith.

The Company was unable to regain compliance with the Bid Price Rule by January 6, 2020. Accordingly, on January 7, 2020, the Company received a letter from the Staff notifying it that its Common Stock would be subject to delisting from Nasdaq unless the Company timely appealed Nasdaq's determination to a Nasdaq Listing Qualifications Panel, or Panel.

The Company effected a 1-for-20 reverse stock split of its common stock on April 15, 2020, and on April 29, 2020, the Company was informed by Nasdaq that it had regained compliance with the Minimum Bid Price Rule as a result of the closing bid price of the Company's common stock being $1.00 per share or greater for the 10 consecutive business day period from April 15, 2020 to April 28, 2020.

Notwithstanding the reverse stock split and our compliance with the Nasdaq Capital market requirements, we cannot be sure that our share price will comply with the requirements for continued listing of our common stock on the Nasdaq Capital Market in the future, or that we will comply with the other continued listing requirements. If our shares of Common Stock lose their status on the Nasdaq Capital Market, we believe that our shares of Common Stock would likely be eligible to be quoted on the inter-dealer electronic quotation and trading system operated by Pink OTC Markets Inc., commonly referred to as the Pink Sheets and now known as the OTCQB market. Our shares of Common Stock may also be quoted on the Over-the-Counter Bulletin Board, an electronic quotation service maintained by the Financial Industry Regulatory Authority. These markets are generally not considered to be as efficient as, and not as broad as, the Nasdaq Capital Market. Selling our shares of Common Stock on these markets could be more difficult because smaller quantities of shares would likely be bought and sold, and transactions could be delayed. In addition, in the event our shares of Common Stock are delisted, broker-dealers have certain regulatory burdens imposed upon them, which may discourage broker-dealers from effecting transactions in our Common Stock, further limiting the liquidity of our Common Stock. These factors could result in lower prices and larger spreads in the bid and ask prices for our Common Stock.

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

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

- fund research and development and clinical trials connected with our research;
- fund clinical trials and seek regulatory approvals;

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

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

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- the costs and timing of seeking and obtaining regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs associated with establishing sales and marketing capabilities;
- the costs of acquiring or investing in businesses, products and technologies;
- 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 to attract and retain highly skilled personnel. We may have difficulty retaining and attracting such personnel as a result of a perceived risk of future workforce and expense reductions. Finally, the implementation of expense reduction programs may result in the diversion of the time and attention of our executive management team and other key employees, which could adversely affect our business.

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

Research and development is an expensive process. As part of our operating plan, we have decided to concentrate our clinical development strategy on our two ongoing, oncology clinical programs in transcriptional regulation and mitosis control biology, which include our areas of historical expertise in CDK and PLK inhibitors. 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 material legal claims and liability, damage to our reputation, suffer loss or harm to our intellectual property rights and the further research, development and commercial efforts of our products and product candidates could be delayed. The loss of drug development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Our business may be adversely affected by the ongoing coronavirus pandemic.

In December 2019, a novel strain of coronavirus (COVID-19) was reported to have surfaced in Wuhan, China, and has since spread worldwide, including to the United States and Europe. In March 2020, the World Health Organization characterized COVID-19 as a pandemic, and the President of the United States declared the COVID-19 outbreak a national emergency. The outbreak has resulted in governments around the world implementing increasingly stringent measures to help control the spread of the virus, including quarantines, "shelter in place" and "stay at home" orders, travel restrictions, business curtailments, and other measures. We have followed the guidelines from the U.S. Center for Disease Control (CDC) and implemented the recommended safety protocols, and the spread of COVID-19 has also caused us to modify our business practices (including curtailing employee travel and mandatory work-from-home policies where necessary).

These and similar, and perhaps more severe, disruptions could negatively impact our business, operating results and financial condition as well as third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain.

The global outbreak of COVID-19 could adversely affect, delay, or interrupt our clinical trials. Restrictions on travel and/or transport of clinical materials, as well as diversion of hospital staff and resources to COVID-19 infected patients, could delay our clinical trial operations. These challenges may lead to difficulties in meeting protocol-specified procedures. The extent and severity of the impact on our business and clinical trials will be determined largely by the extent of disruptions in the supply chains for our product candidates, and delays in the conduct of current and future clinical trials.

COVID-19 may also affect patient recruitment and the pace of enrollment in our clinical trials. Some patients and clinical investigators may not be able to comply with clinical trial protocols and patients may choose to withdraw from our studies as quarantines impede patients' movement or interrupt healthcare services. Additionally, we may have to pause enrollment in our ongoing clinical trials in order to protect clinical trial participants.

The spread of COVID-19 may also materially affect us economically. While the disruptions and restrictions on the ability to travel, quarantines, the successful use of vaccines and other measures taken as a result of the COVID-19 pandemic are expected to be temporary, the duration of any of these measures, and related financial impact, cannot be estimated at this time. Should these measures continue for an extended period of time, the impact on our supply chain and customers could have a material adverse effect on our results of operations and cash flows. Further, while the potential economic impact and duration of the COVID-19 pandemic on the global economy and our business in particular may be difficult to assess or predict, the COVID-19 pandemic has resulted in, and may continue to result in, significant disruption of global financial markets and an economic downturn that may affect demand for our products and services, reduce our ability to access capital or our customers' ability to pay us for past or future purchases, impact our operating results, and have a negative impact on our liquidity and stock price. A recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The ultimate impact of the COVID-19 outbreak or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, the effects could have a material impact on our business, results of operations and financial condition, and we will continue to monitor the COVID-19 situation closely.

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.

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

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

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

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

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

We may be subject to damages resulting from claims that our employees or we have wrongfully used or disclosed alleged trade secrets of 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 uses of our drug candidates fadraciclib, CYC140 and sapacitabine, 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 fadraciclib, CYC140 and sapacitabine 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.

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), Post Grant Review (PGR) 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.

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, 2020, 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, 2020 because we are a smaller reporting company. In the event our independent auditor is required to provide an opinion on such controls in the future, there is a risk that the auditor would conclude that such controls are ineffective.

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

Our common stock may have a volatile public trading price.

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

- 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 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, 2020, 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.

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

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 2017 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 $59,220 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.

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 April 21, 2020, we entered into a co-placement agency agreement with Roth Capital Partners, LLC, Ladenburg Thalmann & Co. Inc., and Brookline Capital Markets, a division of Arcadia Securities, LLC (the “Co-Placement Agents”) and a securities purchase agreement with certain purchasers for the purchase and sale of (i) 1,910,000 shares of common stock, (ii) pre-funded warrants to purchase up to 2,090,000 shares of common stock, and (iii) accompanying common stock warrants to purchase up to 4,000,000 shares of common stock.

The shares of common stock and accompanying common stock warrants were sold at a combined public offering price of $5.00 per share and common stock warrant. Each common stock warrant sold with the shares of common stock represents the right to purchase one share of common stock at an exercise price of $5.00 per share.

The pre-funded warrants and accompanying common stock warrants were sold at a combined public offering price of $4.999 per pre-funded warrant and common stock warrant.

The Co-Placement Agents were paid a total cash fee at the closing of the offering equal to 7% of the gross cash proceeds we received from the sale of the securities in the public offering. After deducting Co-Placement Agent fees and other offering expenses, total net proceeds of the public offering were approximately $18.3 million.

On December 18, 2020, Cyclacel Pharmaceuticals, Inc. (the "Company") entered into a Securities Purchase Agreement (the "Purchase Agreement") with Acorn Bioventures, LP (the "Purchaser"), pursuant to which the Company agreed to offer, issue and sell to the Purchaser, (i) in a registered direct offering, (a) an aggregate of 485,912 shares (the "Common Shares") of common stock, par value $0.001 per share ("Common Stock"), and (b) an aggregate of 237,745 shares of Series B Convertible Preferred Stock (the "Preferred Shares," and collectively with the Common Shares, the "Shares"), par value $0.001 per share ("Series B Preferred Stock"), and (ii) in a concurrent private placement, warrants (the "Warrants") to purchase up to an aggregate of 669,854 shares (the "Warrant Shares") of Common Stock.

The combined purchase price for each Share, together with one Warrant to purchase 0.4 shares of Common Stock, is $4.18. Each Warrant shall be exercisable beginning on the 12-month anniversary of the date of issuance for a period of five years after the date of issuance, at an exercise price of $4.13 per Warrant Share. The exercise price of the Warrants will be subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described in the Warrants. The Warrants may be exercised on a "cashless" basis.

Each share of Series B Convertible Preferred Stock will convert into five shares of Common Stock.

The closing of the offering occurred on December 22, 2020 and the net proceeds to the Company were approximately $6.9 million, after deducting offering expenses payable by the Company.

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

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

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

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

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

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, 2020, we were not a party to any material legal proceedings.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

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 February 24, 2021, we had approximately 19 registered holders of record of our 7,103,650 shares of common stock outstanding. On February 24, 2021, the closing sale price of our common stock as reported by NASDAQ was $7.41 per share.

Dividends

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

Item 6. Selected Financial Data

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

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Cautionary Statement Regarding Forward-Looking Statements

This report contains certain statements that may be deemed 'forward-looking statements' within the meaning of United States securities laws. All statements, other than statements of historical fact, that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future are forward-looking statements. Such statements are based upon certain assumptions and assessments made by our management in light of their experience and their perception of historical trends, current 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, 2020 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

We are a clinical-stage biopharmaceutical company developing innovative cancer medicines based on cell cycle, transcriptional regulation and mitosis control biology. We are 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 that can overcome resistance and ultimately increase a patient's overall survival. Our strategy is to build a diversified biopharmaceutical business based on a pipeline of novel drug candidates addressing oncology and hematology indications.

During 2020, our primary focus has been on our transcriptional regulation program which is evaluating fadraciclib as a single agent in solid tumors and in combination with venetoclax in patients with relapsed or refractory AML/MDS and CLL. The anti-mitotic program is evaluating CYC140, a PLK1 inhibitor, in advanced leukemia/MDS patients. The DNA damage response program is evaluating an oral combination of sapacitabine and venetoclax in patients with relapsed or refractory AML/MDS and an investigator sponsored trial is evaluating an oral combination of sapacitabine and olaparib in patients with BRCA mutant breast cancer.

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

Agreements to sell Securities

On December 18, 2020 we entered into a definitive securities purchase agreement with Acorn Bioventures, LP, a biotech-focused fundamental investor. Under the agreement, Acorn Bioventures has agreed to purchase in a registered direct offering 485,912 shares of common stock and 237,745 shares of newly designated Series B Preferred Stock (convertible into shares of common stock at a ratio of 1:5), and in a concurrent private placement, warrants to purchase 669,854 shares of common stock, for aggregate net proceeds of approximately $6.9 million. The offering is priced at-the-market pursuant to the rules of the Nasdaq Stock Market. The warrants will be exercisable beginning twelve months following the date of issuance, will expire on the five-year anniversary of the date of issuance, and have an exercise price of $4.13 per share.

