Cyclacel Pharmaceuticals, Inc.
Form 10-Q
August 11, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016

OR

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

Commission file number 000-50626

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**

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x 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 definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

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

As of August 9, 2016 there were 3,118,389 shares of the registrant's common stock outstanding.

CYCLACEL PHARMACEUTICALS, INC.

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EXPLANATORY NOTE

Unless stated otherwise, the information contained in these consolidated financial statements gives effect to a one-for-twelve reverse stock split of our common shares effected on May 27, 2016. See Note 1 to our consolidated financial statements for further information.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

CYCLACEL PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(In $000s, except share, per share, and liquidation preference amounts)

	December 31, 2015	June 30, 2016 (Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,440	$ 15,931
Prepaid expenses and other current assets	4,051	2,762
Current assets of discontinued operations	75	75
Total current assets	24,566	18,768
Property, plant and equipment (net)	198	109
Total assets	$ 24,764	$ 18,877
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,940	$ 1,898
Accrued and other current liabilities	3,738	3,592
Current liabilities of discontinued operations	75	75
Total current liabilities	5,753	5,565
Other liabilities	176	150
Total liabilities	5,929	5,715
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2015 and June 30, 2016; 335,273 shares issued and outstanding at December 31, 2015 and June 30, 2016. Aggregate preference in liquidation of $4,006,511 at December 31, 2015 and June 30, 2016.	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2015 and June 30, 2016; 2,965,208 and 3,007,204 shares issued and outstanding at December 31, 2015 and June 30, 2016, respectively.	3	3
Additional paid-in capital	342,587	343,150

Accumulated other comprehensive loss	(596)	(737)
Accumulated deficit	(323,159)	(329,254)
Total stockholders' equity	18,835	13,162
Total liabilities and stockholders' equity	$ 24,764	$ 18,877

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

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CYCLACEL PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In $000s, except share and per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six months Ended June 30,	
	2015	2016	2015	2016
Revenues:				
Grant revenue	$296	$222	$808	$361
Operating expenses:				
Research and development	2,580	2,637	6,922	5,136
General and administrative	1,333	1,345	2,801	2,729
Total operating expenses	3,913	3,982	9,723	7,865
Operating loss	(3,617)	(3,760)	(8,915)	(7,504)
Other income (expense):				
Change in valuation of financial instruments associated with stock purchase agreement	(4)	—	(24)	—
Foreign exchange gains (losses)	(195)	138	(573)	318
Interest income	2	13	3	23
Other income, net	62	18	82	38
Total other income (expense)	(135)	169	(512)	379
Loss before taxes	(3,752)	(3,591)	(9,427)	(7,125)
Income tax benefit	405	626	1,168	1,119
Net loss	(3,347)	(2,965)	(8,259)	(6,006)
Dividend on convertible exchangeable preferred shares	(50)	(50)	(100)	(100)
Net loss applicable to common shareholders	$(3,397)	$(3,015)	$(8,359)	$(6,106)
Basic and diluted earnings per common share:				
Net loss per share – basic and diluted	$(1.19)	$(1.01)	$(3.32)	$(2.05)
Weighted average common shares outstanding	2,865,707	3,000,192	2,520,897	2,982,508

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

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CYCLACEL PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In $000s)

(Unaudited)

	Three Months Ended June 30,		Six months Ended June 30,	
	2015	2016	2015	2016
Net loss	(3,347)	(2,965)	(8,259)	(6,006)
Translation adjustment	(8,491)	(10,620)	(2,227)	(15,047)
Unrealized foreign exchange gain on intercompany loans	8,794	10,545	2,319	14,906
Comprehensive loss	$(3,044)	$(3,040)	$(8,167)	$(6,147)

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

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CYCLACEL PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In $000s)

(Unaudited)

	Six Months Ended June 30,	
	2015	2016
Operating activities:		
Net loss	$(8,259)	$(6,006)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in valuation of financial instruments associated with stock purchase agreement	24	—
Depreciation	102	75
Stock-based compensation	323	420
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,198	1,012
Accounts payable and other current liabilities	(1,066)	316
Net cash used in operating activities	(7,678)	(4,183)
Investing activities:		
Purchase of property, plant and equipment	(22)	—
Minimum royalty payments received from termination of ALIGN license agreement	23	—
Net cash provided by investing activities	1	—
Financing activities:		
Proceeds from issuance of common stock, net of issuance costs	10,356	154
Payment of preferred stock dividend	(100)	(100)
Net cash provided by financing activities	10,256	54
Effect of exchange rate changes on cash and cash equivalents	134	(380)
Net increase / (decrease) in cash and cash equivalents	2,713	(4,509)
Cash and cash equivalents, beginning of period	24,189	20,440
Cash and cash equivalents, end of period	$26,902	$15,931
Supplemental cash flow information:		
Cash received during the period for:		
Interest	3	21
Taxes	2,875	1,965
Non cash financing activities:		
Accrual of preferred stock dividends	50	50

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

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CYCLACEL PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Nature of Operations

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

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

Sapacitabine is being evaluated in the SEAMLESS Phase 3 study, which completed enrollment in December 2014 and is being conducted under a Special Protocol Assessment ("SPA") agreement with the US Food and Drug Administration ("FDA") for the front-line treatment of acute myeloid leukemia ("AML") in the elderly. In December 2014, the study's Data Safety Monitoring Board, or DSMB, conducted a planned interim analysis for futility after 247 events, or patient deaths, and the final safety review of 470 randomized patients. The DSMB found no safety concerns. However, the planned futility boundary has been crossed and the DSMB determined that, based on available interim data, it would be unlikely for the study to reach statistically significant improvement in survival. The DSMB saw no reasons why patients should discontinue treatment on their assigned arm and recommended that recruited patients stay on treatment.

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

In accordance with the DSMB's recommendations, the Company continued to follow-up patients as per the study protocol. The required number of events has been reached and the Company is conducting data cleaning and validation operations prior to determining that the study data base can be locked. Study data will then be transferred to the Company's independent statistical analysis vendor. When final analysis becomes available, the Company will report outcomes for the primary and secondary endpoints and determination of submissibility of the SEAMLESS data set to regulatory authorities in Europe and the United States. The procedures to be followed prior to reporting topline data and determination of submissibility to regulatory authorities may take several months.

In parallel to the follow-up of enrolled patients, the Company submitted, and has received validation of, a Pediatric Investigation Plan, or PIP, to the European Medicines Agency ("EMA"). The EMA requires sponsors to agree to a PIP before a marketing authorization application, or MAA, can be accepted, and because the lead times can be long, the Company submitted the PIP ahead of any MAA submission.

Sapacitabine is also being explored in other indications, including myelodysplastic syndromes ("MDS") and in the Company's DNA damage response program in solid tumors in combination with Cyclacel's own drug candidate, seliciclib. Sapacitabine has been evaluated in over 1,000 patients with various cancers. The FDA and the EMA have designated sapacitabine as an orphan drug for the treatment of both AML and MDS.

In the Company's DNA damage response program, durable antitumor activity was reported at an oral presentation at the 2016 American Society of Clinical Oncology Annual Meeting with a combination of sapacitabine and seliciclib, Cyclacel's CDK2/9 inhibitor, in heavily pretreated patients with breast, ovarian and pancreatic cancers who tested positive for BRCA mutations. A disease control rate of 35.6% was observed, with ongoing responding patients achieving treatment durations exceeding 1 and 4.7 years, respectively.

Seliciclib is the Company's lead CDK inhibitor. CDKs are involved in cancer cell growth, survival, metastatic spread and DNA damage repair and are central to the process of cell division and cell cycle control. Seliciclib is an oral, highly selective inhibitor of CDK enzymes that has been evaluated in over 450 patients with various cancers, including a Phase 2b randomized study in third-line non-small cell lung cancer ("NSCLC"), and nasopharyngeal cancer ("NPC"), and has shown signs of anticancer activity. Cyclacel has retained worldwide rights to commercialize seliciclib. Seliciclib is also being evaluated in Investigator Sponsored Trials, or ISTs, to treat Cushing's disease and rheumatoid arthritis, or RA and in a licensing and supply agreement to treat cystic fibrosis.

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

In addition to these development programs, in Cyclacel's polo-like kinase ("PLK") inhibitor program, the Company has discovered CYC140 and other potent and selective small molecule inhibitors of PLK1, a kinase that is active during cell division, which targets the mitotic phase of the cell cycle. PLK1 was discovered by Professor David Glover, the Company's Chief Scientist. The Company is progressing CYC140 through Investigational New Drug ("IND") directed preclinical development with the support of government funding.

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

As of June 30, 2016, 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.

Capital Resources

The Company has incurred recurring operating losses since inception. For the six months ended June 30, 2016, the Company incurred a net loss applicable to common stockholders of $6.1 million and as of June 30, 2016 the Company had generated an accumulated deficit of $329.3 million. The Company anticipates operating losses to continue 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. At June 30, 2016, the Company had cash and cash equivalents of $15.9 million. The Company will need to raise substantial additional capital to pursue a regulatory strategy for the potential approval and commercialization of sapacitabine, its product candidate for the potential treatment of AML, and to continue the development of sapacitabine in other indications and the CDK inhibitor program. The Company has funded all of its operations and capital expenditures with proceeds from the issuance of public equity securities, private placements of securities, interest on investments, government grants, research and development tax credits, product revenue and licensing revenue. Additional funding may not be available to the Company on favorable terms, or at all. If the Company is unable to obtain additional funds, it will need to reduce operating expenses, enter into a collaboration or other similar arrangement with respect to development and/or commercialization rights to sapacitabine or its CDK inhibitors, if available, or be forced to delay or reduce the scope of its sapacitabine or CDK inhibitor development programs, potentially including any potential regulatory filings related to the SEAMLESS study, and/or limit or cease our operations.

