

Cyclacel Pharmaceuticals, Inc.  
Form 10-Q  
November 12, 2015

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

**(Mark One)**

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

**For the quarterly period ended September 30, 2015**

**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**

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(State or Other Jurisdiction (I.R.S. Employer  
of Incorporation or Organization) Identification No.)

**200 Connell Drive, Suite 1500**

**07922**

**Berkeley Heights, New Jersey**

(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  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark 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

Smaller reporting filer

(Do not check if a smaller reporting company)

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

As of November 11, 2015 there were 34,702,910 shares of the registrant's common stock outstanding.

**CYCLACEL PHARMACEUTICALS, INC.**

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Table of Contents**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, 2014	September 30, 2015 (Unaudited)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 24,189	\$ 22,728
Prepaid expenses and other current assets	4,640	3,966
Current assets of discontinued operations	171	100
Total current assets	29,000	26,794
Property, plant and equipment (net)	387	255
Total assets	\$ 29,387	\$ 27,049
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,792	\$ 1,616
Accrued and other current liabilities	4,626	3,572
Current liabilities of discontinued operations	75	75
Total current liabilities	7,493	5,263
Other liabilities	206	186
Total liabilities	7,699	5,449
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 31, 2014 and September 30, 2015; 335,273 shares issued and outstanding at December 31, 2014 and September 30, 2015. Aggregate preference in liquidation of \$3,989,749 at December 31, 2014 and September 30, 2015.	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized at December 31, 2014 and September 30, 2015; 23,199,469 and 34,702,910 shares issued and outstanding at December 31, 2014 and September 30, 2015, respectively.	23	34
Additional paid-in capital	330,962	341,891

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Accumulated other comprehensive loss	(480	)	(540	)
Accumulated deficit	(308,817	)	(319,785	)
Total stockholders' equity	21,688		21,600	
Total liabilities and stockholders' equity	\$ 29,387		\$ 27,049	

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

Table of Contents**CYCLACEL PHARMACEUTICALS, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS****(In \$000s, except share and per share amounts)****(Unaudited)**

	Three Months Ended September 30,		Nine months Ended September 30,	
	2014	2015	2014	2015
Revenues:				
Grant revenue	\$735	\$462	\$1,487	\$1,270
Collaboration and research and development revenue	—	253	—	253
Total revenues	735	715	1,487	1,523
Operating expenses:				
Research and development	4,972	2,904	13,861	9,826
General and administrative	1,433	1,205	4,281	4,006
Total operating expenses	6,405	4,109	18,142	13,832
Operating loss	(5,670	) (3,394	) (16,655	) (12,309
Other income (expense):				
Change in valuation of financial instruments associated with stock purchase agreement	(4	) (27	) (115	) (51
Change in valuation of liabilities measured at fair value	—	—	20	—
Foreign exchange gains (losses)	10	219	(23	) (354
Interest income	3	2	5	5
Other income, net	—	13	26	95
Total other income (expense)	9	207	(87	) (305
Loss from continuing operations before taxes	(5,661	) (3,187	) (16,742	) (12,614
Income tax benefit	750	478	2,135	1,646
Net loss from continuing operations	(4,911	) (2,709	) (14,607	) (10,968
Discontinued operations:				
Income from discontinued operations	6	—	29	—
Income tax on discontinued operations	(2	) —	(10	) —
Net income from discontinued operations	4	—	19	—
Net loss	(4,907	) (2,709	) (14,588	) (10,968
Dividend on convertible exchangeable preferred shares	(50	) (50	) (150	) (150
Net loss applicable to common shareholders	\$(4,957	) \$(2,759	) \$(14,738	) \$(11,118
Basic and diluted earnings per common share:				
Net loss per share, continuing operations – basic and diluted	\$(0.22	) \$(0.08	) \$(0.68	) \$(0.35
Net income per share, discontinued operations – basic and diluted	\$0.00	\$0.00	\$0.00	\$0.00

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Net loss per share – basic and diluted	\$ (0.22 )	\$ (0.08 )	\$ (0.68 )	\$ (0.35 )
Weighted average common shares outstanding	22,676,475	34,675,569	21,607,888	31,741,910

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		Nine months Ended	
	September 30,		September 30,	
	2014	2015	2014	2015
Net loss from continuing operations	\$ (4,911 )	\$ (2,709 )	\$ (14,607 )	\$ (10,968 )
Net income from discontinued operations	4	—	19	—
Net loss	(4,907 )	(2,709 )	(14,588 )	(10,968 )
Translation adjustment	6,214	5,107	2,134	2,880
Unrealized foreign exchange gain on intercompany loans	(6,422 )	(5,259 )	(2,330 )	(2,940 )
Comprehensive loss	\$ (5,115 )	\$ (2,861 )	\$ (14,784 )	\$ (11,028 )

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



Table of Contents**CYCLACEL PHARMACEUTICALS, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS****(In \$000s)****(Unaudited)**

	Nine months Ended September 30, 2014	2015
Operating activities:		
Net loss	\$ (14,588 )	\$ (10,968 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in valuation of liabilities measured at fair value	(20 )	—
Change in valuation of financial instruments associated with stock purchase agreement	115	51
Depreciation	115	157
Stock-based compensation	589	464
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(842 )	583
Accounts payable and other current liabilities	(403 )	(2,071 )
Net cash used in operating activities	(15,034 )	(11,784 )
Investing activities:		
Purchase of property, plant and equipment	(302 )	(32 )
Minimum royalty payments received from termination of ALIGN license agreement	288	23

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Net cash used in investing activities	(14 )	(9 )
Financing activities:		
Proceeds from issuance of common stock, net of issuance costs	10,965	10,576
Payment of preferred stock dividend	(150 )	(150 )
Net cash provided by financing activities	10,815	10,426
Effect of exchange rate changes on cash and cash equivalents	(206 )	(94 )
Net decrease in cash and cash equivalents	(4,439 )	(1,461 )
Cash and cash equivalents, beginning of period	31,146	24,189
Cash and cash equivalents, end of period	\$ 26,707	\$ 22,728
Supplemental cash flow information:		
Cash received during the period for:		
Interest	5	6
Taxes	1,811	2,875

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.