On April 24, 2020 we announced the public offering of (i) 4,000,000 shares of its common stock (or pre-funded warrants to purchase common stock in lieu thereof) and (ii) common warrants to purchase up to 4,000,000 shares of common stock. Each share of common stock and, as applicable, each pre-funded warrant, was sold together with a common warrant to purchase one share of common stock at a combined effective price to the public of $5.00 per share and accompanying common warrant, and/or $4.999 per pre-funded warrant and accompanying common warrant. For each pre-funded warrant the Company sold, the number of shares of common stock the Company offered was decreased on a one-for-one basis. The common warrants are immediately exercisable at a price of $5.00 per share of common stock and will expire five years from the date of issuance. The shares of common stock and/or the pre-funded warrants, and the accompanying common warrants, were purchased together in the offering, but were issued separately and became immediately separable upon issuance. After deducting placement agent fees and other offering expenses payable by the Company, total net proceeds of the public offering are approximately $18.3 million.

Dividend on Preferred Stock

On December 11, 2020, 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, 2021 to the holders of record of the Preferred Stock as of the close of business on January 15, 2021.

Results of Operations

Years Ended December 31, 2019 and 2020

Results of Continuing Operations

Revenues

There were no revenues for the years ended December 31, 2019 and 2020.

The future

We do not anticipate any revenues for the foreseeable future.

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, 2019 and 2020 (in thousands except percentages):

	Year Ended December 31,		Difference	
	2019	2020	$	%
Transcriptional Regulation (fadraciclib)	$ 3,057	$ 3,665	$ 608	20
Anti-mitotic (CYC140)	660	579	(81)	(12)
DNA Damage Response (sapacitabine)	489	203	(286)	(58)
Other research and development programs and expenses	452	312	(140)	(31)
Total research and development expenses	$ 4,658	$ 4,759	$ 101	2

Research and development expenses represented 48% and 45% of our operating expenses for the years ended December 31, 2019 and 2020, respectively.

Research and development expenses remained relatively flat at $4.7 million and $4.8 million for the years ended December 31, 2019 and December 31, 2020, respectively. Research and development expenses relating to transcriptional regulation increased by $0.6 million from $3.1 million for the year ended December 31, 2019 to $3.7 million for the year ended December 31, 2020, as the clinical evaluation of fadraciclib progressed. Research and development expenses relating to CYC140 decreased by $0.1 million from $0.7 million for the year ended December 31, 2019 to $0.6 million for the year ended December 31, 2020, primarily as a result of a reduction in expenditures associated with drug supply manufacturing which were not required in 2020. Research and development expenses relating to DNA Damage Response decreased by $0.3 million from $0.5 million for the year ended December 31, 2019 to $0.2 million for the year ended December 31, 2020, primarily as a result of expenditures associated with drug supply manufacturing not being required in 2020. Research and development expenses relating to other research and development decreased by $0.1 million from approximately $0.4 million for the year ended December 31, 2019 to $0.3 million for the year ended December 31, 2020, due to a reduction in consultancy costs.

The future

We anticipate that overall research and development expenses for the year ended December 31, 2021 will increase compared to the year ended December 31, 2020 as we progress our clinical development programs.

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, 2019 and 2020 (in thousands except percentages):

	Year Ended December 31,		Difference	
	2019	2020	$	%
Total general and administrative expenses	$ 5,024	$ 5,877	$ 853	17

Total general and administrative expenses represented 52% and 55% of our operating expenses for the years ended December 31, 2019 and 2020, respectively.

Our general and administrative expenditures increased by $0.9 million from $5.0 million for the year ended December 31, 2019 to $5.9 million for the year ended December 31, 2020 due to an increase in legal, professional and recruitment costs relating to expansion of clinical team.

The future

We expect general and administrative expenditures for the year ended December 31, 2021 to reduce slightly compared to our expenditures for the year ended December 31, 2020, due to lower recruitment and professional costs.

Other income (expense), net

The following table summarizes the other income (expense) for years ended December 31, 2019 and 2020 (in thousands except percentages):

	Year Ended December 31,		Difference	
	2019	2020	$	%
Foreign exchange gains	$ 101	$ 22	$ (79)	78
Interest income	224	42	(182)	(81)
Other income, net	231	891	660	286
Total other income	$ 556	955	$ 399	72

Total other income, net, increased by approximately $0.4 million from approximately $0.6 million for the year ended December 31, 2019 to approximately $1.0 million for the year ended December 31, 2020. The increase in other income is primarily related to higher 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 $231,000 and $891,000 of other income arising from sales related to this transaction during the years ended December 31, 2019 and 2020, respectively. We have no knowledge of TSC's activities and cannot predict when we may receive income under the APA, if any. Increases in other income was offset by a $0.2 million reduction in interest income due to lower yields during the year ended December 31, 2020 compared to the year ended December 31, 2019.

Foreign exchange gains (losses)

Foreign exchange gains decreased by $79,000 to a gain of $22,000 for the year ended December 31, 2020 compared to a gain of approximately $0.1 million for the year ended December 31, 2019.

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. Favorable unrealized foreign exchange movements related to intercompany loans resulted in a gain of $7.6 million for the year ended December 31, 2020 and a gain of $6.8 million for the year ended December 31, 2019.

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 (HMRC), in respect of qualifying research and development costs incurred.

The following table summarizes total income tax benefit for the years ended December 31, 2019 and 2020 (in thousands except percentages):

	Year Ended December 31,		Difference	
	2019	2020	$	%
Total income tax benefit	$ 1,296	$ 1,236	$ (60)	(5)

The income tax benefit remained relatively flat at approximately $1.3 million and $1.2 million the years ended December 31, 2019 and December 31, 2020, respectively. 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 and could be restricted by any future cap introduced by HMRC. As we expect our eligible expenses to be higher in the fiscal year ended December 31, 2021, the level of tax credits recoverable is anticipated to be higher in 2021 compared to the fiscal year ended December 31, 2020.

Liquidity and Capital Resources

The following is a summary of our key liquidity measures as of December 31, 2019 and 2020 (in thousands):

	Year Ended December 31,	
	2019	2020
Cash and cash equivalents	$ 11,885	$ 33,406
Working capital:		
Current assets	$ 14,017	$ 35,469
Current liabilities	(2,420)	(2,486)
Total working capital	$ 11,597	$ 32,983

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, 2020, we had an accumulated deficit of $366.1 million.

Cash Flows

Cash provided by (used in operating, investing and financing activities for the years ended December 31, 2019 and 2020 is summarized as follows (in thousands):

	Year Ended December 31,	
	2019	2020
Net cash used in operating activities	$ (9,447)	$ (7,934)
Net cash provided by (used in) investing activities	28	(96)
Net cash provided by financing activities	3,848	29,504

Operating activities

Net cash used in operating activities decreased by $1.5 million, from $9.4 million for the year ended December 31, 2019 to $7.9 million for the year ended December 31, 2020. The decrease in cash used by operating activities was primarily the result of a decrease in working capital of $2.1 million, offset by an increase in net loss of $0.6 million. The change in working capital was due to settlement of large, end of clinical trial trade payables during the prior year.

Investing activities

Net cash used in investing activities decreased by $124,000 for the year ended December 31, 2020 due to an increase in capital expenditures on IT software and no proceeds from sale of property and equipment during the current year.

Financing activities

Net cash provided by financing activities was $29.5 million for the year ended December 31, 2020, primarily as a result of approximately $18.3 million in net proceeds from the issuance of common stock and accompanying common stock warrants under a co-placement agency agreement with Roth Capital Partners, LLC, Ladenburg Thalmann & Co. Inc., and Brookline Capital Markets, a division of Arcadia Securities, LLC, approximately $4.5 million from warrant exercises associated with this agreement and approximately $6.9 million of net proceeds from the issuance of common stock and accompanying common stock warrants in a securities purchase agreement with Acorn Bioventures, LP. This was offset by dividend payments of approximately $0.2 million to the holders of our 6% Preferred Stock.

Net cash provided by financing activities was $3.8 million for the year ended December 31, 2019, primarily as a result of approximately $4.1 million in net proceeds from the issuance of common stock under the Sales Agreement with Wainwright, offset by dividend payments of approximately $0.2 million to the holders of our 6% Preferred Stock.

Operating Capital and Capital Expenditure Requirements

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

We believe that existing funds together with cash generated from operations, 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 2022. 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, 2020 (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)	$ 1,771	$ 414	$ 734	$ 623	$ —

(1) Operating lease obligations relate primarily to leasing of office and laboratory space at our Dundee, UK and Berkeley Heights, New Jersey locations. The lease for our Dundee location, which was entered into in October 2000, expires in October 2025 and the lease for our Berkeley Heights location, which was entered into in August 2020, expires in July 2022.

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 (the 2018 Plan) and the 2020 Inducement Equity Incentive 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, 2020, we have outstanding 16,524 restricted stock unit awards that contain one or more performance conditions. None of these awards have satisfied their performance criteria and have not yet vested pursuant to their terms. At this time, management does not believe that the performance conditions are probable of being met. Accordingly, we have not recorded any compensation cost associated with these grants. If our judgment as to the likelihood of the awards vesting changes, we could recognize up to approximately $187,000 of compensation cost in future periods.

Recent Accounting Pronouncements Not Yet Effective

The FASB has issued ASU 2020-06, “Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity”. This standard simplifies the accounting for convertible instruments, such as convertible debt or convertible preferred stock, by eliminating two potential methods in accounting for the embedded conversion feature. The standard also removes certain conditions previously used to evaluate whether a freestanding financial instrument, or certain types of embedded features, are considered to be settled in the issuer’s own equity. Finally, ASU 2020-06 requires that an entity use the if-converted method in calculating the effects of convertible instruments on diluted earnings per share, with one limited exception. As a smaller reporting company, the amendments in this ASU are effective for the Company for fiscal years beginning after December 15, 2023, including interim periods within those years. Early adoption is permitted, but no earlier than for fiscal years beginning after December 15, 2020. The Company is currently evaluating the effects of this 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.

Item 8. Financial Statements and Supplementary Data

INDEX TO CYCLACEL PHARMACEUTICALS, INC. FINANCIAL STATEMENTS

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, 2020 and 2019, 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, 2020 and 2019, 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.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

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

/s/ RSM US LLP

New York, New York
March 1, 2021

CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31, 2019	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,885	$ 33,406
Prepaid expenses and other current assets	2,132	2,063
Total current assets	14,017	35,469
Property and equipment, net	27	106
Right-of-use lease asset	1,264	1,227
Total assets	$ 15,308	$ 36,802
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 890	$ 514
Accrued and other current liabilities	1,530	1,972
Total current liabilities	2,420	2,486
Lease liability	1,191	1,057
Total liabilities	3,611	3,543
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2019 and December 31, 2020;		
6% Convertible Exchangeable preferred stock; 335,273 shares issued and outstanding at December 31, 2019 and December 31, 2020. Aggregate preference in liquidation of $4,006,512 as of December 31, 2019 and December 31, 2020.	—	—
Series A convertible preferred stock, $0.001 par value; 264 shares issued and outstanding at December 31, 2019 and December 31, 2020.	—	—
Series B convertible preferred stock, $0.001 par value; 0 and 237,745 shares issued and outstanding at December 31, 2019 and December 31, 2020.	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2019 and December 31, 2020; 859,998 and 6,246,896 shares issued and outstanding at December 31, 2019 and December 31, 2020.	1	6
Additional paid-in capital	370,142	400,071
Accumulated other comprehensive loss	(819)	(746)
Accumulated deficit	(357,627)	(366,072)
Total stockholders' equity	11,697	33,259
Total liabilities and stockholders' equity	$ 15,308	$ 36,802