On June 23, 2016 the Company entered into an At Market Issuance Sales Agreement (the "FBR Sales Agreement") with FBR Capital Markets & Co. ("FBR") under which it may, from time to time, sell through FBR up to an aggregate of $4.0 million shares of the Company's common stock.

Basis of Presentation

The consolidated balance sheet as of June 30, 2016, the consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2016 and 2015, the consolidated statements of cash flows for the six months ended June 30, 2016 and 2015, and all related disclosures contained in the accompanying notes are unaudited. The consolidated balance sheet as of December 31, 2015 is derived from the audited consolidated financial statements included in the 2015 Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC"). The consolidated financial statements are presented on the basis of accounting principles that are generally accepted in the United States ("GAAP") for interim financial information and in accordance with the rules and regulations of the SEC. Accordingly, they do not include all the information and footnotes required by accounting principles generally accepted in the United States for a complete set of financial statements. In the opinion of management, all adjustments, which include only normal recurring adjustments necessary to present fairly the consolidated balance sheet as of June 30, 2016, and the results of operations and comprehensive loss for the three and six months ended June 30, 2016, and the consolidated statements of cash flows for the six months ended June 30, 2016, have been made. The interim results for the six months ended June 30, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016 or for any other year. The consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the accompanying notes for the year ended December 31, 2015 that are included in the Company's Annual Report on Form 10-K filed with the SEC.

Reverse Stock Split

On May 27, 2016 the Company completed a one-for-twelve reverse stock split (the "Reverse Stock Split"), which reduced the number of shares of the Company's common stock that were issued and outstanding immediately prior to the effectiveness of the Reverse Stock Split. The number of shares of the Company's authorized common stock was not affected by the Reverse Stock Split and the par value of Cyclacel's common stock remained unchanged at $0.001 per share. The Reverse Stock Split reduced the number of shares of the Company's common stock that were outstanding at May 27, 2016 from 36,075,730 to 3,006,311 after the cancellation of 11 fractional shares. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who otherwise held fractional shares of the Company's common stock as a result of the Reverse Stock Split received a cash payment in lieu of such fractional shares. All amounts related to number of shares and per share amounts have been retroactively restated in these consolidated financial statements.

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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 stock-based compensation expenses. Cyclacel reviews its estimates on an ongoing basis. The estimates are based on historical experience and on various other assumptions that the Company believes to be reasonable under the circumstances. Actual results may differ from these estimates. Cyclacel believes the judgments and estimates required by the following accounting policies to be significant in the preparation of the Company's consolidated financial statements.

Risks and Uncertainties

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

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.

Segments

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

Cash and Cash Equivalents

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

The Company maintains its cash and cash equivalents in bank deposits and other interest bearing accounts, the balances of which exceeded federally insured limits.

Fair Value of Financial Instruments

Financial instruments consist of cash and cash equivalents, accounts payable, accrued liabilities, financial instruments associated with stock purchase agreements and other arrangements. The carrying amounts of cash and cash equivalents, accounts payable and accrued liabilities approximate their respective fair values due to the nature of the accounts, notably their short maturities. The financial instruments associated with stock purchase agreements are measured at fair value using applicable inputs as described in *Note 3 — Fair Value*.

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Revenue Recognition

Collaboration, supply and licensing agreements

Consideration received is allocated to each of the separable elements in an arrangement using the relative selling price method. An element is separable if it has value to the customer on a stand-alone basis.

The selling price used for each separable element will be based on vendor-specific objective evidence ("VSOE") if available, third party evidence if VSOE is not available, or estimated selling price if neither VSOE nor third party evidence is available. Revenue is recognized for each separate element when persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured.

Grant revenue

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

Clinical Trial Accounting

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

Research and Development Expenditures

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

Income Taxes

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

The Company applies the accounting guidance codified in Accounting Standards Codification Topic 740 "Income taxes" ("ASC 740") related to accounting for uncertainty in income taxes. ASC 740 specifies the accounting for uncertainty in income taxes recognized in a company's financial statements by prescribing a more likely than not probability threshold that a tax position is required to meet before being recognized in the financial statements.

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

Stock-based Compensation

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

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ASC 718 requires measurement of compensation cost for all stock-based awards at fair value on the date of grant and recognition of compensation over the requisite service period for awards expected to vest. The fair value of restricted stock and restricted stock units is determined based on the number of shares granted and the quoted price of the Company's common stock on the date of grant. The determination of grant-date fair value for stock option awards is estimated using the Black-Scholes model, which includes variables such as the expected volatility of the Company's share price, the anticipated exercise behavior of employees, interest rates, and dividend yields. These variables are projected based on historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for share-based payments. Such value is recognized as expense over the requisite service period, net of forfeitures, using the straight-line attribution method.

Effective January 1, 2016, the Company has elected to account for forfeitures as they occur, as permitted by Accounting Standards Update ("ASU") 2016-09, Compensation — Stock Compensation (Topic 718), Improvements to Employee Share-Based Payment Accounting. See the *Accounting Standards Adopted in the Period* section below for further details.

Prior to the adoption of ASU 2016-09, the Company estimated the number of stock-based awards that were expected to vest, and only recognized compensation expense for such awards. The estimation of stock awards that will ultimately vest required judgment, and to the extent actual results or updated estimates differed from current estimates, such amounts were recorded as a cumulative adjustment in the period during which estimates were revised. The Company considered many factors when estimating expected forfeitures, including type of awards granted, employee class, and historical experience.

Net Loss Per Common Share

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

The following potentially dilutive shares of common stock have not been included in the computation of diluted net loss per share for the six months ended June 30, 2015 and 2016, as the result would be anti-dilutive:

	June 30, 2015	June 30, 2016
Stock options	111,163	393,723
Convertible preferred stock	1,698	1,698

Common stock warrants	94,886	45,343
Total shares excluded from calculation	207,747	440,764

Comprehensive Income (Loss)

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

Accounting Standards Adopted in the Period

In March 2016, the Financial Accounting Standards Boards ("FASB") issued ASU 2016-09, which simplified several aspects of employee share-based payment accounting. In particular, the ASU permits entities to make an accounting policy election to either estimate forfeitures on share-based payment awards, as previously required, or to recognize forfeitures as they occur. Effective January 1, 2016, the Company elected to recognize forfeitures as they occur. The impact of that change in accounting policy has been recorded as an $89,000 cumulative effect adjustment to accumulated deficit, as of January 1, 2016. The Company expects that it will recognize slightly higher share-based payment expense for the remainder of 2016, relative to prior periods, as the effects of forfeitures will not be recognized until they occur, rather than being estimated at the time of grant and subsequently adjusted as and when necessary. The effects of adopting the remaining provisions in ASU 2016-09 affecting the income tax consequences of share-based payments, classification of awards as either equity or liabilities when an entity partially settles the award in cash in excess of the employer's minimum statutory withholding requirements and classification in the statement of cash flows did not have any impact on the Company's financial position, results of operations or cash flows.

The Company has adopted guidance issued by the FASB in April 2015 which clarifies a customer's accounting for fees paid in a cloud computing arrangement (ASU 2015-05, Intangibles — Goodwill and Other — Internal-Use Software (Subtopic 350-40): Customer's Accounting for Fees Paid in a Cloud Computing Arrangement). The guidance provides a customer with guidance on whether a cloud computing arrangement includes a software license and clarifies that the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. The guidance has been adopted prospectively to all arrangements entered into or materially modified after January 1, 2016. The adoption of this guidance did not have any impact on the financial position, results of operations or cash flows.

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The Company has adopted guidance issued by the FASB in June 2014 which requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition (ASU 2014-12, Compensation — Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period (a consensus of the FASB Emerging Issues Task Force)). The guidance has been adopted prospectively to all awards granted or modified after January 1, 2016. The adoption of this guidance did not have any impact on the consolidated financial position, results of operations or cash flows.

Recent Accounting Pronouncements Not Yet Effective

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

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

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

In May 2014, the FASB issued new guidance on accounting for revenue from contracts with customers. This new guidance will replace existing revenue guidelines with a new model, in which revenue is recognized upon transfer of control over goods or services to a customer. In August 2015, the FASB deferred the effective date of the guidance, which will now be effective for the Company on January 1, 2018, for both interim and annual periods. Early adoption is permitted for both interim and annual periods commencing on January 1, 2017. The guidance can be adopted using either a full retrospective (with certain practical expedients) or a modified retrospective method of transition. Under the modified retrospective approach, financial statements will be prepared for the year of adoption using the new standard, but prior periods will not be adjusted. Instead, companies will recognize a cumulative catch-up adjustment to the opening balance of retained earnings at the effective date for contracts that still require performance by the company, and disclose all line items in the year of adoption as if they were prepared under current revenue requirements.

In March 2016 the FASB issued further clarification on the principal versus agent considerations (reporting revenue gross versus net) included within the new revenue recognition guidance. This guidance will be effective upon the adoption of the new revenue recognition guidance.