Sapacitabine is being evaluated in the SEAMLESS Phase 3 study, which completed enrollment in December 2014 and is being conducted under a Special Protocol Assessment (“SPA”) agreement with the US Food and Drug Administration (“FDA”) for the front-line treatment of acute myeloid leukemia (“AML”) in the elderly and in other indications including myelodysplastic syndromes (“MDS”). Sapacitabine is also being evaluated in a Phase 1 study in combination with seliciclib, the Company’s second clinical candidate, in solid tumor patients including patients who are BRCA carriers with Homologous Recombination (“HR”) repair-deficient breast, ovarian and pancreatic cancers. The FDA and the European Medicines Agency (“EMA”) have designated sapacitabine as an orphan drug for the treatment of both AML and MDS.

In Cyclacel’s second development program, the Company is evaluating cyclin dependent kinase, or CDK, inhibitors. CDKs are involved in cancer cell growth, metastatic spread and DNA damage repair. Seliciclib, the Company’s most advanced CDK inhibitor, is an oral, highly selective inhibitor of CDK enzymes. To date, seliciclib has been evaluated in over 450 patients with various cancers, including non-small cell lung cancer (“NSCLC”) and nasopharyngeal cancer (“NPC”), and has shown signs of anticancer activity. Cyclacel’s second generation CDK inhibitor, CYC065, is a highly selective CDK2/9 inhibitor with potential utility in both hematological malignancies and solid tumors. CYC065 has been shown to have 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 patients with advanced solid tumors and lymphomas. CYC065 was selected from the Company’s discovery program in Dundee, Scotland and its development was supported in part by a \$1.9 million grant from the Biomedical Catalyst of the United Kingdom government.

In addition to these development programs, in 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, targeting the mitotic phase of the cell cycle. PLK was discovered by Professor David Glover, the Company's Chief Scientist. The Company has received a grant award of approximately \$3.5 million from the Biomedical Catalyst of the United Kingdom government to complete IND-directed preclinical development of CYC140.

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

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's existing capital resources are expected to be sufficient beyond the availability of mature data for final analysis of the SEAMLESS Phase 3 trial, which is expected to occur during the first half of 2016, but will not be sufficient to complete development of other indications or product candidates or to commercialize any of the Company's product candidates. On July 10, 2015, we entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement with Cantor Fitzgerald & Co., as sales agent ("Cantor") under which we may, from time to time, sell shares of our common stock having an aggregate offering price of up to \$8.35 million through Cantor.

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***Basis of Presentation***

The consolidated balance sheet as of September 30, 2015, the consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2014 and 2015, the consolidated statements of cash flows for the nine months ended September 30, 2015, and all related disclosures contained in the accompanying notes are unaudited. The consolidated balance sheet as of December 31, 2014 is derived from the audited consolidated financial statements included in the 2014 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 September 30, 2015, and the results of operations and comprehensive loss for the three and nine months ended September 30, 2015, and the consolidated statements of cash flows for the nine months ended September 30, 2015, have been made. The interim results for the three and nine months ended September 30, 2015 are not necessarily indicative of the results to be expected for the year ending December 31, 2015 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, 2014 that are included in the Company’s Annual Report on Form 10-K filed with the SEC.

**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 expense and the fair value of financial instruments. 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 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 was denied approval or clearance or such approval was delayed, or is unable to obtain the necessary financing to complete development and approval, there will be a material adverse impact on the Company's financial condition and results of operations.

### ***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.

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***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.

***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*.

***Revenue Recognition***

*Collaboration, supply and licensing agreements*

In June 2015, the Company entered into a collaboration, licensing and supply agreement with ManRos Therapeutics SA ("ManRos"), for the exclusive development and commercialization of the Company's oral seliciclib capsules by ManRos as a treatment for cystic fibrosis ("CF"). Among other terms of the agreement, ManRos licensed rights to the Company's proprietary clinical data to enable clinical development of seliciclib for CF indications. The agreement provides for supply of seliciclib investigational product for clinical trials of seliciclib in CF and technical assistance related to the Company's know-how to facilitate these trials.

The Company received an up-front payment in July 2015 and reached a development milestone in September 2015. The Company will receive further milestone payments and tiered royalties if seliciclib is commercialized for the treatment of CF.