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

CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS (LOSS)

(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2019	2020
Revenues	$ —	$ —
Operating expenses:		
Research and development	4,658	4,759
General and administrative	5,024	5,877
Total operating expenses	9,682	10,636
Operating loss	(9,682)	(10,636)
Other income (expense):		
Foreign exchange gains (losses)	101	22
Interest income	224	42
Other income, net	231	891
Total other income, net	556	955
Loss before taxes	(9,126)	(9,681)
Income tax benefit	1,296	1,236
Net loss	(7,830)	(8,445)
Dividend on convertible exchangeable preferred shares	(201)	(201)
Beneficial conversion feature of Series B preferred stock	—	(3,775)
Net loss applicable to common shareholders	$ (8,031)	$ (12,421)
Basic and diluted earnings per common share:		
Net loss per share – basic and diluted	$ (9.84)	$ (3.42)
Weighted average common shares outstanding	816,080	3,633,385

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

CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	Year Ended December 31,	
	2019	2020
Net loss	$ (7,830)	$ (8,445)
Translation adjustment	(6,812)	(7,491)
Unrealized foreign exchange gain on intercompany loans	6,753	7,564
Comprehensive loss	$ (7,889)	$ (8,372)

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

CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands, except share amounts)

	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, 2018	**335,537**	**$ —**	**624,872**	**$ 1**	**$ 365,828**	**$ (760)**	**$ (349,797)**	**$ 15,272**
Issue of common stock on At Market Issuance sales agreement, net of expenses	—	—	235,126	0	4,049	—	—	4,049
Stock-based compensation	—	—	—	—	466	—	—	466
Preferred stock dividends	—	—	—	—	(201)	—	—	(201)
Unrealized foreign exchange on intercompany loans	—	—	—	—	—	6,753	—	6,753
Translation adjustment	—	—	—	—	—	(6,812)	—	(6,812)
Loss for the period	—	—	—	—	—	—	(7,830)	(7,830)
Balances at December 31, 2019	**335,537**	**$ —**	**859,998**	**$ 1**	**$ 370,142**	**$ (819)**	**$ (357,627)**	**$ 11,697**
Issue of common stock, preferred stock, pre-funded warrants and warrants on equity financing, net of expenses	237,745	—	4,485,898	4	21,441	—	—	21,445
Beneficial conversion feature of Series B preferred stock	—	—	—	—	3,775	—	—	3,775
Warrant exercises	—	—	901,000	1	4,484	—	—	4,485
Stock-based compensation	—	—	—	—	430	—	—	430
Preferred stock dividends	—	—	—	—	(201)	—	—	(201)
Unrealized foreign exchange on intercompany loans	—	—	—	—	—	7,564	—	7,564
Translation adjustment	—	—	—	—	—	(7,491)	—	(7,491)
Loss for the period	—	—	—	—	—	—	(8,445)	(8,445)
Balances at December 31, 2020	**573,282**	**$ —**	**6,246,896**	**$ 6**	**$ 400,071**	**$ (746)**	**$ (366,072)**	**$ 33,259**

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

CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,	
	2019	2020
Operating activities:		
Net loss	$ (7,830)	$ (8,445)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	20	20
Gain on disposal of property and equipment	(38)	—
Stock-based compensation	466	430
Changes in lease liability	(71)	(93)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	214	124
Accounts payable and other current liabilities	(2,208)	30
Net cash used in operating activities	(9,447)	(7,934)
Investing activities:		
Purchase of property, plant and equipment	(10)	(96)
Proceeds from sale of property and equipment	38	—
Net cash provided by (used in) investing activities	28	(96)
Financing activities:		
Proceeds from issuing common stock, preferred stock and pre-funded warrants, net of issuance costs	4,049	29,705
Payment of preferred stock dividend	(201)	(201)
Net cash provided by financing activities	3,848	29,504
Effect of exchange rate changes on cash and cash equivalents	(48)	47
Net increase in cash and cash equivalents	(5,619)	21,521
Cash and cash equivalents, beginning of period	17,504	11,885
Cash and cash equivalents, end of period	$ 11,885	$ 33,406
Supplemental cash flow information:		
Cash received during the period for:		
Interest	224	42
Taxes	1,163	1,291
Non cash activities on transition to ASC 842: Leases		
Lease liability	(1,505)	—
Right-of-use asset	1,385	—
Non cash financing activities:		
Accrual of preferred stock dividends	50	50

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

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 cell cycle control, transcriptional regulation and DNA damage response biology to develop innovative, targeted medicines for cancer and other proliferative diseases. Cyclacel is a pioneer company in the field of cell cycle biology with a vision to improve patient healthcare by translating cancer biology into medicines.

As of December 31, 2020, 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, the fact that 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 any of the Company's drug candidates are denied approval or clearance or such approval is delayed, or if the Company 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, 2020, 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 $7.8 million and $8.5 million for the years ended December 31, 2019 and 2020, respectively. As of December 31, 2020, the Company had an accumulated deficit of $366.1 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 $33.4 million as of December 31, 2020 will be sufficient to fund its operating expenses and capital expenditure requirements through 2022.

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.

The future viability of the Company beyond 2022 is dependent on its ability to raise additional capital to finance its operations. The Company does not currently have sufficient funds to complete development and commercialization of any of its drug candidates. Additional funding may not be available to the Company on favorable terms, or at all. If the Company is not able to secure additional funding when needed, it may have to delay, reduce the scope of or eliminate one or more of its clinical trials or research and development programs or make changes to its operating plan. In addition, it may have to partner one or more of its product candidate programs at an earlier stage of development, which would lower the economic value of those programs to the Company. 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.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or 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 and stock-based compensation expense. 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 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, 2020 was $33.4 million and it maintains its cash accounts in several entities both within the United States and the United Kingdom. The total cash balances for amounts held in the United States are insured by the Federal Deposit Insurance Corporation, or FDIC up to $250,000 per account. The Company has cash balances exceeding the balance insured by the FDIC that totaled approximately $31.8 million at December 31, 2020. The total cash balances for amounts held in the United Kingdom are insured by the UK Government Financial Services Compensation Scheme, or FSCS up to £85,000 per account. The Company has cash balances exceeding the balance insured by the FSCS that totaled approximately $1.3 million at December 31, 2020.

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.
- 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 mitosis control 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

The Company recognizes revenue in accordance to Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers, or* ASC 606.

The Company had no revenue in 2019 or 2020 under such contracts. Royalty income, if any, is recognized when the licensee sells the underlying product to which the royalty relates.

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, or CROs or clinical research associates, or 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.

Leases

The Company accounts for lease contracts in accordance with ASC 842. As of December 31, 2019 and 2020, all of the Company's leases are classified as operating leases.

The Company recognizes an asset for the right to use an underlying leased asset for the lease term and records lease liabilities based on the present value of the Company's obligation to make lease payments under the lease. As the Company's leases do not indicate an implicit rate, the Company uses a best estimate of its incremental borrowing rate to discount the future lease payments. The Company estimates its incremental borrowing rate based on observable information about risk-free interest rates that are the same tenure as the lease term, adjusted for various factors, including the effects of assumed collateral, the nature of how the loan is repaid (e.g., amortizing versus bullet), and the Company's credit risk.

The Company evaluates options included in its lease agreements to extend or terminate the lease. The Company will reflect the effects of exercising those options in the lease term when it is reasonably certain that the Company will exercise that option. In assessing whether it is reasonably certain that the Company will exercise an option, the Company considers factors such as:

- The lease payments due in any optional period;
- Penalties for failure to exercise (or not exercise) the option;
- Market factors, such as the availability of similar assets and current rental rates for such assets;
- The nature of the underlying leased asset and its importance to the Company's operations; and
- The remaining useful lives of any related leasehold improvements.

Lease expense for the Company's operating leases are recognized on a straight-line basis over the lease term. Variable lease payments, if any, are recognized in the period when the obligation to make those payments is incurred. Lease incentives received prior to lease commencement are recorded as a reduction in the right-of-use asset. Fixed lease incentives received after lease commencement reduces both the lease liability and the right-of-use asset.

The Company has elected an accounting policy to account for the lease and non-lease components as a single lease component.

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 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 will grant share-based payment awards to employees that are 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.

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 zero, 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 for 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, or 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", or 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 potentially 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, 2019 and 2020.

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, 2019 and 2020.

Recently Issued Accounting Pronouncements

In July 2017, the FASB issued Accounting Standards Update, or ASU, No. 2017-11, Accounting for Certain Financial Instruments with Down Round Features, or 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 was effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. 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 was effective for fiscal years beginning after December 15, 2018. The Company has applied the new leases standard at the adoption date. Upon adoption, there was no cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. However, upon adoption of ASU No. 2016-02, the Company initially recognized an operating lease liability, and a corresponding right-of-use asset, of approximately $1.5 million.

The Company has elected the package of practical expedients permitted in ASC 842. Accordingly, the Company accounted for its existing operating leases as operating leases under the new guidance, without reassessing (a) whether the contracts contain a lease under ASC 842, (b) whether classification of the operating leases would be different in accordance with ASC 842, (c) whether any unamortized initial direct costs would have met the definition of initial direct costs in ASC 842 at lease commencement, or (d) whether existing or expired land easements contain a lease under ASC 842. In addition, the Company has elected an accounting policy to not allocate payments made under the lease agreement between lease and non-lease components.

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.

Under 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 country, whichever is later. 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 2019 or 2020.

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.

4. Cash and Cash Equivalents

The following is a summary of cash and cash equivalents at December 31, 2019 and 2020 (in thousands):

	December 31,	
	2019	2020
Cash	$ 743	$ 28,080
Investments with original maturity of less than three months at the time of purchase	11,142	5,326
Total cash and cash equivalents	$ 11,885	$ 33,406

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

5. Fair Value 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, 2019 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 11,142	$ —	$ —	$ 11,142
Total Assets	$ 11,142	$ —	$ —	$ 11,142

	Fair Value Measurements as of December 31, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 5,326	$ —	$ —	$ 5,326
Total Assets	$ 5,326	$ —	$ —	$ 5,326

6. Prepaid Expenses and Other Current Assets

The following is a summary of prepaid expenses and other current assets at December 31, 2019 and 2020 (in thousands):

	December 31, 2019	December 31, 2020
Research and development tax credit receivable	$ 1,326	$ 1,313
Prepayments and VAT receivable	703	684
Other current assets	103	66
	$ 2,132	$ 2,063

7. Property and Equipment

Property and equipment consisted of the following at December 31, 2019 and 2020 (in thousands):

	Lives in years	December 31, 2019	December 31, 2020
Leasehold improvements	5 to 15	$ 824	$ 409
Research and laboratory equipment	3 to 5	4,287	—
Office equipment and furniture	3 to 5	1,169	583
		6,280	992
Less: accumulated depreciation and amortization		(6,253)	(886)
		$ 27	$ 106

Depreciation and amortization expense for property and equipment was $20,000 for each of the years ended December 31, 2019 and 2020. During the year ended December 31, 2020, the Company wrote-off fully depreciated assets which were no longer in use and had no associated re-sale value other than scrap value.

8. Accrued and Other Current Liabilities

Accrued and other current liabilities consisted of the following at December 31, 2019 and 2020 (in thousands):

	December 31, 2019	December 31, 2020
Accrued research and development	$ 617	$ 781
Accrued legal and professional fees	235	325
Other current liabilities	678	866
	$ 1,530	$ 1,972

Other current liabilities includes an approximately $80,000 Payment Protection Program loan received during the year from the US Federal government and subsequently repaid in February 2021.