In April 2016 the FASB issued further clarification on identifying performance obligations in a contract with a customer and provided implementation guidance on whether licenses are satisfied at a point in time or over time. This guidance will be effective upon the adoption of the new revenue recognition guidance.

In May 2016, the FASB issued further guidance, which provided clarification on the new revenue recognition guidance. This clarification did not change the core principles but provided narrow-scope improvements to the guidance and certain practical expedients available upon transitioning to the guidance. The Company is currently assessing the impact of adopting the guidance.

At this time, the Company has not decided on which method it will use to adopt the new standard, nor has it determined the effects of the new guidelines on its results of operations and financial position. For the foreseeable future, the Company’s revenues will be limited to grants received from government agencies or nonprofit organizations and revenues from collaboration, supply and licensing agreements, and the Company is evaluating the effects of the new standard on these types of revenue streams.

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3. FAIR VALUE

Fair Value Measurements

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

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

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

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

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

The fair value of the Company's financial assets that are measured on a recurring basis as of December 31, 2015 consisted of the following (in $000s):

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

The fair value of the Company's financial assets and liabilities that are measured on a recurring basis as of June 30, 2016 consisted of the following (in $000s):

	Level 1	Level 2	Level 3	Total
ASSETS				
Cash equivalents	$11,973	$ —	$ —	$11,973

The fair value and carrying value of the Company's financial assets as of December 31, 2015 and June 30, 2016 are substantially the same.

4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following (in $000s):

	December 31, 2015	June 30, 2016
Research and development tax credit receivable	$ 2,093	$ 945
Prepayments	893	1,105
Grant receivable	326	221
VAT receivable	607	339
Deposits	132	132
Other current assets	—	20
	$ 4,051	$ 2,762

5. ACCRUED AND OTHER CURRENT LIABILITIES

Accrued and other current liabilities consisted of the following (in $000s):

	December 31, 2015	June 30, 2016
Accrued research and development	$ 3,284	$ 3,422
Accrued legal and professional fees	291	118
Other current liabilities	163	52
	$ 3,738	$ 3,592

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6. STOCK BASED COMPENSATION

ASC 718 requires compensation expense associated with share-based awards to be recognized over the requisite service period, which for the Company is the period between the grant date and the date the award vests or becomes exercisable. Most of the outstanding awards granted by the Company vest ratably over one to four years.

Effective January 1, 2016, the Company recognizes all share-based awards under the straight-line attribution method, assuming that all granted awards will vest. Forfeiture will be recognized in the periods when they occur. Refer to Note 2, Summary of Significant Accounting Policies, for further information. In prior periods, ASC 718 required forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company evaluated its forfeiture assumptions quarterly and the expected forfeiture rate adjusted when necessary. Ultimately, the actual expense recognized over the vesting period is based on only those shares that vest.

Stock based compensation has been reported within expense line items on the consolidated statement of operations for the three and six months ended June 30, 2015 and 2016 as shown in the following table (in $000s):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2016	2015	2016
General and administrative	$ 108	$ 120	$ 215	$ 262
Research and development	51	79	108	158
Stock-based compensation costs	$ 159	$ 199	$ 323	$ 420

The Company does not expect to be able to benefit from a tax deduction for stock option exercises that may occur during the year ended December 31, 2016 because the company has tax loss carryforwards from prior periods that would be expected to offset any potential taxable income for the year ended December 31, 2016.

2015 Plan

On May 22, 2015, the Company's stockholders approved the 2015 Equity Incentive Plan (the "2015 Plan"), under which Cyclacel may make equity incentive grants to its officers, employees, directors and consultants. The company has reserved 291,667 shares of the Company's common stock under the 2015 Plan. The 2015 Plan replaces the 2006 Equity Incentive Plan (the "2006 Plan"), under which there were no remaining reserved shares as of June 30, 2016. Stock option awards granted under the Company's equity incentive plans have a maximum life of 10 years and

generally vest over a one to four-year period from the date of grant.

There were 197,841 options granted during the six months ended June 30, 2016. Of these options, 189,091 are performance based, which will vest upon the fulfilment of certain clinical conditions and will terminate if they have not vested by December 31, 2020. The Company determined that the satisfaction of the vesting criteria was not probable as of June 30, 2016 and, as a result, did not record any expense related to these awards for the six months ended June 30, 2016.

2006 Plan

On March 16, 2006, the 2006 Plan was adopted, under which Cyclacel may make equity incentive grants to its officers, employees, directors and consultants. The Company had reserved 119,047 shares of the Company's common stock under the 2006 Plan. Stock option awards granted under the 2006 Plan have a maximum life of 10 years and generally vest over a one to four-year period from the date of grant.

There were 27,221 options granted under the 2006 Plan during the six months ended June 30, 2015.

There were no stock options exercised during each of the six months ended June 30, 2015 and 2016, respectively.

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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, 2015	206,298	$ 72.60	8.09	$ —
Granted	197,841	$ 4.68		
Cancelled/forfeited	(10,416)	$ 335.19		
Options outstanding at June 30, 2016	393,723	$ 31.52	6.28	$ 69
Unvested at June 30, 2016	(292,815)	$ 6.51	6.20	$ 69
Vested and exercisable at June 30, 2016	100,908	$ 104.11	6.51	$ —

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

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.

In periods prior to January 1, 2016, estimates of pre-vesting option forfeitures were based on the Company’s experience. The Company used a forfeiture rate of 0 - 30% depending on when and to whom the options are granted. The Company adjusted its estimate of forfeitures over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures were recognized through a cumulative adjustment in the period of change. The Company considered many factors when estimating expected forfeitures, including types of awards, employee class, and historical experience.

Restricted Stock Units

Summarized information for restricted stock unit activity for the six months ended June 30, 2015 is as follows:

	Restricted Stock Units	Weighted Average Grant Date Value Per Share
Non-vested at December 31, 2014	7,418	$ 66.72
Granted	—	$ —
Vested	(7,418)	$ 66.72
Non-vested at June 30, 2015	—	$ —

During the six months ended June 30, 2015, 7,418 restricted stock units vested. The Company did not issue any restricted stock units during the six months ended June 30, 2015 and 2016, respectively.

7. COMMITMENTS AND CONTINGENCIES

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.

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Pursuant to the Daiichi Sankyo license under which the Company licenses certain patent rights for sapacitabine, its lead drug candidate, the Company has agreed to pay Daiichi Sankyo an up-front fee, to reimburse Daiichi Sankyo for enumerated expenses, and to make milestone payments and to pay royalties on a country-by-country basis. The up-front fee, Phase 3 entry milestone, and certain past reimbursements have been paid. A further $10.0 million in aggregate milestone payments could be payable subject to achievement of all the specific contractual milestones, which are primarily related to regulatory approval in various territories and the Company's decision to continue with these projects. Royalties are payable in each country for the term of patent protection in the country or for ten years following the first commercial sale of licensed products in the country, whichever is later. Royalties are payable on net sales. Net sales are defined as the gross amount invoiced by the Company or its affiliates or licensees, less discounts, credits, taxes, shipping and bad debt losses. The agreement extends from its commencement date to the date on which no further amounts are owed under it. If the Company wishes to appoint a third party to develop or commercialize a sapacitabine-based product in Japan, within certain limitations, Daiichi Sankyo must be notified and given a right of first refusal, with the right of first refusal ending sixty days after notification, to develop and/or commercialize in Japan. In general, the license may be terminated by the Company for technical, scientific, efficacy, safety, or commercial reasons on six months' notice, or twelve months' notice, if after a launch of a sapacitabine-based product, or by either party for material default.

8. STOCKHOLDERS' EQUITY

Preferred Stock

As of June 30, 2016, there were 335,273 shares of the Company's 6% Convertible Exchangeable Preferred Stock ("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 and must come from funds that are legally available for dividend payments. The Preferred Stock has a liquidation preference of $10.00 per share, plus accrued and unpaid dividends.

The Preferred Stock is convertible at the option of the holder at any time into the Company's shares of common stock at a conversion rate of approximately 0.00507 shares of common stock for each share of Preferred Stock based on a price of $1,974.00 per share. The Company has reserved 1,698 shares of common stock for issuance upon conversion of the remaining shares of Preferred Stock outstanding on June 30, 2016. The shares of previously-converted Preferred Stock have been retired, cancelled and restored to the status of authorized but unissued shares of preferred stock, subject to reissuance by the Board of Directors as shares of Preferred Stock of one or more series.

The Company may automatically convert the Preferred Stock into common stock if the closing price of the Company's common stock has exceeded $2,961.00 per share, 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 Preferred Stock has no maturity date and no voting rights prior to conversion into common stock, except under limited circumstances.

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

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

On March 29, 2016, the Board of Directors (the "Board") of the Company declared a quarterly cash dividend in the amount of $0.15 per share on the Company's Preferred Stock. The cash dividend was paid on May 2, 2016 to the holders of record of the Preferred Stock as of the close of business on April 18, 2016.

On May 26, 2016, the Board of the Company declared a quarterly cash dividend in the amount of $0.15 per share on the Company's Preferred Stock. The cash dividend was paid on August 1, 2016 to the holders of record of the Preferred Stock as of the close of business on July 17, 2016.