The Company has elected not to apply the optional accounting policy for recognizing substantive milestones when earned. Instead, the Company is allocating all arrangement consideration – both nonrefundable upfront fees and any milestone payments – to the separable elements based on a relative selling price method. As the ManRos agreement contained no general rights of return, an element was determined to be separable if it had value to the customer on a stand-alone basis. The Company identified five separable elements in the ManRos collaboration arrangement. The Company did not have vendor-specific objective evidence or third party evidence as to the price at which each of those five separate elements were sold on a standalone basis. Accordingly, in applying the relative selling price method, the Company made its best estimate of the standalone selling price for each of the separable elements. After applying the relative selling price method, nearly all of the arrangement consideration was allocated to the initial deliverable in the arrangement – the transfer of seliciclib know-how to ManRos. Accordingly, in the three and nine months ended September 30, 2015, the Company recognized revenue of \$0.3 million.

Royalty income under the ManRos agreement, if any, will be recognized when ManRos or its sublicensee sells the underlying product.

#### 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.

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***Income Taxes***

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

The Company applies the accounting guidance codified in ASC 740 “Income taxes” (“ASC 740”) related to accounting for uncertainty in income taxes. ASC 740 specifies the accounting for uncertainty in income taxes recognized in a company’s financial statements by prescribing a minimum probability threshold 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”).

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 estimated forfeitures, using the straight-line attribution method. The estimation of

stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from current estimates, such amounts are recorded as a cumulative adjustment in the period estimates are revised. The Company considers many factors when estimating expected forfeitures, including type of awards granted, employee class, and historical experience. Actual results and future estimates may differ substantially from current estimates.

*Net Loss Per Common Share*

The Company calculates net loss per common share in accordance with ASC 260 “Earnings Per Share” (“ASC 260”). Basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted average number of 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 three months ended September 30, 2014 and 2015, as the result would be anti-dilutive:

	September 30, 2014	September 30, 2015
Stock options	1,010,298	1,333,954
Restricted Stock and Restricted Stock Units	119,015	—
Convertible preferred stock	20,381	20,381
Common stock warrants	1,341,129	1,138,630
Total shares excluded from calculation	2,490,823	2,492,965

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***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).

***Recent Events***

***Deficiency and Compliance Notice from The NASDAQ Stock Market***

On August 4, 2015, the Company received approval from The NASDAQ Stock Market LLC (“NASDAQ”) to transfer the listing of the Company’s common stock from the NASDAQ Global Market to the NASDAQ Capital Market. This transfer was effective at the opening of business on August 6, 2015. The Company’s common stock will continue to trade under the symbol “CYCC.” The NASDAQ Capital Market is a continuous trading market that operates in substantially the same manner as the NASDAQ Global Market and requires listed companies to meet certain financial requirements and to comply with NASDAQ’s corporate governance requirements.

As previously reported, the Company was notified by NASDAQ on February 2, 2015 that it no longer satisfied the minimum bid price requirement of \$1.00 per share for continued listing as set forth in NASDAQ Listing Rule 5450(a)(1). In anticipation of not meeting the minimum bid price requirement by August 3, 2015, the end of its initial 180-day grace period, the Company had previously applied to transfer the listing of its stock to the NASDAQ Capital Market. The Company currently meets the NASDAQ Capital Market initial listing criteria, except for the bid price requirement. Upon transfer to the NASDAQ Capital Market, the Company is being afforded an additional 180-day grace period to regain compliance with NASDAQ’s minimum bid price requirement. In order to regain compliance, the minimum bid price per share of the Company’s common stock must be at least \$1.00 for at least ten consecutive business days during the second 180-day grace period, which will end on February 2, 2016. If the Company fails to regain compliance during this grace period, the Company’s common stock will be subject to delisting by NASDAQ.

***Accounting Standards Adopted in the Period***

On January 1, 2015 the Company early adopted guidance issued by the Financial Accounting Standards Board (“FASB”), which eliminated the concept of extraordinary items. This guidance has been adopted on a prospective basis and the adoption of this guidance has not had a material impact on the Company’s consolidated financial statements.

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

***Recent Accounting Pronouncements Not Yet Effective***

In September 2015, the FASB issued guidance that requires an acquirer in a business combination to recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period for which the adjustment amounts are determined. The guidance should be applied prospectively and is effective for fiscal years beginning after December 15, 2015, including interim periods within those fiscal years.

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

In April 2015, the FASB issued guidance on a customer’s accounting for fees in a cloud computing arrangement. The guidance is adopted on a retrospective basis. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of the guidance on its consolidated financial statements.

In February 2015, the FASB issued guidance on the consolidation, which changes the analysis an entity must perform to determine whether it should consolidate certain legal entities. This guidance is effective for annual periods, and interim periods within

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those annual periods, beginning after December 15, 2015. Early adoption is permitted. The guidance can be adopted using either a full retrospective or a modified retrospective method of transition. The Company is currently evaluating the impact of the guidance on its consolidated financial statements.

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

In June 2014, the FASB issued guidance on accounting for share based payments when the terms of an award provide that a performance target could be achieved after the requisite service period. The guidance requires that a performance target that affects vesting and that could be achieved after the requisite service period should be treated as a performance condition. This guidance is effective for annual periods, and interim periods within those annual periods, after December 15, 2015. The Company is currently evaluating the impact of the guidance on its 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 that guidance, which will now be effective for the Company on January 1, 2018, for both interim and annual periods. Early adoption is permitted for both interim and annual periods commencing on January 1, 2017. The guidance can be adopted using either a full retrospective (with certain practical expedients) or a modified retrospective method of transition. Under the modified retrospective approach, financial statements will be prepared for the year of adoption using the new standard, but prior periods will not be adjusted. Instead, companies will recognize a cumulative catch-up adjustment to the opening balance of retained earnings at the effective date for contracts that still require performance by the company, and disclose all line items in the year of adoption as if they were prepared under current revenue requirements. At this time, the Company has not decided on which method it will use to adopt the new standard, nor has it determined the effects of the new guidelines on its results of operations and financial position. For the foreseeable future, the Company's revenues will be limited to grants received from government agencies or nonprofit organizations and revenues from collaboration, supply and licensing agreements, and we are evaluating the effects of the new standard on these types of revenue streams.