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. In August 2020, the Company extended for a further two years, the lease for its corporate headquarters facility in Berkeley Heights, New Jersey.

Rent expense, which includes lease payments related to the Company's research and development facilities and corporate headquarters and other rent related expenses was $0.4 million each of the years ended December 31, 2019 and 2020.

The following is a summary of the Company's future contractual obligations and commitments relating to its facilities leases as at December 31, 2020 (in thousands):

	Operating Lease Obligation
2021	$ 414
2022	386
2023	348
2024	345
2025	278
thereafter	—
Total future minimum lease obligations	$ 1,771

10. Stockholders' Equity

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

December 2020 equity financing

On December 18, 2020, Cyclacel Pharmaceuticals, Inc. (the "Company") entered into a Securities Purchase Agreement (the "Purchase Agreement") with Acorn Bioventures, LP (the "Purchaser"), pursuant to which the Company agreed to offer, issue and sell to the Purchaser, (i) in a registered direct offering, (a) an aggregate of 485,912 shares (the "Common Shares") of common stock, par value $0.001 per share ("Common Stock"), and (b) an aggregate of 237,745 shares of Series B Convertible Preferred Stock (the "Preferred Shares," and collectively with the Common Shares, the "Shares"), par value $0.001 per share ("Series B Preferred Stock"), and (ii) in a concurrent private placement, warrants (the "Warrants") to purchase up to an aggregate of 669,854 shares (the "Warrant Shares") of Common Stock.

The combined purchase price for each Share, together with one Warrant to purchase 0.4 shares of Common Stock, is $4.18. Each Warrant shall be exercisable beginning on the 12-month anniversary of the date of issuance for a period of five years after the date of issuance, at an exercise price of $4.13 per Warrant Share. The exercise price of the Warrants will be subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described in the Warrants. The Warrants may be exercised on a "cashless" basis.

Each share of Series B Convertible Preferred Stock will convert into five shares of Common Stock.

The conversion feature within the Series B Convertible Preferred Stock was determined to be beneficial as of the offering date. A beneficial conversion feature is defined as a nondetachable conversion feature that is "in-the-money" at issuance. The Company calculated the value of the beneficial conversion feature based on its intrinsic value, which is the difference between the "effective conversion price" (after allocating the proceeds of the offering between the Series B Convertible Preferred Stock, the Warrants and Common Stock issued) and the market price of the Company's common shares, multiplied by the number of shares into which the Series B Convertible Preferred Stock is convertible. The effective conversion price of $3.18 per share is different from the $4.18 per share contractual conversion price.

As the series B 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 common stock, Warrants and Series B 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 B Preferred Stock is classified within permanent equity in the consolidated balance sheet.

The closing of the offering occurred on December 22, 2020 and the net proceeds to the Company were approximately $6.9 million, after deducting offering expenses payable by the Company.

April 2020 equity financing

On April 21, 2020, the Company entered into a co-placement agency agreement with Roth Capital Partners, LLC, Ladenburg Thalmann & Co. Inc., and Brookline Capital Markets, a division of Arcadia Securities, LLC (the "Co-Placement Agents") and a securities purchase agreement with certain purchasers for the purchase and sale of (i) 1,910,000 shares of common stock, (ii) pre-funded warrants to purchase up to 2,090,000 shares of common stock at an exercise price of $0.001 per share, and (iii) accompanying common stock warrants to purchase up to 4,000,000 shares of common stock at an exercise price of $5.00 per share. The shares of common stock and accompanying common stock warrants were sold at a combined public offering price of $5.00 per share and common stock warrant. Each common stock warrant sold with the shares of common stock represents the right to purchase one share of common stock at an exercise price of $5.00 per share. The common stock warrants are exercisable immediately and expire five years from the date of issuance.

The pre-funded warrants and accompanying common stock warrants were sold at a combined public offering price of $4.999 per pre-funded warrant and common stock warrant. The pre-funded warrants were sold to purchasers whose purchase of shares of common stock in the public offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of the Company's outstanding common stock immediately following the consummation of the public offering, in lieu of shares of common stock. Each pre-funded warrant represents the right to purchase one share of the Company's common stock at an exercise price of $0.001 per share. The pre-funded warrants are exercisable immediately and may be exercised at any time until the pre-funded warrants are exercised in full. The shares of common stock and pre-funded warrants, and accompanying common stock warrants, were issued separately and are immediately separable upon issuance.

The closing of the offering occurred on April 24, 2020, and the net proceeds to the Company were approximately $18.3 million, after deducting placement agent fees and other offering expenses payable by the Company.

The common stock, pre-funded warrants and common stock warrants (together the "warrants") 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.

Subsequent to the closing of the offering and within the year ended December 31, 2020, all of the pre-funded warrants issued in connection therewith were exercised in exchange for 2,090,000 shares of common stock.

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 was permitted to 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 were 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 paid Wainwright a commission of 3.0% of the gross sales price per share sold. The Sales Agreement was concluded during the first quarter of 2019, and thus terminated by its terms. Pursuant to the Sales Agreement, the Company sold an aggregate 260,126 shares for net proceeds of approximately $4.7 million, after deducting commissions and other expenses.

July 2017 Underwritten Public Offering

On July 21, 2017, the Company issued (i) 157,700 Class A Units for $40 per unit, each consisting of one share of the Company's common stock, and a warrant to purchase one share of common stock, or 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, or Series A Preferred Stock, convertible into 25 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, or 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 following is a description of the Company's outstanding equity instruments.

Warrants

December 2020 Warrants

As of December 31, 2020, 669,854 warrants issued in the December 2020 offering remained outstanding. All such warrants were issued in connection with the December 2020 Securities Purchase Agreement. Each Warrant shall be exercisable beginning on the 12-month anniversary of the date of issuance for a period of five years after the date of issuance, at an exercise price of $4.13 per Warrant Share. The exercise price of the Warrants will be subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described in the Warrants. The Warrants may be exercised on a "cashless" basis.

No warrants were exercised during the year ended December 31, 2020.

April 2020 Warrants

As of December 31, 2020, 3,099,000 warrants issued in the April 2020 offering remained outstanding, each with an exercise price of $5.00. All such warrants were issued in connection with the April 2020 co-placement agency agreement. The common warrants are immediately exercisable and will expire on the fifth anniversary of the original issuance date. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting the Company's common stock. The common warrants were issued separately from the common stock and were eligible for transfer immediately after issuance. A common warrant to purchase one share of common stock was issued for every share of common stock purchased in this offering.

A total of 901,000 warrants, totaling approximately $4.5 million were exercised during the year ended December 31, 2020.

July 2017 Warrants

As of December 31, 2020, 374,525 warrants issued in connection with the July 2017 underwritten public offering remained outstanding, each with an exercise price of $40.00. All such warrants were issued in connection with the July 2017 underwritten public offering and are immediately exercisable. The warrants expire in 2024.

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.

There were no warrants exercised during each of the years ended December 31, 2019 and 2020.

Series B Preferred Stock

237,745 shares of the Company's Series B Preferred Stock were issued in the December 2020 Securities Purchase Agreement. Each share of Series B Preferred Stock shall initially be convertible into five shares of Common Stock (the "Conversion Shares"), subject to adjustment in accordance with the Certificate of Designation.

Holders of Series B Preferred Stock are entitled to receive dividends on shares of Series B Preferred Stock equal, on an as-if-converted-to-Common-Stock basis, and in the same form as dividends actually paid on shares of the Common Stock. Except as otherwise required by law, the Series B Preferred Stock does not have voting rights. However, as long as any shares of Series B Preferred Stock are outstanding, the Company will not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series B Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series B Preferred Stock, (b) alter or amend the Certificate of Designation, (c) amend its certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series B Preferred Stock, (d) increase the number of authorized shares of Series B Preferred Stock, (e) pay certain dividends or (f) enter into any agreement with respect to any of the foregoing. The Series B Preferred Stock does not have a preference upon any liquidation, dissolution or winding-up of the Company. The Purchaser may convert shares of Series B Preferred Stock through a conversion into shares of Common Stock if and solely to the extent that such conversion would not result in the Purchaser beneficially owning in excess of 9.99% of then-outstanding Common Stock or aggregate voting power of the Company (such limitation, the "Ownership Limitation") and any portion in excess of such limitation will remain outstanding as Series B Preferred Stock.

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 $40.00 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.

As of December 31, 2019 and 2020, 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, 2020, are convertible into 6,600 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, or 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, 2019 and 2020, there were 335,273 shares of the Company's 6% Convertible Exchangeable, or 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. Accumulated but unpaid dividends in arrears on preferred stock were $0.7 million, or $1.95 per share, of preferred stock, as of December 31, 2019 and 2020.

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 0.00025 shares of common stock for each share of Preferred Stock based on a price of $39,480. The Company has reserved 85 shares of common stock for issuance upon conversion of the remaining shares of Preferred Stock outstanding at December 31, 2020. 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 $59,220, 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, or Exchange Date for the Company's 6% Convertible Subordinated Debentures, or 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, 2020.

For the year ended December 31, 2020, the company declared dividends of $0.15 per share quarterly on its 6% Convertible Exchangeable Preferred Stock. These dividends were paid on May 1, August 1 and November 1, 2020, and February 1, 2021, respectively.

11. Stock-Based Compensation

Stock based compensation has been reported within expense line items on the consolidated statement of operations for the years ended 2019 and 2020 as shown in the following table (in thousands):

	Year Ended December 31,	
	2019	2020
Research and development	166	$ 152
General and administrative	300	278
Stock-based compensation costs before income taxes	$ 466	$ 430

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 775,000 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 35,494 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.

As of December 31, 2020, the Company has reserved 328,035 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.

2020 Inducement Equity Incentive Plan

In October 2020, the Inducement Equity Incentive Plan (the "Inducement Plan"), became effective. Under this Plan, Cyclacel may make equity incentive grants to new senior level Employees (persons to whom the Company may issue securities without stockholder approval). The Inducement Plan allows for the issuance of up to 200,000 shares of the Company's common stock (or the equivalent of such number). As of December 31, 2020, 120,000 shares under the Inducement Plan have been issued, leaving a remaining reserve of 80,000 shares.

Option Grants

There were 77,514 options granted during the year ended December 31, 2019.

There were 511,800 options granted during the year ended December 31, 2020. Of these awards, 391,800 were issued under the 2018 Plan and the remaining 120,000 shares were issued under the Inducement Plan.

The weighted average grant-date fair values of options granted during the years ended December 31, 2019 and 2020 were $11.51 and $3.47, respectively.

As of December 31, 2020, the total remaining unrecognized compensation cost related to the non-vested stock options with service conditions amounted to approximately $1.9 million, which will be amortized over the weighted-average remaining requisite service period of 2.66 years.

During the years ended December 31, 2019 and 2020, the Company did not settle any equity instruments with cash.

There were no stock option exercises during the years ended 2019 and 2020. No income tax benefits were recorded for the years ended December 31, 2019 and 2020. As the Company has accumulated net operating losses for tax purposes, it is not likely to benefit from any deductions associated with future exercises of granted option awards.