Common Stock

June 2016 At Market Issuance

On June 23, 2016, the Company entered into the FBR Sales Agreement, under which the Company may, from time to time, sell through FBR up to an aggregate of $4.0 million in shares of the Company's common stock. Under the FBR Sales Agreement FBR may sell the shares of common stock 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 (the "Securities Act"). The Company will pay FBR a commission of 3.0% of the gross sales price per share sold. The Company is not obligated to make any sales of common stock under the FBR Sales Agreement. The Company has not made any sales

under the FBR Sales Agreement as of June 30, 2016.

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July 2015 Controlled Equity Offering SM

On July 10, 2015, the Company entered into a Controlled Equity Offering[SM] Sales Agreement (the "Cantor Sales Agreement") with Cantor Fitzgerald & Co., ("Cantor"), under which the Company was able, from time to time, to sell shares of its common stock having an aggregate offering price of up to $8.35 million through Cantor. Effective as of June 17, 2016, and prior to entering into the FBR Sales Agreement, the Company and Cantor agreed to terminate the Cantor Sales Agreement. The Company had issued an aggregate of 114,078 shares pursuant to the Cantor Sales Agreement of which 40,779 were issued in the six months ended June 30, 2016 for net proceeds of approximately $0.2 million.

March 2015 Public Offering

On March 9, 2015, the Company completed a public offering of 833,333 shares of its common stock at a price to the public of $12.0 per share for proceeds, net of certain fees and expenses, of approximately $9.2 million.

November 2013 Stock Purchase Agreement

On November 14, 2013, the Company entered into a common stock Purchase Agreement with Aspire (the "Purchase Agreement"). Upon execution of the Purchase Agreement, Aspire purchased 42,626 shares of common stock for an aggregate purchase price of $2.0 million. Under the terms of the Purchase Agreement, Aspire committed to purchase up to an additional 253,503 shares from time to time as directed by the Company or, in certain instances, as agreed to by both parties, over the next two years at prices derived from the market prices on or near the date of each sale. However, such commitment was limited to an additional $18.0 million of share purchases. In consideration for entering into the Purchase Agreement, concurrent with the execution of the Purchase Agreement, the Company issued 13,842 shares of the Company's common stock to Aspire in lieu of a commitment fee. The fair value of these shares has been recorded as a component of other assets and remeasured each reporting period, until the agreement expired on July 8, 2015, with gains or losses reported in the consolidated statements of operations. During the six months ended June 30, 2015, the Company sold 91,667 shares to Aspire under the Purchase Agreement for proceeds of approximately $1.2 million. The Purchase Agreement terminated according to its terms.

Common Stock Warrants

The following table summarizes information about warrants outstanding at June 30, 2016:

Issued in Connection With	Expiration Date	Common Shares Issuable	Weighted Average Exercise Price
July 2011 stock issuance	2016	45,343	$ 114.24

There were no exercises of warrants during the six months ended June 30, 2015 and 2016, respectively. All outstanding warrants lapsed in July 2016.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, including, without limitation, Management's Discussion and Analysis of Financial Condition and Results of Operations, contains "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We intend that the forward-looking statements be covered by the safe harbor for forward-looking statements in the Exchange Act. The forward-looking information is based on various factors and was derived using numerous assumptions. 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. These forward-looking statements are usually accompanied by words such as "believe," "anticipate," "plan," "seek," "expect," "intend" and similar expressions.

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Forward-looking statements necessarily involve risks and uncertainties, and our actual results could differ materially from those anticipated in the forward looking statements due to a number of factors, including those set forth in Part I, Item 1A, entitled "Risk Factors," of our Annual Report on Form 10-K for the year ended December 31, 2015, as updated and supplemented by Part II, Item 1A, entitled "Risk Factors," of our Quarterly Reports on Form 10-Q, and elsewhere in this report. These factors as well as other cautionary statements made in this Quarterly Report on Form 10-Q, should be read and understood as being applicable to all related forward-looking statements wherever they appear herein. The forward-looking statements contained in this Quarterly Report on Form 10-Q represent our judgment as of the date hereof. 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. In this report, "Cyclacel," the "Company," "we," "us," and "our" refer to Cyclacel Pharmaceuticals, Inc.

Overview

Through the second quarter of 2016, our focus has been on our lead program sapacitabine in the SEAMLESS Phase 3 study, which has been in the follow-up phase after completing enrollment in December 2014. This study has now reached the prespecified number of events to be observed.

The SEAMLESS Phase 3 study is being conducted under a Special Protocol Assessment, or SPA, agreement with the US Food and Drug Administration, or FDA, for the front-line treatment of acute myeloid leukemia, or AML, in the elderly. In December 2014, the study's Data Safety Monitoring Board, or DSMB, conducted a planned interim analysis for futility after 247 events, or patient deaths, and the final safety review of 470 randomized patients. The DSMB found no safety concerns. However, the planned futility boundary has been crossed and the DSMB determined that, based on available interim data, it would be unlikely for the study to reach statistically significant improvement in survival. The DSMB saw no reasons why patients should discontinue treatment on their assigned arm and recommended that recruited patients stay on treatment

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

In accordance with the DSMB's recommendations, the Company continued to follow-up patients as per the study protocol. The required number of events has been reached and the Company is conducting data cleaning and validation operations prior to determining that the study data base can be locked. Study data will then be transferred to the Company's independent statistical analysis vendor. When final analysis becomes available, the Company will report outcomes for the primary and secondary endpoints and determination of submissibility of the SEAMLESS data set to regulatory authorities in Europe and the United States. The procedures to be followed prior to reporting topline data and determination of submissibility to regulatory authorities may take several months.

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

Sapacitabine is also being evaluated in other indications including in our DNA damage response program in combination with our CDK inhibitor seliciclib in solid tumors. Additionally, we are progressing clinical development of our second-generation CDK inhibitor CYC065 into a first-in human study in solid tumors and lymphomas and advanced our PLK-1 inhibitor, CYC140, through IND-directed studies with the support of government funding.

Recent Events

Deficiency and Compliance Notices from The NASDAQ Stock Market and Reverse Stock Split

At the 2016 Annual Meeting of Stockholders, which was held on May 26, 2016, holders of the Company's common stock approved a proposed amendment to the Company's amended and restated certificate of incorporation, by way of a certificate of amendment, to effectuate a reverse stock split at a ratio of up to and including one-for-twenty. Pursuant thereto, the Board determined to use a ratio of one-for-twelve, so that every twelve shares of the Company's outstanding common stock would be combined and reclassified into one share of common stock, after which the certificate of amendment was filed with the Secretary of State of the State of Delaware. The Reverse Stock Split became effective at 5:00 p.m., Eastern Time, on May 27, 2016, and the Company's common stock began trading on the NASDAQ Capital Market on a post-split basis at the open of business on May 31, 2016. The Reverse Stock Split was effectuated in order to increase the per share trading price of the Company' common stock so as to satisfy the $1.00 minimum bid price requirement for continued listing on The NASDAQ Capital Market.

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On June 15, 2016, the Company received notification from the listing qualifications staff of NASDAQ that, as of June14, 2016, it had evidenced a closing per share bid price in excess of the $1.00 minimum closing bid price requirement for at least ten consecutive trading days, and that it had thus regained compliance with the minimum bid price rule for continued listing on The NASDAQ Capital Market.

Unless otherwise noted, references in this Form 10-Q to any number of shares of common stock, price per share and weighted average shares of common stock, have been adjusted to reflect the Reverse Stock Split on a retroactive basis for all periods presented.

Entry into At Market Issuance Sales Agreement with FBR Capital Markets & Co.

On June 23, 2016, the Company entered into the FBR Sales Agreement under which the Company may, from time to time, sell through FBR up to an aggregate of $4.0 million in shares of the Company's common stock. The Company is not obligated to make any sales of common stock under the FBR Sales Agreement. The Company has not made any sales under the FBR Sales Agreement as of June 30, 2016.

Recent Vote by the United Kingdom electorate in favor of a Referendum for its Exit from the European Union

The UK held a referendum on June 23, 2016 in which a majority of voters voted to exit the EU ("Brexit"). Brexit could cause disruptions to and create uncertainty surrounding our business, including affecting our future foreign exchange gains (losses), and relationships with our existing and future employees, consultants, and contractors based in the UK. See further discussion in Item 1A. Risk Factors.

Results of Operations

Three Months Ended June 30, 2015 and 2016

Results of Continuing Operations

Revenues

The following table summarizes the components of our revenues for the three months ended June 30, 2015 and 2016 (in $000s, except percentages):

	Three Months Ended June 30,		Difference	
	2015	2016	$	%
Grant revenue	$ 296	$ 222	$(74)	(25)

We recognized $0.3 million and $0.2 million in grant revenue for the three months ended June 30, 2015 and 2016, respectively, from the European Union and the Biomedical Catalyst of the United Kingdom government.

The future

We expect to recognize approximately $0.5 million in grant revenue over the period to November 2016 from the Biomedical Catalyst of the United Kingdom government. We may recognize collaboration and research and development revenues relating to our collaboration, licensing and supply agreement with ManRos Therapeutics SA (“ManRos”) if certain development milestones are achieved.

Research and development expenses

From our inception, we have focused on drug discovery and development programs, with a particular emphasis on orally-available anticancer agents, and our research and development expenses have represented costs incurred to discover and develop novel small molecule therapeutics, including clinical trial costs for sapacitabine, seliciclib, sapacitabine in combination with seliciclib and CYC065. We have also incurred costs in the advancement of product candidates toward clinical and pre-clinical trials and the development of in-house research to advance our biomarker program and technology platforms. 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;

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- Preclinical studies and laboratory supplies and materials;
- Technology license costs; and
- Rent and facility expenses for our laboratories.