**3.**

**FAIR VALUE**

*Fair Value Measurements*

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

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

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

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

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

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

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

The fair value of the Company’s financial assets and liabilities that are measured on a recurring basis were determined using the following inputs as of September 30, 2015 (in \$000s):

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	Level 1	Level 2	Level 3	Total
<b>ASSETS</b>				
Cash equivalents	\$ 11,949	\$ —	\$ —	\$ 11,949
Total assets	\$ 11,949	\$ —	\$ —	\$ 11,949

***Financial Instrument Associated with Stock Purchase Agreement***

On November 14, 2013, the Company entered into a common stock purchase agreement with Aspire Capital Fund, LLC (“Aspire”) (the “Purchase Agreement”) under which Aspire purchased 511,509 shares of common stock for an aggregate purchase price of \$2.0 million and committed to purchase up to an additional 3,042,038 shares from time to time as directed by the Company over the next two years at prices derived from the market prices on or near the date of each sale (see *Note 8 — Stockholders’ Equity*).

The Company has accounted for the right to sell additional shares under the Purchase Agreement based on the guidance of ASC 815 “Derivative Financial Instruments” (“ASC 815”), which requires the instrument to be measured at fair value with changes in fair value reported in earnings each reporting period until the agreement is exhausted or expired. The primary inputs used to determine fair value are the price of the Company’s common stock, the remaining term, and aggregate share purchases on the measurement date. The instrument had a fair value of approximately \$51,000 as of December 31, 2014.

On July 8, 2015, the Company sold all remaining 314,424 shares of common stock that were subject to its agreement with Aspire and the Aspire Agreement has automatically terminated by its terms. As a result, the Purchase Agreement had no value as of September 30, 2015. The decrease of approximately \$27,000 in the fair value of the Purchase Agreement during the three months and nine months ended September 30, 2015, respectively, was recognized as a loss in the consolidated statements of operations.



Table of Contents**4. PREPAID EXPENSES AND OTHER CURRENT ASSETS**

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

	December 31, 2014	September 30, 2015
Research and development tax credit receivable	\$ 3,017	\$ 1,674
Prepayments	902	963
Grant receivable	134	304
Sales tax receivable	309	718
Deposits	132	132
Other current assets	146	175
	\$ 4,640	\$ 3,966

**5. ACCRUED AND OTHER CURRENT LIABILITIES**

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

	December 31, 2014	September 30, 2015
Accrued research and development	\$ 4,161	\$ 3,210
Accrued legal and professional fees	303	248
Other current liabilities	162	114
	\$ 4,626	\$ 3,572

**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 awards granted by the Company (and still outstanding) vest ratably over one to four years.

The Company recognizes all share-based awards under the straight-line attribution method. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company evaluates its forfeiture assumptions quarterly and the expected forfeiture

rate is adjusted when necessary. Ultimately, the actual expense recognized over the vesting period is based on only those shares that vest.

Stock based compensation has been reported within expense line items on the consolidated statement of operations for the three and nine months ended September 30, 2014 and 2015 as shown in the following table (in \$000s):

	Three Months Ended		Nine months Ended	
	September 30,		September 30,	
	2014	2015	2014	2015
General and administrative	\$ 160	\$ 97	\$ 415	\$ 312
Research and development	59	44	174	152
Stock-based compensation costs before income taxes	\$ 219	\$ 141	\$ 589	\$ 464

### ***2015 Plan***

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

There were 63,000 and 326,656 options granted during the nine months ended September 30, 2014 and 2015, respectively.

There were no stock options exercised during each of the nine months ended September 30, 2014 and 2015. The Company does not expect to be able to benefit from the deduction for stock option exercises that may occur during the year ended December 31, 2015 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, 2015.

Table of Contents*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, 2014	1,010,298	\$ 14.24	6.58	\$ —
Granted	326,656	\$ 0.84		
Cancelled/forfeited	(3,000 )	\$ 105.00		
Options outstanding at September 30, 2015	1,333,954	\$ 10.75	6.73	\$ —
Unvested at September 30, 2015	(494,382 )	\$ 2.27	8.91	\$ —
Vested and exercisable at September 30, 2015	839,572	\$ 15.75	5.45	\$ —

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.

Estimates of pre-vesting option forfeitures are based on the Company's experience. Currently the Company uses a forfeiture rate of 0 - 30% depending on when and to whom the options are granted. The Company adjusts its estimate of forfeitures over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures are recognized through a cumulative adjustment in the period of change and may impact the amount of compensation expense to be recognized in future periods.

The Company considers many factors when estimating expected forfeitures, including types of awards, employee class, and historical experience.

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

expected term of the employee option.

### *Restricted Stock Units*

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

	Restricted Stock Units	Weighted Average Grant Date Value Per Share
Non-vested at December 31, 2014	89,016	\$ 5.56
Granted	—	\$ —
Vested	(89,016)	) \$ 5.56
Non-vested at September 30, 2015	—	\$ —

During the nine months ended September 30, 2015, 89,016 restricted stock units vested. The Company did not issue any restricted stock units during the nine months ended September 30, 2015.