In September 2020, the Company modified outstanding stock option awards for two of its directors, whose service terminated in September 2020. Specifically, the Company immediately vested a total of 10,400 options that otherwise would have been forfeited. In addition, the Company extended the period in which all of these directors' outstanding vested awards could be exercised from one to three years (but not beyond the contractual term of the awards). The Company recognized a charge of approximately $20,000 in the quarter ended September 30, 2020 related to these modifications.

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 ($000)
Options outstanding at December 31, 2018	41,581	$ 133.60	8.13	$ —
Granted	77,514	$ 14.20	—	—
Exercised	—	—	—	—
Cancelled/forfeited	(18,816)	$ 64.60	—	—
Options outstanding at December 31, 2019	100,279	$ 54.40	8.62	$ 4
Granted	511,800	$ 4.17	—	—
Exercised	—	—	—	—
Cancelled/forfeited	(9,396)	$ 101.05	—	—
Options outstanding at December 31, 2020	602,683	$ 11.01	9.39	$ 1,861
Unvested at December 31, 2020	525,010	$ 4.64	9.80	$ 1,829
Vested and exercisable at December 31, 2020	77,673	$ 54.05	6.61	$ 32

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, 2019	Year Ended December 31, 2020
Expected term (years)	5 – 6	5 – 6
Risk free interest rate	2.105 – 2.610%	0.410% – 0.570%
Volatility	103 – 110%	96 – 115%
Expected dividend yield over expected term	0.00%	0.00%
Resulting weighted average grant date fair value	$14.20	$3.47

Restricted Stock Units

The Company issued 14,000 restricted stock units to employees during the year ended December 31, 2019. The Company issued 3,938 additional restricted stock units to employees during the quarter ended March 31, 2020, of which 1,414 units have been forfeited. The vesting of the remaining 16,524 outstanding restricted stock units is dependent upon the fulfillment of certain clinical conditions. The Company determined that the satisfaction of the clinical conditions was not probable at December 31, 2020 and, as a result, recorded no compensation expense related to restricted stock units for the year ended December 31, 2020. The restricted stock units were valued based on their fair value at the date of grant, which is equivalent to the market price of a share of the Company's common stock. Summarized information for restricted stock units' activity for the year ended December 31, 2020 is as follows:

	Number of Options Outstanding	Weighted Average Grant Date Value Per Share
Restricted Stock Units outstanding at December 31, 2019	14,000	$ 10.60
Granted	3,938	$ 15.20
Cancelled/forfeited	(1,414)	$
Restricted Stock Units outstanding at December 31, 2020	16,524	$ 11.30
Unvested at December 31, 2020	16,524	$ 11.30
Vested and exercisable at December 31, 2020	—	$ —

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 $53,000 and $43,000 for the years ended December 31, 2019 and 2020, 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 $19,500 if under 50 years old and $26,000 if over 50 years old and to have those funds contributed to the 401(k) Plan. The Company made contributions of approximately $55,000 and $57,000 to the 401(k) Plan for the years ended December 31, 2019 and 2020, respectively.

13. Taxes

(Loss) income from continuing operations before taxes is comprised of the following components for the years ended December 31, 2019 and 2020 (in thousands):

	Year Ended December 31,	
	2019	2020
Domestic	$ (437)	$ (428)
Foreign	(8,689)	(9,253)
Loss from continuing operations before taxes	$ (9,126)	$ (9,681)

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

	Year Ended December 31,	
	2019	2020
Current – domestic	$ (3)	$ (2)
Current – foreign	1,299	1,238
Current – total	1,296	1,236
Deferred – domestic	—	—
Income tax benefit	$ 1,296	$ 1,236

The Company has incurred a taxable loss in each of the operating periods since incorporation. The income tax credits of $1.3 million and $1.2 million for the years ended December 31, 2019 and 2020, respectively, represent UK research and development ("R&D") tax credits for expenditures in the United Kingdom that are refundable.

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

	Year Ended December 31,	
	2019	2020
Loss from continuing operations before taxes	$ (9,126)	$ (9,681)
Income tax expense computed at statutory federal tax rate	(1,916)	(2,033)
Disallowed expenses and non-taxable income	345	352
Loss surrendered to generate R&D credit	1,686	1,788
Additional research and development tax relief	(1,299)	(1,238)
Change in valuation allowance	665	3,205
Foreign items, including change in tax rates, and other	176	1,638
Change in UK Tax Rate	—	(3,937)
Other foreign items	(953)	(1,011)
	$ (1,296)	$ (1,236)

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

	Year Ended December 31,	
	2019	2020
Net operating loss and tax credit carryforwards	$ 35,772	$ 42,012
Depreciation, amortization and impairment of property and equipment	104	39
Stock options	1,481	—
Right of use asset	(163)	(183)
Lease liability	176	195
Deferred tax assets	37,370	42,063
Valuation allowance for deferred tax assets	(37,370)	(42,063)
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 $42.1 million has been established at December 31, 2020. The valuation allowance has increased by approximately $4.7 million in 2020.

As of December 31, 2019, the UK government had announced legislation to reduce the corporate tax rate from 19% to 17%. Accordingly, the UK deferred tax assets were tax affected at 17%. As of December 31, 2020, the UK government announced that the corporate tax rate would remain at 19%. As a result of this enacted rate of 19%, the UK deferred tax assets increased by $3.9 million, fully offset by a $3.9 million increase in the valuation allowance.

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 occurred on March 4, 2015 and July 21, 2017. As a result of the ownership changes, the NOLs are limited.

As of December 31, 2019 and 2020, the Company had federal NOLs of $0.4 million and $1.1 million, respectively. The federal NOLs have an indefinite life. As of December 31, 2019 and 2020, the Company has state NOLs of $19.8 million and $20.5 million, respectively, which will begin to expire in 2028. As of December 31, 2019 and 2020, the Company had foreign NOLs of $201.7 million and $212.4 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, 2019 and 2020 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 2017, 2018 and 2019 remain open to examination by major taxing jurisdictions to which the Company is subject, which are primarily in the United Kingdom and the United States, as carryforward attributes generated in years past may still be adjusted upon examination by the United Kingdom's H.M. Revenue & Customs, the Internal Revenue Service ("IRS") or state tax authorities. The Company is currently not under examination by the IRS or any other jurisdictions for any tax years.

We have not provided a deferred tax liability on the cumulative amount of unremitted foreign earnings of international subsidiaries because it is our intent to permanently reinvest such earnings outside of the United States.

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.

On December 27, 2020, the Consolidations Appropriations Act, 2021 ("CAA" or the "Act) was signed into law and included government appropriations and additional economic stimulus. Notable provisions of the CAA included changes to the Paycheck Protection Program including legislation concluding that expenses used to obtain loan forgiveness are tax deductible, as well as extension and expansion of other COVID-19 relief programs and payroll tax credits. The Company evaluated the various aspects of the Act and did not pursue any payroll tax credits or deferrals.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was enacted in response to the COVID-19 pandemic. The CARES Act, provides for economic and cash liquidity stimulus through various means including payroll tax credits, payroll tax deferral, short term changes in tax deductibility of interest expenses among other things. The Act also permits NOL carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. Previously, NOLs generated after December 31, 2017 were limited to 80% of taxable income in future years. In addition, the CARES Act allows NOLs incurred in 2018, 2019 and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. The CARES Act had no material impact the Company.

14. Net Loss Per Share

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

	Years ended December 31,	
	2019	2020
Numerator:		
Net loss	$ (7,830)	$ (8,445)
Dividend on convertible exchangeable preferred shares	(201)	(201)
Beneficial conversion feature of Series B preferred stock	—	(3,775)
Conversion of Series B preferred stock	—	—
Net loss attributable to common shareholders	$ (8,031)	$ (12,421)
Denominator:		
Weighted-average number of common shares used in loss per share – basic and diluted	816,080	3,633,385
Loss per share – basic and diluted	$ (9.84)	$ (3.42)

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:

	December 31, 2019	December 31, 2020
Stock options	100,278	602,683
6% convertible exchangeable preferred stock	85	85
Series A preferred stock	6,600	6,600
Series B preferred stock	—	1,188,725
Common stock warrants	374,525	4,143,379
Total shares excluded from calculation	481,488	5,941,472

15. Geographic Information

Geographic information for the years ended December 31, 2019 and 2020 is as follows (in thousands):

	Year Ended December 31,	
	2019	2020
Revenue		
United Kingdom	$ —	$ —
Total Revenue	$ —	$ —
Net loss		
United States	$ (439)	$ (430)
United Kingdom	(7,391)	(8,015)
Total Net Loss	$ (7,830)	$ (8,445)

	December 31,	
	2019	2020
Total Assets		
United States	$ 11,470	$ 32,322
United Kingdom	3,838	4,480
Total Assets	$ 15,308	$ 36,802
Long Lived Assets, net		
United States	$ 3	$ 1
United Kingdom	24	105
Total Long Lived Assets, net	$ 27	$ 106

16. Subsequent Events

A total of 857,500 warrants, totaling approximately $4.3 million, issued in connection with the April 2020 financing, were exercised after December 31, 2020. Including the 901,000 warrants exercised during 2020, the aggregate exercise proceeds total approximately $8.8 million.

On December 11, 2020, 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, 2021 to the holders of record of the Preferred Stock as of the close of business on January 15, 2021.

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, 2020.

Pursuant to this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2020, 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.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2020. 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, 2020, 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, 2020 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.

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 2020 fiscal year pursuant to Regulation 14A for its 2021 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 2020 fiscal year pursuant to Regulation 14A for its 2021 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 2020 fiscal year pursuant to Regulation 14A for its 2021 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 2020 fiscal year pursuant to Regulation 14A for its 2021 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 2020 fiscal year pursuant to Regulation 14A for its 2021 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 Number	Description
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).
3.3	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 April 14, 2020, and incorporated herein by reference).
3.4	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).
3.5	Second Amended and Restate Bylaws 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 7, 2020, and incorporated herein by reference).
3.6	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).
3.7	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).
3.8	Certificate of Designation of Preferences, Rights and Limitations of the Series B Convertible Preferred Stock (previously filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on December 22, 2020, 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).
4.7	Form of Pre-Funded Warrant (previously filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on April 24, 2020, and incorporated herein by reference).
4.8	Form of Common Warrant (previously filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on April 24, 2020, and incorporated herein by reference).
4.9	Form of Warrant (previously filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on December 22, 2020, and incorporated herein by reference).
4.10*	Description of Securities.
10.1†	Amended and Restated 2006 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†	2015 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†	2018 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, and incorporated by reference)).
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).
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).

Exhibit Number	Description
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).
10.16	Employment Agreement, by and between Cyclacel Pharmaceuticals, Inc. and Spiro Rombotis, dated as of January 1, 2019 (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on January 7, 2019, and incorporated by reference).
10.17	Employment Agreement, by and between Cyclacel Pharmaceuticals, Inc. and Paul McBarron, dated as of January 1, 2019 (previously filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on January 7, 2019, and incorporated by reference).
10.18	Cyclacel Pharmaceuticals, Inc. 2020 Inducement Equity Incentive Plan (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on November 12, 2020, and incorporated by reference).
10.19	Form of Stock Option Grant Notice and Stock Option Agreement under the Cyclacel Pharmaceuticals, Inc. 2020 Inducement Equity Incentive Plan (previously filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on November 12, 2020, and incorporated by reference).
10.20	Form of Securities Purchase Agreement (previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on December 22, 2020, and incorporated by reference).
21	Subsidiaries of Cyclacel Pharmaceuticals, Inc. (previously filed as Exhibit 21 to the Registrant's Annual Report on Form 10-K, originally filed with the SEC on March 26, 2014, and incorporated herein by reference).
23.1*	Consent of Independent Registered Public Accounting Firm.
31.1*	Certification of Spiro Rombotis, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Paul McBarron, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Spiro Rombotis, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code).