The following table provides information with respect to our research and development expenditures for the three months ended June 30, 2015 and 2016 (in $000s except percentages):

	Three Months Ended June 30,		Difference	
	2015	2016	$	%
Sapacitabine	$1,749	$1,855	$106	6
Other costs related to research and development programs, management and exploratory research	831	782	(49)	(6)
Total research and development expenses	$2,580	$2,637	$(57)	2

Total research and development expenses represented 66% of our operating expenses for the three months ended June 30, 2015 and 2016. Research and development expenditures remained consistent at $2.6 million for the three months ended June 30, 2015 and 2016. Sapacitabine research and development expenses are primarily related expenditures associated with the SEAMLESS Phase 3 trial which is in the follow-up phase following the completion of enrollment in December 2014.

The future

We anticipate that overall research and development expenditures for the year ended December 31, 2016 will decrease compared to the year ended December 31, 2015, as we are in the patient follow-up phase of SEAMLESS and clinical study sites are being closed. The timing and extent of SEAMLESS expenditures, including the possibility of registration submissions to regulatory authorities in Europe and the U.S., are dependent upon final data.

General and administrative expenses

General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. The following table summarizes the general and administrative expenses for the three months ended June 30, 2015 and 2016 (in $000s except percentages):

	Three Months Ended June 30,		Difference	
	2015	2016	$	%
Total general and administrative expenses	$ 1,333	$ 1,345	$ 12	1

Total general and administration expenses represented 34% of our operating expenses for the three months ended June 30, 2015 and 2016. General and administrative expenses stayed consistent at $1.3 million for the three months ended June 30, 2015 and 2016.

The future

We expect our general and administrative expenditures for the year ended December 31, 2016 to slightly increase compared with the year ended December 31, 2015. This is primarily because we expect to recognize slightly higher share-based payment expense for the remainder of 2016 as the effects of forfeitures will not be reported in the statement of operations until they occur, rather than being estimated at the time of grant and subsequently adjusted as and when necessary.

Other income (expense), net

The following table summarizes other income (expense), net for the three months ended June 30, 2015 and 2016 (in $000 except percentages):

	Three Months Ended June 30,		Difference	
	2015	2016	$	%
Change in valuation of financial instruments associated with stock purchase agreement	$ (4)	$ —	$4	(100)
Foreign exchange gains / (losses)	(195)	138	333	(171)
Interest income	2	13	11	550
Other income (expenses), net	62	18	(44)	(71)
Total other income (expense), net	$ (135)	$ 169	$304	(225)

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Total other income (expense) increased by approximately $0.3 million, from a loss of $0.1 million for the three months ended June 30, 2015, to a gain of $0.2 million for the three months ended June 30, 2016.

Change in valuation of financial instruments associated with stock purchase agreement

The fair value of the right to sell additional shares under the November 2013 Purchase Agreement with Aspire was remeasured each reporting period with gains or losses were reported within other income until the agreement expired in July 2015 and automatically terminated under its terms . The Company recognized an expense of approximately $4,000 for the three months ended June 30, 2015.

Foreign exchange gains/ (losses)

Foreign exchange gains / (losses) increased by approximately $0.3 million, from a loss of $0.2 million for the three months ended June 30, 2015, to a gain of $0.1 million for the three months ended June 30, 2016. Foreign exchange gains and losses are reported in the consolidated statement of operations as a separate line item within other income (expense). The announcement in June 2016 of the referendum of the United Kingdom’s Membership of the European Union, or Brexit, advising for the exit of the United Kingdom from the European Union caused significant volatility in currency exchange rate fluctuations that resulted in the strengthening of the U.S. dollar against foreign currencies in which we conduct business, primarily the Euro and British Pound. The significant currency exchange rate fluctuations of the U.S. dollar relative to other currencies may adversely affect our results of operations.

The future

Other income (expense) for the year ended December 31, 2016 will continue to be impacted by changes in foreign exchange rates. There will be no further impact from the change in valuation of financial instruments associated with the stock purchase agreement because we sold all of the remaining available shares under the stock purchase agreement in July 2015 and the purchase agreement has terminated according to its terms.

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

Income tax benefit

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

The following table summarizes total income tax benefit for the three months ended June 30, 2015 and 2016 (in $000s except percentages):

	Three Months Ended June 30,		Difference	
	2015	2016	$	%
Total income tax benefit	$ 405	$ 626	$221	55

The total income tax benefit, composed of research and development tax credits recoverable, increased $0.2 million from an income tax benefit of $0.4 million for the three months ended June 30, 2015 to an income tax benefit of $0.6 million for the three months ended June 30, 2016. The level of tax credits recoverable is linked directly to qualifying research and development expenditure incurred in any one year.

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The future

We expect to continue to be eligible to receive United Kingdom research and development tax credits for the foreseeable future and will elect to do so. The amount of tax credits we will receive is entirely dependent on the amount of eligible expenses we incur. We expect our qualifying research and development expenditure to decrease for the year ended December 31, 2016 in comparison to the year ended December 31, 2015.

Six Months Ended June 30, 2015 and 2016

Results of Continuing Operations

Revenues

The following table summarizes the components of our revenues for the six months ended June 30, 2015 and 2016 (in $000s, except percentages):

	Six Months Ended June 30,		Difference	
	2015	2016	$	%
Grant revenue	$ 808	$ 361	$(447)	(55)

We recognized $0.8 million and $0.4 million in grant revenue for the six months ended June 30, 2015 and 2016, respectively, from the European Union and the Biomedical Catalyst of the United Kingdom government.

The future

We expect to recognize approximately $0.5 million in grant revenue over the period to November 2016 from the Biomedical Catalyst of the United Kingdom government. We may receive milestone payments from our collaboration, licensing and supply agreement with ManRos if certain development milestones are achieved.

Research and development expenses

From our inception, we have focused on drug discovery and development programs, with a particular emphasis on orally-available anticancer agents, and our research and development expenses have represented costs incurred to discover and develop novel small molecule therapeutics, including clinical trial costs for sapacitabine, seliciclib, sapacitabine in combination with seliciclib and CYC065. We have also incurred costs in the advancement of product candidates toward clinical and pre-clinical trials and the development of in-house research to advance our biomarker program and technology platforms. We expense all research and development costs as they are incurred. Research and development expenses primarily include:

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

The following table provides information with respect to our research and development expenditures for the six months ended June 30, 2015 and 2016 (in $000s except percentages):

	Six Months Ended June 30,		Difference	
	2015	2016	$	%
Sapacitabine	$4,963	$3,691	$(1,272)	(26)
Other costs related to research and development programs, management and exploratory research	1,959	1,445	(514)	(26)
Total research and development expenses	$6,922	$5,136	$(1,786)	(26)

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Total research and development expenses represented 71% and 65% of our operating expenses for the six months ended June 30, 2015 and 2016, respectively.

Research and development expenditures decreased $1.8 million from $6.9 million for the six months ended June 30, 2015 to $5.1 million for the six months ended June 30, 2016. Research and development expenses relating to sapacitabine decreased by $1.3 million from $5.0 million for the six months ended June 30, 2015 to $3.7 million for the six months ended June 30, 2016, primarily as a result of a reduction in expenditures associated with the SEAMLESS Phase 3 trial which is in the follow-up phase following the completion of enrollment in December 2014.

The future

We anticipate that overall research and development expenditures for the year ended December 31, 2016 will decrease compared to the year ended December 31, 2015, as we are in the patient follow-up phase of SEAMLESS and clinical study sites are being closed. The timing and extent of SEAMLESS expenditures, including the possibility of registration submissions to regulatory authorities in Europe and the U.S., are dependent upon final data.

General and administrative expenses

General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. The following table summarizes the general and administrative expenses for the six months ended June 30, 2015 and 2016 (in $000s except percentages):

	Six Months Ended June 30,		Difference	
	2015	2016	$	%
Total general and administrative expenses	$ 2,801	$ 2,729	$ (72)	(3)

Total general and administration expenses represented 29% and 35% of our operating expenses for the six months ended June 30, 2015 and 2016, respectively. General and administrative expenses decreased $0.1 million from $2.8 million for the six months ended June 30, 2015 to $2.7 million for the six months ended June 30, 2016, primarily as a result of lower patent-related and professional fees.

The future

We expect our general and administrative expenditures for the year ended December 31, 2016 to slightly increase compared with the year ended December 31, 2015. This is primarily because we expect to recognize slightly higher share-based payment expense for the remainder of 2016 as the effects of forfeitures will not be reported in the statement of operations until they occur, rather than being estimated at the time of grant and subsequently adjusted as and when necessary.

Other income (expense), net

The following table summarizes other income (expense), net for the six months ended June 30, 2015 and 2016 (in $000 except percentages):

	Six Months Ended June 30,		Difference	
	2015	2016	$	%
Change in valuation of financial instruments associated with stock purchase agreement	$ (24)	$ —	$24	(100)
Foreign exchange gains / (losses)	(573)	318	891	(155)
Interest income	3	23	20	667
Other income, net	82	38	(44)	(54)
Total other income (expense), net	$ (512)	$ 379	$891	(174)

Total other income (expense), net increased by approximately $0.9 million, from a loss of $0.5 million for the six months ended June 30, 2015, to a gain of $0.4 million for the six months ended June 30, 2016.