## 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.

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 upfront fee, to reimburse Daiichi Sankyo for enumerated expenses, and to make milestone payments and to pay royalties on a country-by-country basis. The upfront fee, the 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 the 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

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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 September 30, 2015, 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 0.06079 shares of common stock for each share of Preferred Stock based on a price of \$164.50. The Company has reserved 20,381 shares of common stock for issuance upon conversion of the remaining shares of Preferred Stock outstanding on September 30, 2015. The shares of previously-converted Preferred Stock have been retired, cancelled and restored to the status of authorized but unissued shares of preferred stock, subject to reissuance by the Board of Directors as shares of Preferred Stock of one or more series.

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

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

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

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

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

On May 22, 2015, 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 August 1, 2015 to the holders of record of the Preferred Stock as of the close of business on July 17, 2015.

### ***Common Stock***

#### *July 2015 Controlled Equity Offering<sup>SM</sup>*

On July 10, 2015, the Company entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement (the “Agreement”) with Cantor under which the Company may, from time to time, sell shares of its common stock having an aggregate offering price of up to \$8.35 million through Cantor. Under the Agreement, Cantor may sell the Shares by methods deemed to be an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the “Securities Act”). The Company will pay Cantor a commission of up to 3.0% of the gross sales price per share sold. The Company is not obligated to make any sales under the Agreement. The Company has not made any sales under the Agreement as of September 30, 2015.

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*March 2015 Public Offering*

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

*November 2013 Stock Purchase Agreement*

On November 14, 2013, the Company entered into a common stock Purchase Agreement with Aspire (the “Purchase Agreement”). Upon execution of the Purchase Agreement, Aspire purchased 511,509 shares of common stock for an aggregate purchase price of \$2.0 million. Under the terms of the Purchase Agreement, Aspire has committed to purchase up to an additional 3,042,038 shares from time to time as directed by the Company or, in certain instances, as agreed to by both parties, over the next two years at prices derived from the market prices on or near the date of each sale. However, such commitment is limited to an additional \$18.0 million of share purchases. In consideration for entering into the Purchase Agreement, concurrent with the execution of the Purchase Agreement, the Company issued 166,105 shares of the Company’s common stock to Aspire in lieu of a commitment fee. The fair value of these shares has been recorded as a component of other assets and will continue to be remeasured each reporting period, until the agreement is exhausted or expired, with gains or losses reported in the consolidated statements of operations. During the nine months ended September 30, 2015, the Company sold 1,100,000 shares to Aspire under the Purchase Agreement for proceeds of \$1.2 million.

On July 8, 2015, the Company sold all remaining 314,424 shares of common stock that were subject to its agreement with Aspire at \$0.70 per share. All of the available shares under the Aspire Agreement have now been sold and the Aspire Agreement has automatically terminated by its terms.

*Common Stock Warrants*

The following table summarizes information about warrants outstanding at September 30, 2015:

Issued in Connection With	Expiration Date	Common Shares Issuable	Weighted Average Exercise Price
October 2010 stock issuance	2015	594,513	\$ 13.44

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July 2011 stock issuance	2016	544,117	\$ 9.52
Total		1,138,630	\$ 11.57

There were no exercises of warrants during the nine months ended September 30, 2014 and 2015. Warrants for 202,499 shares of common stock, issued in connection with the January 2010 stock issuance, expired during the nine months ended September 30, 2015.



Table of Contents**9. DISCONTINUED OPERATIONS**

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

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

	Three Months Ended September 30,		Nine months Ended September 30,	
	2014	2015	2014	2015
Interest income	\$ 6	\$ —	\$ 29	\$ —
Income tax on discontinued operations	(2 )	—	(10 )	—
Net income from discontinued operations	\$ 4	\$ —	\$ 19	\$ —

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

	December 31, 2014	September 30, 2015
Current assets of discontinued operations:		
Short term portion of minimum royalty arrangement receivable, net	\$ 96	\$ 25
Returns indemnification receivable	75	75
Total current assets of discontinued operations	\$ 171	\$ 100
Current liabilities of discontinued operations:		
Returns provision	\$ 75	\$ 75
Total current liabilities of discontinued operations	\$ 75	\$ 75

**10. SUBSEQUENT EVENTS***Preferred Stock Dividend*

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

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**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.*

*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, 2014, 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 third quarter of 2015, we have continued to progress with the clinical development of sapacitabine in acute myeloid leukemia, or AML, and other indications including myelodysplastic syndromes, or MDS and solid tumors in combination with seliciclib. We also began a first-in-human, Phase I clinical trial of CYC065, our investigational CDK inhibitor. We also continued to advance our early pipeline through the support of government

funding or investigator-sponsored trials.

### Sapacitabine

In our SEAMLESS, Phase 3, registration-directed study of sapacitabine in elderly patients with newly diagnosed AML, our lead indication, we completed enrollment in December 2014 in approximately 110 centers in the United States and Europe. In December 2014, the Data Safety Monitoring Board, or DSMB, conducted a planned interim analysis for futility after 247 events, or patient deaths, and the final safety review of 470 randomized patients. The DSMB found no safety concerns. However, the planned futility boundary had been crossed and the DSMB determined that, based on available interim data, it would be unlikely for the study to reach statistically significant improvement in survival. The DSMB saw no reasons why patients should discontinue treatment on their assigned arm and recommended that recruited patients are followed-up. We will continue to follow-up enrolled patients in SEAMLESS until the prespecified 424 events are observed, which is expected to occur during the first half of 2016. Approximately 8% of the prespecified events remain to be observed as of November 12, 2015.