32.2**	Certification of Paul McBarron, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code).
101	The following materials from Cyclacel Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2020, 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.

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.

Date: March 1, 2021

By: /s/ Paul McBarron
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 1, 2021
/s/ Paul McBarron Paul McBarron	Chief Operating Officer, Chief Financial Officer & Executive Vice President, Finance (Principal Financial and Accounting Officer) and Director	March 1, 2021
/s/ Dr. Christopher Henney Dr. Christopher Henney	Chairman	March 1, 2021
/s/ Robert Spiegel Robert Spiegel	Vice Chairman	March 1, 2021
/s/ Samuel L. Barker Samuel L. Barker	Director	March 1, 2021
/s/ Gregory Hradsky Gregory Hradsky	Director	March 1, 2021
/s/ Lloyd Sems Lloyd Sems	Director	March 1, 2021
/s/ Karin L. Walker Karin L. Walker	Director	March 1, 2021
/s/ Brian Schwartz Brian Schwartz	Director	March 1, 2021

DESCRIPTION OF SECURITIES

The following description of our capital stock, certain provisions of our certificate of incorporation and bylaws, and certain provisions of Delaware law are summaries. The following description is not complete and is subject to and qualified in its entirety by our certificate of incorporation and bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of the Delaware General Corporation Law.

As of the date of this prospectus, our certificate of incorporation authorized us to issue 100,000,000 shares of common stock, par value $0.001 per share, and 5,000,000 shares of preferred stock, par value $0.001 per share.

Common Stock

Dividends, Voting Rights and Liquidation

Holders of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, and do not have cumulative voting rights. Our amended and restated certificate of incorporation and amended and restated bylaws provide that our board of directors is divided into three classes, each serving staggered three-year terms ending at the annual meeting of our stockholders. Subject to preferences that may be applicable to any outstanding shares of preferred stock, holders of common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by our board of directors out of funds legally available for dividend payments. All outstanding shares of common stock are fully paid and non-assessable, and the shares of common stock to be issued upon completion of this offering will be fully paid and non-assessable. The holders of common stock have no preferences or rights of conversion, exchange, pre-emption or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. In the event of any liquidation, dissolution or winding-up of our affairs, holders of common stock will be entitled to share ratably in our assets that are remaining after payment or provision for payment of all of our debts and obligations and after liquidation payments to holders of outstanding shares of preferred stock, if any.

Fully Paid and Non-Assessable

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and non-assessable.

Preferred Stock

We have the authority to issue up to 5,000,000 shares of preferred stock. As of December 31, 2020, 335,273 shares of our preferred stock were outstanding as 6% Convertible Exchangeable Preferred Stock (see “6% Convertible Exchangeable Preferred Stock” below), 264 shares of our preferred stock were outstanding as Series A Convertible Preferred Stock (see “Series A Convertible Preferred Stock” below) and 237,745 shares of our preferred stock were outstanding as Series B Convertible Preferred Stock (see “Series B Convertible Preferred Stock” below). The description of preferred stock provisions set forth below is not complete and is subject to and qualified in its entirety by reference to our certificate of incorporation and the certificate of designations relating to each series of preferred stock.

The board of directors has the right, without the consent of holders of common stock, to designate and issue one or more series of preferred stock, which may be convertible into common stock at a ratio determined by the board of directors. A series of preferred stock may bear rights superior to common stock as to voting, dividends, redemption, distributions in liquidation, dissolution, or winding up, and other relative rights and preferences. The board may set the following terms of any series of preferred stock:

- the number of shares constituting the series and the distinctive designation of the series;
- dividend rates, whether dividends are cumulative, and, if so, from what date; and the relative rights of priority of payment of dividends;
- voting rights and the terms of the voting rights;
- conversion privileges and the terms and conditions of conversion, including provision for adjustment of the conversion rate;

- redemption rights and the terms and conditions of redemption, including the date or dates upon or after which shares may be redeemable, and the amount per share payable in case of redemption, which may vary under different conditions and at different redemption dates;
- sinking fund provisions for the redemption or purchase of shares;
- rights in the event of voluntary or involuntary liquidation, dissolution or winding up of the corporation, and the relative rights of priority of payment; and
- any other relative powers, preferences, rights, privileges, qualifications, limitations and restrictions of the series.

Dividends on outstanding shares of preferred stock will be paid or declared and set apart for payment before any dividends may be paid or declared and set apart for payment on the common stock with respect to the same dividend period.

If, upon any voluntary or involuntary liquidation, dissolution or winding up of the Company, the assets available for distribution to holders of preferred stock are insufficient to pay the full preferential amount to which the holders are entitled, then the available assets will be distributed ratably among the shares of all series of preferred stock in accordance with the respective preferential amounts (including unpaid cumulative dividends, if any) payable with respect to each series.

Holders of preferred stock will not be entitled to preemptive rights to purchase or subscribe for any shares of any class of capital stock of the corporation. The preferred stock will, when issued, be fully paid and non-assessable. The rights of the holders of preferred stock will be subordinate to those of our general creditors.

We have previously issued shares of preferred stock in three series, designated as 6% Convertible Exchangeable Preferred Stock, of which 335,273 are currently outstanding, as Series A Convertible Preferred Stock, of which 264 are currently outstanding, and as Series B Convertible Preferred Stock, of which 237,745 are currently outstanding, and are quoted on The Nasdaq Capital Market under the symbol “CYCCP.”

6% Convertible Exchangeable Preferred Stock

General

Our board of directors designated 2,046,813 shares of the preferred stock that were issued as convertible preferred stock on November 3, 2004. The shares of convertible preferred stock are duly and validly issued, fully paid and non-assessable. These shares will not have any preemptive rights if we issue other series of preferred stock. The convertible preferred stock is not subject to any sinking fund. We have no obligation to retire the convertible preferred stock. The convertible preferred stock has a perpetual maturity and may remain outstanding indefinitely, subject to the holder’s right to convert the convertible preferred stock and our right to cause the conversion of the convertible preferred stock and exchange or redeem the convertible preferred stock at our option. Any convertible preferred stock converted, exchanged or redeemed or acquired by us will, upon cancellation, have the status of authorized but unissued shares of convertible preferred stock. We will be able to reissue these cancelled shares of convertible preferred stock.

Dividends

When and if declared by our board of directors out of the legally available funds, holders of the convertible preferred stock are entitled to receive cash dividends at an annual rate of 6% of the liquidation preference of the convertible preferred stock. Dividends are payable quarterly on the first day of February, May, August and November. If any dividends are not declared, they will accrue and be paid at such later date, if any, as determined by our board of directors. Dividends on the convertible preferred stock will be cumulative from the issue date. Dividends will be payable to holders of record as they appear on our stock books not more than 60 days nor less than 10 days preceding the payment dates, as fixed by our board of directors. If the convertible preferred stock is called for redemption on a redemption date between the dividend record date and the dividend payment date and the holder does not convert the convertible preferred stock (as described below), the holder shall receive the dividend payment together with all other accrued and unpaid dividends on the redemption date instead of receiving the dividend on the dividend date. Dividends payable on the convertible preferred stock for any period greater or less

than a full dividend period will be computed on the basis of a 360-day year consisting of twelve 30-day months. Accrued but unpaid dividends will not bear interest.

If we do not pay or set aside cumulative dividends in full on the convertible preferred stock and any other preferred stock ranking on the same basis as to dividends, all dividends declared upon shares of the convertible preferred stock and any other preferred stock ranking on the same basis as to dividends will be declared on a pro rata basis until all accrued dividends are paid in full. For these purposes, "pro rata" means that the amount of dividends declared per share on the convertible preferred stock and any other preferred stock ranking on the same basis as to dividends bear to each other will be the same ratio that accrued and unpaid dividends per share on the shares of the convertible preferred stock and such other preferred stock bear to each other. We will not be able to redeem, purchase or otherwise acquire any of our stock ranking on the same basis as the convertible preferred stock as to dividends or liquidation preferences unless we have paid or set aside full cumulative dividends, if any, accrued on all outstanding shares of convertible preferred stock.

Unless we have paid or set aside cumulative dividends in full on the convertible preferred stock and any other of the convertible preferred stock ranking on the same basis as to dividends:

- we may not declare or pay or set aside dividends on common stock or any other stock ranking junior to the convertible preferred stock as to dividends or liquidation preferences, excluding dividends or distributions of shares, options, warrants or rights to purchase common stock or other stock ranking junior to the convertible preferred stock as to dividends; or

- we will not be able to redeem, purchase or otherwise acquire any of our other stock ranking junior to the convertible preferred stock as to dividends or liquidation preferences, except in very limited circumstances.

Under Delaware law, we may only make dividends or distributions to our stockholders from:

- our surplus; or

- the net profits for the current fiscal year before which the dividend or distribution is declared under certain circumstances.

For the year ended December 31, 2020, the company declared dividends of $0.15 per share quarterly. These dividends were paid on May 1, August 1 and November 1, 2020, and February 1, 2021, respectively.

Conversion

Conversion Rights

Holders of our convertible preferred stock may convert the convertible preferred stock at any time into a number of shares of common stock determined by dividing the $10.00 liquidation preference by the conversion price of $39,480.00. This conversion price is equivalent to a conversion rate of approximately 0.00025 shares of common stock for each share of convertible preferred stock. We will not make any adjustment to the conversion price for accrued or unpaid dividends upon conversion. We will not issue fractional shares of common stock upon conversion. However, we will instead pay cash for each fractional share based upon the market price of the common stock on the last business day prior to the conversion date. If we call the convertible preferred stock for redemption, the holder's right to convert the convertible preferred stock will expire at the close of business on the business day immediately preceding the date fixed for redemption, unless we fail to pay the redemption price.

Automatic Conversion

Unless we redeem or exchange the convertible preferred stock, we may elect to convert some or all of the convertible preferred stock into shares of our common stock if the closing price of our common stock has exceeded 150% of the conversion price for at least 20 out of 30 consecutive trading days ending within five trading days prior

to the notice of automatic conversion. If we elect to convert less than all of the shares of convertible preferred stock, we shall select the shares to be converted by lot or pro rata or in some other equitable manner in our discretion. On or after November 3, 2007, we may not elect to automatically convert the convertible preferred stock if full cumulative dividends on the convertible preferred stock for all past dividend periods have not been paid or set aside for payment.