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Change in valuation of financial instruments associated with stock purchase agreement

The fair value of the right to sell additional shares under the November 2013 Purchase Agreement with Aspire was remeasured each reporting period with gains or losses were reported within other income until the agreement expired in July 2015 and automatically terminated under its terms. The Company recognized an expense of $24,000 for the six months ended June 30, 2015.

Foreign exchange gains

Foreign exchange gains increased by approximately $0.9 million, from a loss of $0.6 million for the six months ended June 30, 2015, to a gain of $0.3 million for the six months ended June 30, 2016. Foreign exchange gains and losses are reported in the consolidated statement of operations as a separate line item within other income (expense). The announcement in June 2016 of the referendum of the United Kingdom's Membership of the European Union, or Brexit, advising for the exit of the United Kingdom from the European Union caused significant volatility in currency exchange rate fluctuations that resulted in the strengthening of the U.S. dollar against foreign currencies in which we conduct business, primarily the Euro and British Pound. The significant currency exchange rate fluctuations of the U.S. dollar relative to other currencies may adversely affect our results of operations.

The future

Other income (expense), net for the year ended December 31, 2016 will continue to be impacted by changes in foreign exchange rates. There will be no further impact from the change in valuation of financial instruments associated with the stock purchase agreement because we sold all of the remaining available shares under the stock purchase agreement in July 2015 and the purchase agreement has terminated according to its terms.

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

Income tax benefit

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

The following table summarizes total income tax benefit for the six months ended June 30, 2015 and 2016 (in $000s except percentages):

	Six Months Ended June 30,		Difference	
	2015	2016	$	%
Total income tax benefit	$ 1,168	$ 1,119	$ (49)	(4)

The total income tax benefit, primarily composed of research and development tax credits recoverable, decreased $0.1 million from an income tax benefit of $1.2 million for the six months ended June 30, 2015 to an income tax benefit of $1.1 million for the six months ended June 30, 2016. The level of tax credits recoverable is linked directly to qualifying research and development expenditure incurred in any one year.

The future

We expect to continue to be eligible to receive United Kingdom research and development tax credits for the foreseeable future and will elect to do so. The amount of tax credits we will receive is entirely dependent on the amount of eligible expenses we incur. We expect our qualifying research and development expenditure to decrease for the year ended December 31, 2016 in comparison to the year ended December 31, 2015.

Operating Capital Requirements

We expect to continue to incur substantial operating losses in the future. We will not receive any product revenue until a product candidate has been approved by the EMA, FDA, or similar regulatory agencies in other countries, and has been successfully commercialized, if at all. We will need to raise substantial additional funding to complete the development and potential commercialization of sapacitabine. Additionally, we may 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.

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

- the rate of progress and cost of our clinical trials;
- the need for additional or expanded clinical trials;
- the timing, economic and other terms of any licensing, collaboration or other similar arrangement into which we may enter;
- the costs and timing of seeking and obtaining EMA, FDA, or other regulatory approvals;
- the extent of our other development activities;
- the costs associated with building or accessing commercialization and additional manufacturing capabilities and supplies;
- the costs of acquiring or investing in businesses, product candidates and technologies, if any;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the effect of competing technological and market developments.

We believe that we currently have the resources to fund our operations through the end of 2017. We will need to raise substantial additional capital to complete the development and potential commercialization of sapacitabine and our CDK inhibitor program. Until we can generate a sufficient amount of licensing or collaboration or product revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs primarily through equity issuances, the Research & Development tax credit, grants, one or more possible licenses, collaborations or other similar arrangements with respect to development and/or commercialization rights to sapacitabine or our CDK inhibitor program, if available, or a combination of the above.

Our failure to raise significant additional capital in the future would force us to delay or reduce the scope of our sapacitabine and other development programs, potentially including any additional clinical trials or subsequent regulatory filings in Europe or the United States, and/or limit or cease our operations. Any one of the foregoing would have a material adverse effect on our business, financial condition and results of operations.

Contractual Obligations

The following table summarizes our long-term contractual obligations as of June 30, 2016 (in thousands):

	Payments Due by Period			
	Total	**< 1 Year**	**2-5 Years**	**>5 Years**
Operating lease obligations[1]	**$3,255**	**$ 440**	**$ 1,351**	**$ 1,464**

(1) Operating lease obligations relate to:

(1) the leasing of office space in a building at 200 Connell Drive, suite 1500, Berkeley Heights, New Jersey, USA, which is currently our corporate headquarters. The lease was entered into in December 2006 for a period up to November 2011, and in May 2011, extended to February 2017.

(2) the leasing of office and laboratory space at 1 James Lindsay Place, Dundee, UK. The lease, entered into in October 2000, expires October 2025.

The above amounts exclude potential payments under our 2003 license agreement with Daiichi Sankyo Co., Ltd. regarding sapacitabine, pursuant to which we are required to make certain milestone payments primarily related to regulatory approval in various territories and the Company's decision to continue with these projects. We are also required to make royalty payments to Daiichi Sankyo in the event that sapacitabine is commercialized.

We also have agreements with contract research organizations clinical sites and other third party contractors for the conduct of our clinical trials. We generally make payments to these entities based upon the activities they perform related to the particular clinical trial. There are generally no penalty clauses for cancellation of these agreements if notice is duly given and payment is made for work performed by the third party under the related agreement.

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Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial and accounting officer, we conducted an evaluation of the effectiveness, as of June 30, 2016, of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based upon such evaluation, our principal executive officer and principal financial and accounting officer have concluded that, as of June 30, 2016, our disclosure controls and procedures were effective to provide reasonable assurance that the information we are required to disclose in our filings with the Securities and Exchange Commission, or SEC, under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (ii) accumulated and communicated to our management, including our chief executive officer and principal financial and accounting officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended June 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitation on the Effectiveness of Internal Controls

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute, assurances. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

PART II. Other Information

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

In analyzing our company, you should consider carefully the following risk factors, together with all of the other information included in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2015. Factors that could cause or contribute to differences in our actual results include those discussed in the following subsection, as well as those discussed above in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this Quarterly Report on Form 10-Q. Each of the following risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our Company. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Associated with Development and Commercialization of Our Drug Candidates

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

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On September 13, 2010, and as amended on October 11, 2011, we reached agreement with the FDA regarding an SPA on the design of a pivotal Phase 3 clinical trial for our sapacitabine oral capsules as a front-line treatment in elderly patients aged 70 years or older with newly diagnosed AML, who are not candidates for intensive induction chemotherapy, or the SEAMLESS trial. An SPA is an agreement between a sponsor of an NDA and the FDA on the design of the Phase 3 clinical trial protocol design and statistical analysis that will form the primary basis of an efficacy claim. If such an agreement is reached, it will be binding on the FDA unless the sponsor fails to follow the agreed upon protocol, data supporting the request are found to be false or incomplete, or the FDA determines that a substantial scientific issue essential to product efficacy or safety was identified. An SPA, however, neither guarantees approval nor provides any assurance that a marketing application will be approved by the FDA. There are companies that have been granted SPAs but that have ultimately failed to obtain final approval to market their drugs. In January 2011, we opened enrollment in the lead-in portion of the SEAMLESS trial and in October 2011, we opened enrollment in the randomized portion of the trial. We completed enrollment of the SEAMLESS trial in December 2014.

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

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

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

- delays in securing clinical investigators or trial sites for our clinical trials;
- delays in obtaining IRB and regulatory approvals to commence a clinical trial;

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

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

- unforeseen safety issues;

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

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

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

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

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

- unavailability of clinical trial supplies.

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

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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 decrease in potassium levels have been observed in patients receiving seliciclib.

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

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

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

For most purposes, however, biomarkers have not been scientifically validated. If our understanding and use of biomarkers is inaccurate or flawed, or if our reliance on them is otherwise misplaced, then we will not only fail to realize any benefits from using biomarkers, but may also be led to invest time and financial resources inefficiently in

attempting to develop inappropriate drug candidates. Moreover, although the FDA has issued for comment a draft guidance document on the potential use of biomarker data in clinical development, such data are not currently accepted by the FDA or other regulatory agencies in the United States, the European Union or elsewhere in applications for regulatory approval of drug candidates, and there is no guarantee that such data will ever be accepted by the relevant authorities in this connection. Our biomarker data should not be interpreted as evidence of efficacy.

Due to our reliance on contract research organizations and other third parties to conduct clinical trials, we may be unable to directly control the timing, conduct and expense of our clinical trials.

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

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

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

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

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

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

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

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

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

We do not currently operate manufacturing facilities for clinical or commercial production of our drug candidates under development. We currently lack the resources or the capacity to manufacture any of our products on a clinical or commercial scale. We anticipate future reliance on a limited number of third party manufacturers until we are able, or decide to, expand our operations to include manufacturing capacities. If the FDA or EMA approve any of our drug candidates for commercial sale, or if we significantly expand our clinical trials, we will need to manufacture them in larger quantities and will be required to secure alternative third-party suppliers to our current suppliers. To date, our drug candidates have been manufactured in small quantities for preclinical testing and clinical trials and we may not be able to successfully increase the manufacturing capacity, whether in collaboration with our current or future third-party manufacturers or on our own, for any of our drug candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA and EMA must review and approve. If we are unable to successfully increase the manufacturing capacity for a drug candidate, whether for late stage clinical trials or for commercial sale or are unable to secure alternative third-party suppliers to our current suppliers, the drug development, regulatory approval or commercial launch of any related drugs may be delayed or blocked or there may be a shortage in supply. Even if any third party manufacturer makes improvements in the manufacturing process for our drug candidates, we may not own, or may have to share, the intellectual property rights to such innovation. Any performance failure on the part of manufacturers could delay late stage clinical development or regulatory approval of our drugs, the commercialization of our drugs or our ability to sell our commercial products, producing additional losses and depriving us of potential product revenues.