In parallel to the follow-up of enrolled patients, we also plan to submit a Pediatric Investigation Plan, or PIP, to the European Medicines Agency, or 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 plan to submit a PIP ahead of any MAA submission. Depending on the final SEAMLESS data, we may meet with regulatory authorities in Europe and the U.S. to discuss registration submissions for sapacitabine for the AML indication.

The second indication for sapacitabine is high-risk MDS after failure of front-line hypomethylating agents, or HMA, azacitidine and/or decitabine. We have recently completed enrollment of a patient cohort in an additional part of the ongoing MDS Phase 2 study in order to evaluate better dosing regimens. We will follow-up these additional Phase 2 patients until mature survival data become available. In parallel, we have conducted a feasibility analysis in preparation for a Phase 2b randomized controlled trial of sapacitabine in this patient population, which indicated that our proposed study design is feasible.

We reported updated data from the Phase 1 study of sapacitabine in combination with seliciclib as an all-oral, sequentially-administered regimen in heavily-pretreated patients with advanced solid tumors, in particular those carrying BRCA mutations. Initial data with this Cyclacel drug regimen were reported at the American Association of Cancer Research 2013 conference by Dr. Shapiro of Dana Farber Cancer Institute, and included confirmed durable partial responses in BRCA positive patients. In this updated data set, we observed an overall response rate of 55 percent in heavily-pretreated breast, ovarian and pancreatic cancer patients with BRCA mutations, with some patients achieving a partial response staying on study for more than 30 and 60 cycles of treatment.

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Cyclin Dependent Kinase (CDK) Inhibitors

*CYC065 (Second Generation CDK Inhibitor)*

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

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

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

In 2011, independent investigators published preclinical evidence that CYC065 as a single-agent can induce tumor growth delay to HER2-positive breast cancer cells addicted to cyclin E and resistant to trastuzumab (Herceptin®), while the administration of CYC065 in combination with trastuzumab resulted in regression or sustained tumor growth inhibition. Mixed lineage leukemia (MLL) gene status and levels of Bcl-2 family proteins correlated with sensitivity of AML cell lines to CYC065. Combination studies revealed the potential to combine CYC065 with available and experimental leukemia therapies, including cytarabine and Bcl-2 inhibitors. Potent anticancer activity of CYC065 was demonstrated *in vivo* in AML xenograft models resulting in over 90% inhibition of tumor growth. The potent *in vitro* and *in vivo* anti-cancer activity, opportunity for patient stratification and the ability to combine with antileukemic agents suggest that CYC065 may have therapeutic potential in AML.

*Seliciclib (First Generation CDK Inhibitor)*

Seliciclib, is a novel, orally-available, CDK inhibitor. The compound selectively inhibits a spectrum of enzyme targets, CDK2, -7 and -9 that are central to the process of cell division and cell cycle control. The target profile of seliciclib is differentiated from the published target profile of other CDK inhibitors. Recent publications by independent investigators showed that seliciclib (i) is more active against non-small cell lung cancer, or NSCLC, cells with K-Ras or N-Ras mutations than those with wild type Ras, and (ii) overcomes resistance to letrozole in breast cancer cells caused by a particular form of cyclin E in complex with CDK2. Preclinical studies have shown that the drug works by inducing cell apoptosis, or cell suicide, in multiple phases of the cell cycle. To date, seliciclib has been evaluated in approximately 450 patients in several Phase 1 and 2 trials, including NSCLC and nasopharyngeal cancer studies, and has shown signs of anti-cancer activity. Seliciclib is also in an on-going Phase 1 study in combination with sapacitabine.

Polo-like Kinase (PLK) Inhibitors

*CYC140*

We are progressing the IND-directed preclinical development of CYC140, a novel, orally available, PLK1 inhibitor supported by an approximately \$3.5 million grant from the Biomedical Catalyst of the United Kingdom government.

Non-oncology Programs

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

In this regard, we are supporting investigator sponsored trials, or ISTs, evaluating seliciclib in endocrinologic and inflammatory indications in patients who have failed prior treatments. Specifically, in an IST at Cedars-Sinai, Los Angeles, the first

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patients are being treated in an on-going Phase 2 trial to evaluate seliciclib as a potential therapy for Cushing's disease caused by pituitary tumors. There are limited options for Cushing's disease patients today. The investigator was awarded a grant from The National Institute of Diabetes and Digestive and Kidney Diseases. In a European IST, seliciclib is being evaluated as a potential treatment for rheumatoid arthritis, or RA, where it may work for RA by targeting proliferating fibroblasts, a different type of approach than conventional RA therapies. This study is also being supported by an approximately \$1.5 million grant from the United Kingdom's Medical Research Council. As with all ISTs, we do not control the timing or conduct of such studies and will report updates as the investigators may notify us from time to time.

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

## **Recent Events**

### *Deficiency and Compliance Notice from The NASDAQ Stock Market*

On August 4, 2015, we received approval from The NASDAQ Stock Market LLC, or NASDAQ, to transfer the listing of the Company's common stock from the NASDAQ Global Market to the NASDAQ Capital Market. This transfer was effective at the opening of business on August 6, 2015. Our common stock will continue to trade under the symbol "CYCC." The NASDAQ Capital Market is a continuous trading market that operates in substantially the same manner as the NASDAQ Global Market and requires listed companies to meet certain financial requirements and comply with NASDAQ's corporate governance requirements.