Conversion Price Adjustment — General

The conversion price of $39,480.00 will be adjusted if:

(1) we dividend or distribute common stock in shares of our common stock;

(2) we subdivide or combine our common stock;

(3) we issue to all holders of common stock certain rights or warrants to purchase our common stock at less than the current market price;

(4) we dividend or distribute to all holders of our common stock shares of our capital stock or evidences of indebtedness or assets, excluding:

- those rights, warrants, dividends or distributions referred to in (1) or (3), or

- dividends and distributions paid in cash;

(5) we made a dividend or distribution consisting of cash to all holders of common stock;

(6) we purchase common stock pursuant to a tender offer made by us or any of our subsidiaries; and

(7) a person other than us or any of our subsidiaries makes any payment on a tender offer or exchange offer and, as of the closing of the offer, the board of directors is not recommending rejection of the offer. We will only make this adjustment if the tender or exchange offer increases a person's ownership to more than 25% of our outstanding common stock, and only if the payment per share of common stock exceeds the current market price of our common stock. We will not make this adjustment if the offering documents disclose our plan to engage in any consolidation, merger, or transfer of all or substantially all of our properties and if specified conditions are met.

If we implement a stockholder rights plan, this new rights plan must provide that, upon conversion of the existing convertible preferred stock the holders will receive, in addition to the common stock issuable upon such conversion, the rights under such rights plan regardless of whether the rights have separated from the common stock before the time of conversion. The distribution of rights or warrants pursuant to a stockholder rights plan will not result in an adjustment to the conversion price of the convertible preferred stock until a specified triggering event occurs.

The occurrence and magnitude of certain of the adjustments described above is dependent upon the current market price of our common stock. For these purposes, "current market price" generally means the lesser of:

- the closing sale price on certain specified dates, or

- the average of the closing prices of the common stock for the ten trading day period immediately prior to certain specified dates.

We may make a temporary reduction in the conversion price of the convertible preferred stock if our board of directors determines that this decrease would be in our best interest. We may, at our option, reduce the conversion price if our board of directors deems it advisable to avoid or diminish any income tax to holders of common stock

resulting from any dividend or distribution of stock or rights to acquire stock or from any event treated as such for income tax purposes.

Conversion Price Adjustment — Merger, Consolidation or Sale of Assets

If we are involved in a transaction in which shares of our common stock are converted into the right to receive other securities, cash or other property, or a sale or transfer of all or substantially all of our assets under which the holders of our common stock shall be entitled to receive other securities, cash or other property, then appropriate provision shall be made so that the shares of convertible preferred stock will convert into:

(1) if the transaction is a common stock fundamental change, as defined below, common stock of the kind received by holders of common stock as a result of common stock fundamental change in accordance with paragraph (1) below under the subsection entitled "— Fundamental Change Conversion Price Adjustments," and

(2) if the transaction is not a common stock fundamental change, and subject to funds being legally available at conversion, the kind and amount of the securities, cash or other property that would have been receivable upon the recapitalization, reclassification, consolidation, merger, sale, transfer or share exchange by a holder of the number of shares of common stock issuable upon conversion of the convertible preferred stock immediately prior to the recapitalization, reclassification, consolidation, merger, sale, transfer or share exchange, after giving effect to any adjustment in the conversion price in accordance with paragraph (2) below under the subsection entitled "— Fundamental Change Conversion Price Adjustments."

The company formed by the consolidation, merger, asset acquisition or share acquisition shall provide for this right in its organizational document. This organizational document shall also provide for adjustments so that the organizational document shall be as nearly practicably equivalent to adjustments in this section for events occurring after the effective date of the organizational document.

The following types of transactions, among others, would be covered by this adjustment:

(1) we recapitalize or reclassify our common stock, except for:
- a change in par value,
- a change from par value to no par value,
- a change from no par value to par value, or
- a subdivision or combination of our common stock.

(2) we consolidate or merge into any other person, or any merger of another person into us, except for a merger that does not result in a reclassification, conversion, exchange or cancellation of common stock,

(3) we sell, transfer or lease all or substantially all of our assets and holders of our common stock become entitled to receive other securities, cash or other property, or

(4) we undertake any compulsory share exchange.

Fundamental Change Conversion Price Adjustments

If a fundamental change occurs, the conversion price will be adjusted as follows:

(1) in the case of a common stock fundamental change, the conversion price shall be the conversion price after giving effect to any other prior adjustments effected pursuant to the preceding paragraphs, multiplied by a fraction, the numerator of which is the purchaser stock price, as defined below, and the denominator of which is the applicable price, as defined below. However, in the event of a common stock fundamental

change in which:

- 100% of the value of the consideration received by a holder of our common stock is common stock of the successor, acquirer or other third party, and cash, if any, paid with respect to any fractional interests in such common stock resulting from such common stock fundamental change, and

- All of our common stock shall have been exchanged for, converted into or acquired for, common stock of the successor, acquirer or other third party, and any cash with respect to fractional interests,

- the conversion price shall be the conversion price in effect immediately prior to such common stock fundamental change multiplied by a fraction, the numerator of which is one (1) and the denominator of which is the number of shares of common stock of the successor, acquirer or other third party received by a holder of one share of our common stock as a result of the common stock fundamental change; and

(2) in the case of a non-stock fundamental change, the conversion price shall be the lower of:

- the conversion price after giving effect to any other prior adjustments effected pursuant to the preceding paragraph and

- the product of

  A. the applicable price, and

  B. a fraction, the numerator of which is $10 and the denominator of which is (x) the amount of the redemption price for one share of convertible preferred stock if the redemption date were the date of the non-stock fundamental change (or if the date of such non-stock fundamental change falls within the period beginning on the first issue date of the convertible preferred stock through October 31, 2005, the twelve-month period commencing November 1, 2005 and the twelve-month period commencing November 1, 2006, the product of 106.0%, 105.4% or 104.8%, respectively, and $10) plus (y) any then-accrued and unpaid distributions on one share of convertible preferred stock.

Holders of convertible preferred stock may receive significantly different consideration upon conversion depending upon whether a fundamental change is a non-stock fundamental change or a common stock fundamental change. In the event of a non-stock fundamental change, the shares of convertible preferred stock will convert into stock and other securities or property or assets, including cash, determined by the number of shares of common stock receivable upon conversion at the conversion price as adjusted in accordance with (2) above. In the event of a common stock fundamental change, under certain circumstances, the holder of convertible preferred stock will receive different consideration depending on whether the holder converts his or her shares of convertible preferred stock on or after the common stock fundamental change.

Definitions for the Fundamental Change Adjustment Provision

“applicable price” means:

- in a non-stock fundamental change in which the holders of common stock receive only cash, the amount of cash received by a holder of one share of common stock, and

- in the event of any other fundamental change, the average of the daily closing price for one share of common stock during the 10 trading days immediately prior to the record date for the determination of the holders of common stock entitled to receive cash, securities, property or other assets in connection with the fundamental change or, if there is no such record date, prior to the date upon which the holders of common stock shall have the right to receive such cash, securities, property or other assets.

"common stock fundamental change" means any fundamental change in which more than 50% of the value, as determined in good faith by our board of directors, of the consideration received by holders of our common stock consists of common stock that, for the 10 trading days immediately prior to such fundamental change, has been admitted for listing or admitted for listing subject to notice of issuance on a national securities exchange or quoted on The NASDAQ National Market, except that a fundamental change shall not be a common stock fundamental change unless either:

- we continue to exist after the occurrence of the fundamental change and the outstanding convertible preferred stock continues to exist as outstanding convertible preferred stock, or

- not later than the occurrence of the fundamental change, the outstanding convertible preferred stock is converted into or exchanged for shares of preferred stock, which preferred stock has rights, preferences and limitations substantially similar, but no less favorable, to those of the convertible preferred stock.

"fundamental change" means the occurrence of any transaction or event or series of transactions or events pursuant to which all or substantially all of our common stock shall be exchanged for, converted into, acquired for or shall constitute solely the right to receive cash, securities, property or other assets, whether by means of an exchange offer, liquidation, tender offer, consolidation, merger, combination, reclassification, recapitalization or otherwise. However, for purposes of adjustment of the conversion price, in the case of any series of transactions or events, the fundamental change shall be deemed to have occurred when substantially all of the common stock shall have been exchanged for, converted into or acquired for, or shall constitute solely the right to receive, such cash, securities, property or other assets, but the adjustment shall be based upon the consideration that the holders of our common stock received in the transaction or event as a result of which more than 50% of our common stock shall have been exchanged for, converted into or acquired for, or shall constitute solely the right to receive, such cash, securities, property or other assets.

"non-stock fundamental change" means any fundamental change other than a common stock fundamental change.

"purchaser stock price" means the average of the daily closing price for one share of the common stock received by holders of the common stock in the common stock fundamental change during the 10 trading days immediately prior to the date fixed for the determination of the holders of the common stock entitled to receive such common stock or, if there is no such date, prior to the date upon which the holders of the common stock shall have the right to receive such common stock.

Liquidation Rights

In the event of our voluntary or involuntary dissolution, liquidation, or winding up, the holders of the convertible preferred stock shall receive a liquidation preference of $10 per share and all accrued and unpaid dividends through the distribution date. Holders of any class or series of preferred stock ranking on the same basis as the convertible preferred stock as to liquidation shall also be entitled to receive the full respective liquidation preferences and any accrued and unpaid dividends through the distribution date. Only after the preferred stock holders have received their liquidation preference and any accrued and unpaid dividends will we distribute assets to common stock holders or any of our other stock ranking junior to the shares of convertible preferred stock upon liquidation. If upon such dissolution, liquidation or winding up, we do not have enough assets to pay in full the amounts due on the convertible preferred stock and any other preferred stock ranking on the same basis with the convertible preferred stock as to liquidation, the holders of the convertible preferred stock and such other preferred stock will share ratably in any such distributions of our assets:

- first in proportion to the liquidation preferences until the preferences are paid in full, and

- then in proportion to the amounts of accrued but unpaid dividends.

After we pay any liquidation preference and accrued dividends, holders of the convertible preferred stock will not be entitled to participate any further in the distribution of our assets. The following events will not be deemed to be a dissolution, liquidation or winding up of Cyclacel:

- the sale of all or substantially all of the assets;
- our merger or consolidation into or with any other corporation; or
- our liquidation, dissolution, winding up or reorganization immediately followed by a reincorporation as another corporation.

Optional Redemption

The Company may, at its option, redeem the Preferred Stock in whole or in part, out of funds legally available at the redemption prices per share stated below, plus an amount equal to accrued and unpaid dividends up to the date of redemption:

Year from November 1, 2012 to October 31, 2013	$10.12
Year from November 1, 2013 to October 31, 2014	$10.06
November 1, 2014 and thereafter	$10.00

If we redeem less than all of the shares of convertible preferred stock, we shall select the shares to be redeemed by lot or pro rata or in some other equitable manner in our sole discretion.

Exchange Provisions

We may exchange the convertible preferred stock in whole, but not in part, for debentures on any dividend payment date on or after November 1, 2005 at the rate of $10 principal amount of debentures for each outstanding share of convertible preferred stock. Debentures will be issuable in denominations of $1,000 and integral multiples of $1,000. If the exchange results in an amount of debentures that is not an integral multiple of $1,000, we will pay in cash an amount in excess of the closest integral multiple of $1,000. We will mail written notice of our intention to exchange the convertible preferred stock to each record holder not less than 30 nor more than 60 days prior to the exchange date.

We refer to the date fixed for exchange of the convertible preferred stock for debentures as the “exchange date.” On the exchange date, the holder’s rights as a stockholder of Cyclacel shall cease, the shares of convertible preferred stock will no longer be outstanding, and will only represent the right to receive the debentures and any accrued and unpaid dividends, without interest. We may not exercise our option to exchange the convertible preferred stock for the debentures if:

- full cumulative dividends on the convertible preferred stock to the exchange date have not been paid or set aside for payment, or
- an event of default under the indenture would occur on conversion, or has occurred and is continuing.