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.

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

Obtaining an NDA or MAA approval is expensive and is a complex, lengthy and uncertain process. For example, The FDA approval process for a new drug involves submission of an IND, which must include information about preclinical studies proposed clinical protocols and manufacturing information. Clinical development under an IND typically involves three phases of study: Phase 1, 2 and 3. The most significant costs associated with clinical development are typically the pivotal late Phase 2 or Phase 3 clinical trials, as they tend to be the longest and largest studies conducted during the drug development process. After completion of clinical trials, an NDA may be submitted to the FDA. In responding to an NDA, the FDA may refuse to file the application, or if accepted for filing, the FDA may request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. If the NDA supports the safety and efficacy of the drug candidate and satisfies other requirements, the FDA may grant marketing approval. Failure to comply with the FDA and other applicable foreign and U.S. regulatory requirements may subject us to administrative or judicially imposed sanctions. These include warning letters, civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production and refusal to approve either pending NDAs, or supplements to approved NDAs.

There is substantial time and expense invested in 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. In light of the futility cross reported by the SEAMLESS DSMB, there can be no assurance that data from SEAMLESS will be sufficient to submit registration submissions or that regulatory authorities will accept or approve any such submissions.

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

- those discussed in the risk factor which immediately follows;

- the fact that FDA or EMA officials may find that our or our third party manufacturer’s processes or facilities are not in compliance with cGMPs; or

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

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

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

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

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

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

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

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

- fail to receive the regulatory approvals required to market them as drugs;

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

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

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

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

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

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- commercializing product candidates.

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

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

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

- timing of market introduction, number and clinical profile of competitive drugs;
- our ability to provide acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- pricing and cost-effectiveness, which may be subject to regulatory control;
- availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third party payors; and
- prevalence and severity of adverse side effects; and other potential advantages over alternative treatment methods.

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

profitability.

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

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

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

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

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

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

There are existing products in the marketplace that compete with our products. Companies may develop new products that compete with our products. Certain of these competitors and potential competitors have longer operating histories, substantially greater product development capabilities and financial, scientific, marketing and sales resources. Competitors and potential competitors may also develop products that are safer, more effective or have other potential advantages compared to our products. In addition, research, development and commercialization efforts by others could render our products obsolete or non-competitive. Certain of our competitors and potential competitors have broader product offerings and extensive customer bases allowing them to adopt aggressive pricing policies that would enable them to gain market share. Competitive pressures could result in price reductions, reduced margins and loss of market share. We could encounter potential customers that, due to existing relationships with our competitors, are committed to products offered by those competitors. As a result, those potential customers may not consider purchasing our products.

The failure to attract and retain skilled personnel and key relationships could impair our drug development and commercialization efforts.

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

or delay our product development efforts, which would adversely affect the development of our drug candidates and commercialization of our potential drugs and growth of our business.

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

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

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

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

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

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Our activities relating to the sale and marketing of our products will be subject to scrutiny under these laws and regulations. It may be difficult to determine whether or not our activities comply with these complex legal requirements. Violations are punishable by significant criminal and/or civil fines and other penalties, as well as the possibility of exclusion of the product from coverage under governmental healthcare programs, including Medicare and Medicaid. If the government were to investigate or make allegations against us or any of our employees, or sanction or convict us or any of our employees, for violations of any of these legal requirements, this could have a material adverse effect on our business, including our stock price. Our activities could be subject to challenge for many reasons, including the broad scope and complexity of these laws and regulations, the difficulties in interpreting and applying these legal requirements, and the high degree of prosecutorial resources and attention being devoted to the biopharmaceutical industry and health care fraud by law enforcement authorities. During the last few years, numerous biopharmaceutical companies have paid multi-million dollar fines and entered into burdensome settlement agreements for alleged violation of these requirements, and other companies are under active investigation. Although we have developed and implemented corporate and field compliance programs as part of our commercialization efforts, we cannot assure you that we or our employees, directors or agents were, are or will be in compliance with all laws and regulations or that we will not come under investigation, allegation or sanction.

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

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

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

In all the countries where we may sell our products, governmental regulations exist to define standards for manufacturing, packaging, labeling and storing. All of our suppliers of raw materials and contract manufacturers must comply with these regulations. Failure to do so could result in supply interruptions. In the United States, the FDA requires that all suppliers of pharmaceutical bulk material and all manufacturers of pharmaceuticals for sale in or from

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

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

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

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

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

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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.

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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 of focusing on the advancement of sapacitabine, we expect our existing resources to be sufficient to fund our planned operations for at least the next twelve months. To meet our long-term financing requirements, we may raise funds through public or private equity offerings, debt financings or strategic alliances. Raising additional funds by issuing equity or convertible debt securities may cause our stockholders to experience substantial dilution in their ownership interests and new investors may have rights superior to the rights of our other stockholders. Raising additional funds through debt financing, if available, may involve covenants that restrict our business activities and options. To the extent that we raise additional funds through collaborations and licensing arrangements, we may have to relinquish valuable rights to our drug discovery and other technologies, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. Additional funding may not be available to us on favorable terms, or at all, particularly in light of the current economic conditions. If we are unable to obtain additional funds, we may be forced to delay or terminate our current

clinical trials and the development and marketing of our drug candidates including sapacitabine.

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

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

A recent vote by the United Kingdom electorate in favor of a referendum for its exit from the European Union could adversely impact our business, results of operations and financial condition.

The announcement in June 2016 of the referendum of the United Kingdom's Membership of the European Union, or Brexit, advising for the exit of the United Kingdom from the European Union, could cause disruptions to and create uncertainty surrounding our business, including affecting our relationships with our future customers, suppliers and employees, which could have an adverse effect on our business, financial results and operations. The referendum is non-binding; however, if passed into law, negotiations would commence to determine the future terms of the United Kingdom's relationship with the European Union, including the terms of trade between the United Kingdom and the European Union. 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.

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The announcement of Brexit caused significant volatility in global stock markets and currency exchange rate fluctuations that resulted in the strengthening of the U.S. dollar against foreign currencies in which we conduct business. The strengthening of the U.S. dollar relative to other currencies may adversely affect our results of operations.

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

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

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

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

We are at an early stage of development as a company and have a limited operating history on which to evaluate our business and prospects. While we earned modest product revenues from the ALIGN business prior to terminating operations effective September 30, 2012, we have not generated any product revenues from our product candidates currently in development. We cannot guarantee that any of our product candidates currently in development will ever become marketable products. We must demonstrate that our drug candidates satisfy rigorous standards of safety and efficacy for their intended uses before the FDA, EMA and other regulatory authorities in the United States, the European Union and elsewhere. Significant additional research, preclinical testing and clinical testing is required before we can file applications with the FDA or EMA for approval of our drug candidates. In addition, to compete effectively, our drugs must be easy to administer, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives. Sapacitabine, our most advanced drug candidates for the treatment of cancer, is currently in Phase 3 for AML and Phase 2 for AML and MDS. A combination of sapacitabine and seliciclib is currently in a Phase 1/2 clinical trial and CYC065 is in a first-in-human Phase 1 study. We cannot be certain that the clinical development of these or any other drug candidates in preclinical testing or clinical development will be successful, that we will receive the regulatory approvals required to commercialize them or that any of our other research and drug discovery programs will yield a drug candidate suitable for investigation through clinical trials. Our commercial revenues from our product candidates currently in development, if any, will be derived from sales of drugs that will not become marketable for several years, if at all.

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, 2015 and June 30, 2016, our accumulated deficit was $323.2 million and $329.3 million, respectively. Our net loss was $38.4 million and $6.1 million for the six months ended June 30, 2015 and 2016, respectively. In addition to the SEAMLESS study, 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.

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

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The Company had a hearing before the Panel on March 31, 2016, at which it presented its plan to regain compliance with the minimum bid price requirement, and requested a further extension of time to do so. On April 4, 2016, the Company received a written ruling from the Panel stating that the Panel had granted the Company's request to remain listed on The NASDAQ Capital Market. At the 2016 Annual Meeting of Stockholders, which was held on May 26, 2016, holders of the Company's common stock approved a proposed amendment to the Company's amended and restated certificate of incorporation, by way of a certificate of amendment, to effectuate a reverse stock split at a ratio of up to and including one-for-twenty. Pursuant thereto, the Board determined to use a ratio of one-for-twelve, and the reverse stock split became effective at 5:00 p.m., Eastern Time, on May 27, 2016, with the Company's common stock trading on the NASDAQ Capital Market on a post-split basis at the open of business on May 31, 2016. On June 15, 2016, we received notification from the Staff that we have regained compliance with the minimum bid price rule for continued listing on The NASDAQ Capital Market. The notification stated that as of June 14, 2016, we have evidenced a closing per share bid price of our common stock in excess of the $1.00 minimum closing bid price requirement for at least ten consecutive trading days. Accordingly, we have regained compliance with NASDAQ Listing Rule 5550(a)(2) and will continue to trade on The NASDAQ Capital Market.