As previously reported, we were notified by NASDAQ on February 2, 2015 that we were no longer in compliance with the minimum bid price requirement of \$1.00 per share for continued listing as set forth in NASDAQ Listing Rule 5450(a)(1). In anticipation of not meeting the minimum bid price requirement by August 3, 2015, the end of its initial 180-day grace period, we had previously applied to transfer the listing of its stock to the NASDAQ Capital Market. The Company currently meets the NASDAQ Capital Market initial listing criteria, except for the bid price requirement. Upon transfer to the NASDAQ Capital Market, we are being afforded an additional 180-day grace period to regain compliance with NASDAQ's minimum bid price requirement. In order to regain compliance, the minimum bid price per share of the Company's common stock must be at least \$1.00 for at least ten consecutive business days during the second 180-day grace period, which will end on February 2, 2016.

If we do not regain compliance within the allotted compliance period(s), including any extensions that may be granted by NASDAQ, NASDAQ will provide notice that our shares of common stock will be subject to delisting. We would then be entitled to appeal NASDAQ's determination to a NASDAQ Hearings Panel and request a hearing.

We intend to consider available options to resolve the noncompliance with the minimum bid price requirement. No determination regarding our response has been made at this time. There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or will otherwise be in compliance with other NASDAQ listing criteria.

### **Subsequent Events**

#### *Preferred Stock Dividend*

On October 14, 2015, the Board of Directors declared a quarterly cash dividend in the amount of \$0.15 per share on our 6% Convertible Exchangeable Preferred Stock, or Preferred Stock. The cash dividend was paid on November 2, 2015 to the holders of record of the Preferred Stock as of the close of business on October 23, 2015.



Table of Contents**Results of Operations***Three Months Ended September 30, 2014 and 2015***Results of Continuing Operations***Revenues*

The following table summarizes the components of our revenues for the three months ended September 30, 2014 and 2015 (in \$000s, except percentages):

	Three Months Ended September 30,		Difference	
	2014	2015	\$	%
Grant revenue	\$ 735	\$ 462	\$(273)	(37)
Collaboration and research and development revenue	—	253	253	—
Total revenue	\$ 735	\$ 715	\$(20 )	(3 )

We recognized \$0.7 million and \$0.5 million in grant revenue for the three months ended September 30, 2014 and 2015, respectively, from the European Union and the Biomedical Catalyst of the United Kingdom government. We recognized \$0.3 million in collaboration and research and development revenue for the three months ended September 30, 2015, from our collaboration, licensing and supply agreement with ManRos.

*The future*

We expect to recognize approximately \$1.4 million in grant revenue from the period starting in October 2015 to November 2016 from the Biomedical Catalyst of the United Kingdom government. We may receive milestone payments from ManRos if the development of seliciclib progresses for the treatment of CF.

***Research and development expenses***

From our inception, we have focused on drug discovery and development programs, with 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, and sapacitabine in combination with seliciclib. 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 three months ended September 30, 2014 and 2015 (in \$000s except percentages):

	Three Months Ended September 30,		Difference	
	2014	2015	\$	%
Sapacitabine	\$ 3,680	\$ 1,586	\$(2,094)	(57)
Other costs related to research and development programs, management and exploratory research	1,292	1,318	26	2
Total research and development expenses	\$ 4,972	\$ 2,904	\$(2,068)	(42)

Total research and development expenses represented 78% and 71% of our operating expenses for the three months ended September 30, 2014 and 2015, respectively.

Research and development expenditures decreased \$2.1 million to \$2.9 million for the three months ended September 30, 2015 from \$5.0 million for the three months ended September 30, 2014. Research and development expenses relating to sapacitabine decreased by \$2.1 million to \$1.6 million for the three months ended September 30, 2015 from \$3.7 million for the three months ended September 30, 2014, primarily as a result of decreased expenditures in study and site startup costs associated with the expansion of the SEAMLESS Phase 3 trial into Europe and the completion of

enrollment in the study in December 2014.

*The future*

We anticipate that overall research and development expenditures for the year ended December 31, 2015 will decrease compared to the year ended December 31, 2014, as we are in the patient follow-up phase of SEAMLESS and clinical study sites are

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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, which is expected during the first half of 2016 after the prespecified number of events have been observed in accordance with the study protocol.

*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 September 30, 2014 and 2015 (in \$000s except percentages):

	Three Months Ended		Difference	
	September 30,		\$	%
	2014	2015		
Total general and administrative expenses	\$ 1,433	\$ 1,205	\$(228)	(16)

Total general and administration expenses represented 22% and 29% of our operating expenses for the three months ended September 30, 2014 and 2015, respectively. General and administrative expenses decreased \$0.2 million from \$1.4 million for the three months ended September 30, 2014 to \$1.2 million for the three months ended September 30, 2015, primarily because of lower patent-related and stock-based compensation costs.

*The future*

We expect our general and administrative expenditures for the year ended December 31, 2015 to be consistent with the year ended December 31, 2014.