Voting Rights

Holders of our convertible preferred stock have no voting rights except as described below or as required by law. Shares of our convertible preferred stock held by us or any entity controlled by us will not have any voting rights.

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.

Without the vote or consent of the holders of at least a majority of the shares of convertible preferred stock, we may not:

- adversely change the rights, preferences and limitations of the convertible preferred stock by modifying our certificate of incorporation or bylaws, or

- authorize, issue, reclassify any of our authorized stock into, increase the authorized amount of, or authorize or issue any convertible obligation or security or right to purchase, any class of stock that ranks senior to the convertible preferred stock as to dividends or distributions of assets upon liquidation, dissolution or winding up of the stock.

No class vote on the part of convertible preferred stock shall be required (except as otherwise required by law or resolution of our board of directors) in connection with the authorization, issuance or increase in the authorized amount of any shares of capital stock ranking junior to or on parity with the convertible preferred stock both as to the payment of dividends and as to distribution of assets upon our liquidation, dissolution or winding up, whether voluntary or involuntary, including our common stock and the convertible preferred stock.

In addition, without the vote or consent of the holders of at least a majority of the shares of convertible preferred stock we may not:

- enter into a share exchange that affects the convertible preferred stock, or

- consolidate with or merge into another entity, or

- permit another entity to consolidate with or merge into us,

unless the convertible preferred stock remains outstanding and its rights, privileges and preferences are unaffected or it is converted into or exchanged for convertible preferred stock of the surviving entity having rights, preferences and limitations substantially similar, but no less favorable, to the convertible preferred stock.

In determining a majority under these voting provisions, holders of convertible preferred stock will vote together with holders of any other preferred stock that rank on parity as to dividends and that have like voting rights.

Series A Preferred Stock

8,872 shares of the Company's Series A Preferred Stock were issued in a underwritten public offering on July 21, 2017 (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 $40.00 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 215,000 shares of common stock. As of December 31, 2020, 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, 2020, are convertible into 6,600 shares of common stock.

In the event of a liquidation, the holders of Series A Preferred Shares are entitled to participate on an as-converted-to-common stock basis with holders of the common stock in any distribution of assets of the Company to the holders of the common stock. The Series A Certificate of Designation provides, among other things, that we 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 we pay dividends on each Series A Preferred Share on an as-converted basis. Other than as set forth in the previous sentence, the Series A Certificate of Designation provides that no other dividends shall be paid on Series A Preferred Shares and that we shall pay no dividends (other than dividends in the form of common stock) on shares of common stock unless we simultaneously comply with the previous sentence. The Series A Certificate of Designation does not provide for any restriction on the repurchase of Series A Preferred Shares by us while there is any arrearage in the payment of dividends on the Series A Preferred Shares. There are no sinking fund provisions applicable to the Series A Preferred Shares.

With certain exceptions, as described in the Series A Certificate of Designation, the Series A Preferred Stock has no voting rights. However, as long as any shares of Series A Preferred Stock remain outstanding, the Series A Certificate of Designation provides that we shall not, without the affirmative vote of holders of a majority of the then-outstanding Series A Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock or alter or amend the Series A Certificate of Designation, (b) increase the number of authorized shares of Series A Preferred Stock or (c) effect a stock split or reverse stock split of the Series A Preferred Stock or any like event.

Each share of Series A Preferred Stock is convertible at any time at the holder's option into a number of shares of common stock equal to $1,000 divided by the Series A Conversion Price. The "Series A Conversion Price" was initially $40.00 and is subject to adjustment for stock splits, stock dividends, distributions, subdivisions and combinations. Notwithstanding the foregoing, the Series A Certificate of Designation further provides that we shall not effect any conversion of Series A Preferred Stock, with certain exceptions, to the extent that, after giving effect to an attempted conversion, the holder of Series A Preferred Shares (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 holder, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise (the "Preferred Stock Beneficial Ownership Limitation"); provided, however, that upon notice to the Company, the holder may increase or decrease the Preferred Stock Beneficial Ownership Limitation, provided that in no event shall the Preferred Stock Beneficial Ownership Limitation exceed 9.99% and any increase in the Preferred Stock Beneficial Ownership Limitation will not be effective until 61 days following notice of such increase from the holder to us.

Subject to certain conditions, at any time following the issuance of the Series A Preferred Stock, we will have 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. Our 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.

Series B Preferred Stock

237,745 shares of the Company's Series B Preferred Stock were issued in connection with a registered direct offering on December 18, 2020 (the "December 2020 Registered Direct Offering"). Each share of Series B Preferred Stock is convertible at any time at the option of the holder thereof, into a five shares of common stock, subject to a 9.99% blocker provision, and is subject to adjustment for stock splits, stock dividends, distributions, subdivisions and combinations.

As of December 31, 2020, 237,745 shares of the Series B Preferred Stock remain issued and outstanding. The 237,745 shares of Series B Preferred Stock issued and outstanding at December 31, 2020, are convertible into 1,188,725 shares of common stock.

In the event of a liquidation, the holders of Series B Preferred Shares are entitled to participate on an as-converted-to-common stock basis with holders of the common stock in any distribution of assets of the Company to the holders of the common stock. The Series B Certificate of Designation provides, among other things, that we 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 we pay dividends on each Series B Preferred Share on an as-converted basis. Other than as set forth in the previous sentence, the Series B Certificate of Designation provides that no other dividends shall be paid on Series B Preferred Shares and that we shall pay no dividends (other than dividends in the form of common stock) on shares of common stock unless we simultaneously comply with the previous sentence.

With certain exceptions, as described in the Series B Certificate of Designation, the Series B Preferred Stock has no voting rights. However, as long as any shares of Series B Preferred Stock remain outstanding, the Series B Certificate of Designation provides that we shall not, without the affirmative vote of holders of a majority of the then-outstanding Series B Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series B Preferred Stock or alter or amend the Series B Certificate of Designation, (b) amend our certificate of incorporation or other charter documents in any manner that adversely affects any rights given to the holders of the Series B Preferred Stock, (c) increase the number of authorized shares of Series B Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing.

Each share of Series B Preferred Stock is convertible at any time at the holder's option into five shares of common stock. The "Series B Conversion Price" was initially $4.18 and is subject to adjustment for stock splits, stock dividends, distributions, subdivisions and combinations. Notwithstanding the foregoing, the Series B Certificate of Designation further provides that we shall not effect any conversion of Series B Preferred Stock, with certain exceptions, to the extent that, after giving effect to an attempted conversion, the holder of Series B Preferred Shares (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 9.99% of the shares of our common stock then outstanding after giving effect to such exercise.

Warrants

As of December 31, 2020, there were 4,143,379 warrants outstanding. 374,525 warrants were outstanding as 2017 Warrants, 3,099,000 warrants were outstanding as April 2020 Warrants and 669,854 were outstanding as December 2020 Warrants.

The 2017 Warrants have an exercise price of $40.00 and were issued in connection with the July 2017 Underwritten Public Offering and are immediately exercisable. The 2017 Warrants expire in 2024. Out of the April 2020 Warrants, 2,090,000 warrants are pre-funded warrants and have an exercise price of $0.001 per share and may be exercised at any time until exercised in full. The remaining 4,000,000 April 2020 Warrants are common stock warrants carrying an exercise price of $5.00 per share and an expiration date in 2025. The December 2020 Warrants have an exercise price of $4.13 and were issued in connection with the December 2020 Registered Direct Offering and will be exercisable on December 18, 2021. The 2020 Warrants expire in 2025.

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.

There were no warrants exercised during the year ended December 31, 2020 in connection to the 2017 warrants or December 2020 warrants. A total of 901,000 warrants were exercised during the year ended December 31, 2020 in connection to the April 2020 warrants.

Anti-Takeover Provisions

The provisions of Delaware law, our amended and restated certificate of incorporation, as amended, and our amended and restated bylaws, certain provisions of which are summarized below, may have the effect of delaying, deferring or discouraging another person from acquiring control of our company. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Certificate of Incorporation and Bylaws to be in Effect upon the Closing of this Offering

Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the voting power of our shares of common stock may be able to elect all of our directors. Our amended and restated certificate of incorporation and amended and restated bylaws provide for stockholder actions at a duly called meeting of stockholders or, before the date on which all shares of common stock convert into a single class, by written consent. A special meeting of stockholders may be called by a majority of our board of directors, the chair of our board of directors, or our chief executive officer. Our amended and restated bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors. Our board of directors is divided into three classes with staggered three-year terms.

The foregoing provisions make it difficult for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, subject to certain exceptions.

Choice of Forum

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a breach of fiduciary duty; (iii) any action asserting a claim against us or any of our directors or officers or other employees arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; or (iv) any action asserting a claim against us that is governed by the internal affairs doctrine. Our amended and restated certificate of incorporation further provides that U.S. federal district courts is the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. However, a Delaware court recently held that such an exclusive forum provision relating to federal courts was unenforceable under Delaware law, and unless and until the Delaware court decision is reversed on appeal or otherwise abrogated, we do not intend to enforce such a provision in the event of a complaint asserting a cause of action arising under the Securities Act. These choice of forum provisions of our amended and restated

certificate of incorporation will not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements (Nos. 333-252235, 333-226906, 333-219055, 333-205153, 333-183483 and 333-143786) on Form S-8 and (Nos. 333-231923, 333-211046 and 333-187801) on Form S-3 of Cyclacel Pharmaceuticals, Inc. of our report dated March 1, 2021, relating to the consolidated financial statements of Cyclacel Pharmaceuticals, Inc. and subsidiaries, appearing in this Annual Report on Form 10-K of Cyclacel Pharmaceuticals, Inc. for the year ended December 31, 2020.

/s/ RSM US LLP

New York, New York
March 1, 2021

Exhibit 31.1

CERTIFICATIONS PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Spiro Rombotis, certify that:

1. I have reviewed this report on Form 10-K for the year ended December 31, 2020 of Cyclacel Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) and internal control over financial reporting (as defined in Exchange Act rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting: and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 1, 2021

/s/ Spiro Rombotis
Spiro Rombotis

President & Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Paul McBarron, certify that:

1. I have reviewed this report on Form 10-K for the year ended December 31, 2020 of Cyclacel Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) and internal control over financial reporting (as defined in Exchange Act rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 1, 2021

/s/ Paul McBarron
Paul McBarron

Chief Operating Officer, Chief Financial Officer and Executive
Vice President, Finance
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION UNDER SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (of subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Cyclacel Pharmaceuticals, Inc. (the "Company") hereby certifies, to such officer's knowledge, that:

(i) the Annual Report on Form 10-K of the Company for the year ended December 31, 2020 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 1, 2021

/s/ Spiro Rombotis
Spiro Rombotis
President & Chief Executive Officer

Exhibit 32.2

CERTIFICATION UNDER SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (of subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Cyclacel Pharmaceuticals, Inc. (the "Company") hereby certifies, to such officer's knowledge, that:

(i) the Annual Report on Form 10-K of the Company for the year ended December 31, 2020 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 1, 2021

/s/ Paul McBarron
Paul McBarron
Chief Operating Officer, Chief Financial Officer and Executive Vice President, Finance