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, including our Phase 3 clinical trials for sapacitabine. To the extent we elect to fund the full development of a drug candidate or the commercialization of a drug at our expense, we will need to raise substantial additional funding to:

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

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

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- the costs and timing of seeking and obtaining regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

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

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

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

Risks Related to our Intellectual Property

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

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

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Sapacitabine is protected by granted, composition of matter patents claiming certain, stable crystalline forms of sapacitabine and their pharmaceutical compositions and therapeutic uses that expire in 2022 (and may be eligible for a Hatch-Waxman term restoration of up to five years, which could extend the expiration date to 2027); United States and European granted patents that expire in 2029, claiming the combination of sapacitabine with hypomethylating agents, including decitabine, which is being tested as the active arm in the SEAMLESS Phase 3 trial, and a United States granted patent claiming a specified method of administration of sapacitabine with patent exclusivity until July 2030. We have used a stable, crystalline form of sapacitabine in nearly all our Phase 1 and all our Phase 2 and Phase 3 clinical studies. We have also chosen this crystalline form for commercialization. Additional patents and applications claim certain medical uses, combinations, formulations and dosing regimens of sapacitabine which have emerged in our clinical trials, as well as a process for the preparation of sapacitabine. Seliciclib is protected by granted, composition of matter patents that expire in 2016. Additional patents and applications claim certain medical uses of seliciclib, including combination use with sapacitabine, which have emerged in our preclinical research and clinical trials. The latest to expire of the granted patents expires in 2028. Failure to obtain, maintain or extend the patents could adversely affect our business. We will only be able to protect our drug candidates and our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

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

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

Proprietary trade secrets and unpatented know-how are also very important to our business. We rely on trade secrets to protect our technology, especially where we do not believe that patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our confidential information to competitors, and

confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third-party obtained illegally and is using trade secrets is expensive and time consuming, and the outcome is unpredictable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

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

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

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

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

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

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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 lead drug candidate sapacitabine, seliciclib or other therapeutic candidates, or gene sequences, substances, processes and techniques that we use in the course of our research and development and manufacturing processes. We are aware that other patents exist that claim substances, processes and techniques, which, if held valid, could potentially restrict the scope of our research, development or manufacturing

operations. In addition, we understand that other applications and patents exist relating to potential uses of sapacitabine and seliciclib that are not part of our current clinical programs for these compounds. Numerous third-party United States and foreign issued patents and pending applications exist in the area of kinases, including CDK, PLK and AK for which we have research programs. For example, some pending patent applications contain broad claims that could represent freedom to operate limitations for some of our kinase programs should they be issued unchanged. Although we intend to continue to monitor these applications, we cannot predict what claims will ultimately be allowed and if allowed what their scope would be. In addition, because the patent application process can take several years to complete, there may be currently pending applications, unknown to us, which may later result in issued patents that cover the production, manufacture, commercialization or use of our drug candidates. If we wish to use the technology or compound claimed in issued and unexpired patents owned by others, we will need to obtain a license from the owner, enter into litigation to challenge the validity of the patents or incur the risk of litigation in the event that the owner asserts that we infringe its patents. In one case we have opposed a European patent relating to human aurora kinase and the patent has been finally revoked (no appeal was filed). We are also aware of a corresponding U.S. patent containing method of treatment claims for specific cancers using aurora kinase modulators which, if held valid, could potentially restrict the use of our aurora kinase inhibitors once clinical trials are completed.

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

- be prohibited from selling or licensing any product that we may develop unless the patent holder licenses the patent to us, which it is not required to do;
- be required to pay substantial royalties or grant a cross license to our patents to another patent holder; decide to locate some of our research, development or manufacturing operations outside of Europe or the United States;
- be required to pay substantial damages for past infringement, which we may have to pay if a court determines that our product candidates or technologies infringe a competitor’s patent or other proprietary rights; or

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

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

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

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

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

Risks Related to Securities Regulations and Investment in Our Securities

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

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

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

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

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our operating results could be harmed. We have completed a formal process to evaluate our internal control over financial reporting. However, guidance from regulatory authorities in the area of

internal controls continues to evolve and substantial uncertainty exists regarding our on-going ability to comply by applicable deadlines. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Our common stock may have a volatile public trading price.

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

- 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;

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

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

- public announcements by our competitors or others; and

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

For example, on December 16, 2014 we announced the enrollment of 486 patients, continuation to final analysis and recommendations of the DSMB of the Company's Phase 3 SEAMLESS study of sapacitabine oral capsules in acute myeloid leukemia, or AML. The DSMB determined that the planned futility boundary has been crossed, but saw no reasons why patients should discontinue treatment on their assigned arm and recommended that recruited patients are followed up. As a result of this announcement, the last reported sale price of our common stock on The NASDAQ Global Market on December 16, 2014 dropped to $8.16 from a last reported sale price of our common stock on December 15, 2014 of $33.96.

We executed a reverse stock split in order to help maintain our continued listing on The NASDAQ Capital Market. The reduction in our outstanding shares may result in reduced liquidity for all stockholders and in increased volatility in our stock price over time.

The reduced trading volume which results from the decreased number of shares that are publically held may make it more difficult to buy or sell our stock, even though we may maintain our listing on The NASDAQ Capital Market. The reduced volume of stock trades that may result as a consequence of the reverse stock split may also increase the volatility of our stock price over time.

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.

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

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

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

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

In addition, in the event a third party seeks to acquire our company or acquire control of our company by way of a merger, but the terms of such offer do not provide for our preferred stock to remain outstanding or be converted into or exchanged for preferred stock of the surviving entity having rights, preferences and limitations substantially similar, but no less favorable, to our preferred stock, the terms of the Certificate of Designations of our preferred stock provide for an adjustment to the conversion ratio of our preferred stock such that, depending on the terms of any such transaction, preferred stockholders may be entitled, by their terms, to receive up to $10.00 per share in common stock, causing our common stockholders not to receive as favorable a price as the price at which such shares may be trading at the time of any such transaction. As of June 30, 2016, 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.

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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:

- additions to or departures of our key personnel;
- announcements of technological innovations or new products or services by us or our competitors; announcements concerning our competitors or the biotechnology industry in general;
- new regulatory pronouncements and changes in regulatory guidelines;
- general and industry-specific economic conditions;
- changes in financial estimates or recommendations by securities analysts;
- variations in our quarterly results; and
- announcements about our collaborators or licensors; and changes in accounting principles.

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. Whether or not meritorious, litigation brought against us could result in substantial costs, divert our management's attention and resources and harm our financial condition and results of operations.

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

If our common or preferred stockholders sell substantial amounts of our stock in the public market, or the market perceives that such sales may occur, the market price of our common and preferred stock could fall. If additional holders of preferred stock elect to convert their shares to shares of common stock at renegotiated prices, such conversion as well as the sale of substantial amounts of our common stock, could cause dilution to existing holders of our common stock, thereby also negatively affecting the price of our common stock. For example, in 2013, we issued an aggregate of 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.

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

We may automatically convert the preferred stock into common stock if the closing price of our common stock exceeds $2,961 per share. There is a risk of fluctuation in the price of our common stock between the time when we may first elect to automatically convert the preferred and the automatic conversion date.

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

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

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 risk related to the marketable securities we may purchase.

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

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

On June 23, 2016 we entered into an At Market Issuance Sales Agreement with FBR, as sales agent, pursuant to which we may sell through FBR up to an aggregate of $4.0 million in shares of our common stock. Our management will use its discretion to direct the net proceeds from the sale of those shares. We intend to use all of the net proceeds, together with cash on hand, for general corporate purposes. General corporate purposes may include working capital, capital expenditures, development costs, strategic investments or possible acquisitions. Our management’s judgments may not result in positive returns on your investment and you will not have an opportunity to evaluate the economic, financial or other information upon which our management bases its decisions. As of June 30, 2016, we have not sold any stock under the Sales Agreement.

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

We have the right to sell up to $4.0 million of our shares of common stock through FBR, as sales agent. Any actual or anticipated sales of shares through FBR may cause the trading price of our common stock to decline. Additional issuances of shares through FBR may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock through FBR, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of sales of our shares through FBR, and the Agreement may be terminated by us at any time at our discretion upon five (5) days' notice without any penalty or cost to us.

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 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

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Item 5. Other Information

None

Item 6. Exhibits

1.1	At Market Issuance Sales Agreement, dated as of June 23, 2016 between the Company and FBR Capital Markets & Co. (previously filed as Exhibit 1.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on June 23, 2016 and incorporated herein by reference).
3.1	Amended and Restated Certificate of Incorporation of Cyclacel Pharmaceuticals, Inc.
3.2	Amended and Restated Bylaws of Cyclacel Pharmaceuticals, Inc. (previously filed as Exhibit 3.2 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on May 27, 2016 and incorporated herein by reference).
31.1	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a) As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a) As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following materials from Cyclacel Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the period ended June 30, 2016, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statements of Income, (ii) the Consolidated Balance Sheets, (iii) the Consolidated Statements of Cash Flows, and (iv) Notes to Consolidated Financial Statements.

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SIGNATURES

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

CYCLACEL PHARMACEUTICALS, INC.

Date: August 11, 2016 By: /s/ Paul McBarron
Paul McBarron
Chief Operating Officer, Chief Financial Officer and
Executive Vice President, Finance