Table of Contents*Other income (expense)*

The following table summarizes other income (expense) for the three months ended September 30, 2014 and 2015 (in \$000 except percentages):

	Three Months Ended September 30,		Difference	
	2014	2015	\$	%
Change in valuation of financial instruments associated with stock purchase agreement	\$ (4 )	\$ (27 )	\$ (23 )	575
Foreign exchange gains	10	219	209	2,090
Interest income	3	2	(1 )	(33 )
Other income, net	—	13	13	—
Total other income (expense)	\$ 9	\$ 207	\$ 198	2,200

Total other income (expense) increased by approximately \$0.2 million, from a gain of \$9,000 for the three months ended September 30, 2014, to a gain of \$0.2 million for the three months ended September 30, 2015.

*Change in valuation of financial instruments associated with stock purchase agreement*

The remaining fair value of the right to sell additional shares under the November 2013 Purchase Agreement with Aspire was recognized during the quarter ended September 30, 2015 when we sold all remaining shares of common stock that were subject to the agreement, at which time the agreement automatically terminated by its terms. Prior to termination, the fair value was remeasured each reporting period. The Company recognized an expense of approximately \$4,000 and approximately \$27,000 for the three months ended September 30, 2014 and 2015, respectively.

*Foreign exchange gains*

Foreign exchange gains increased by approximately \$0.2 million, from a gain of approximately \$10,000 for the three months ended September 30, 2014, to a gain of approximately \$0.2 million for the three months ended September 30, 2015. Foreign exchange gains are reported in the consolidated statement of operations as a separate line item within other income (expense).

*The future*

Other income (expense) for the year ended December 31, 2015 will continue to be impacted by changes in foreign exchange rates. There will be no impact from the change in valuation of financial instruments associated with the stock purchase agreement for the remainder of 2015 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 September 30, 2014 and 2015 (in \$000s except percentages):

	Three Months Ended September 30,		Difference	
	2014	2015	\$	%
Total income tax benefit	\$ 750	\$ 478	\$(272)	(36)

The total income tax benefit, primarily composed of research and development tax credits recoverable, decreased approximately \$0.3 million to an income tax benefit of \$0.5 million for the three months ended September 30, 2015 from an income tax benefit of \$0.8 million for the three months ended September 30, 2014. The level of tax credits recoverable is linked directly to qualifying research and development expenditure incurred in any one year.

Table of Contents*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, 2015 in comparison to the year ended December 31, 2014.

*Nine months Ended September 30, 2014 and 2015***Results of Continuing Operations***Revenues*

The following table summarizes the components of our revenues for the nine months ended September 30, 2014 and 2015 (in \$000s except percentages):

	Nine months		Difference	
	Ended September 30,		\$	%
	2014	2015		
Grant revenue	\$ 1,487	\$ 1,270	\$(217)	(15)
Collaboration and research and development revenue	—	253	253	—
Total revenue	\$ 1,487	\$ 1,523	\$36	2

We recognized approximately \$1.5 million and \$1.3 million in grant revenue for the nine months ended September 30, 2014 and 2015, respectively, from the European Union and the Biomedical Catalyst of the United Kingdom government. We recognized \$0.3 million in collaboration and research and development revenue for the nine months ended September 30, 2015, from our collaboration, licensing and supply agreement with ManRos.

*The future*

We expect to recognize approximately \$1.4 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 ManRos if the development of seliciclib progresses for the treatment of CF.

***Research and development expenses***

The following table provides information with respect to our research and development expenditures for the nine months ended September 30, 2014 and 2015 (in \$000s except percentages):

	Nine months Ended September 30,		Difference	
	2014	2015	\$	%
Sapacitabine	\$ 11,022	\$ 6,547	\$(4,475)	(41)
Other costs related to research and development programs, management and exploratory research	2,839	3,279	440	15
Total research and development expenses	\$ 13,861	\$ 9,826	\$(4,035)	(29)

Total research and development expenses represented 76% and 71% of our operating expenses for the nine months ended September 30, 2014 and 2015, respectively.

Research and development expenditures decreased by \$4.0 million to \$9.8 million for the nine months ended September 30, 2015 from \$13.9 million for the nine months ended September 30, 2014. The decrease was primarily due to study and site startup costs and drug product costs associated with the expansion of the SEAMLESS Phase 3 trial into Europe during the nine months ended September 30, 2014 and completion of enrollment of the study in December 2014. Other costs related to research and development programs, management, and exploratory research increased by \$0.4 million to \$3.3 million for the nine months ended September 30, 2015 from \$2.8 million for the nine months ended September 30, 2014 as a result of increased expenditures related to grant funded research.



Table of Contents*The future*

We anticipate that overall research and development expenditures for the year ended December 31, 2015 will decrease compared to the year ended December 31, 2014, 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, which is expected during the first half of 2016 after the prespecified number of events have been observed in accordance with the study protocol.

***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 nine months ended September 30, 2014 and 2015 (in \$000s except percentages):

	Nine months Ended		Difference	
	September 30,		\$	%
	2014	2015		
Total general and administrative expenses	\$ 4,281	\$ 4,006	(275)	(6)

Total general and administration expenses represented 24% and 29% of our operating expenses for the nine months ended September 30, 2014 and 2015, respectively.

General and administrative expenses decreased \$0.3 million from \$4.3 million for the nine months ended September 30, 2014 to \$4.0 million for the nine months ended September 30, 2015, primarily because of lower patent-related and stock-based compensation costs.

*The future*

We expect our general and administrative expenditures for the year ended December 31, 2015 to be consistent with the year ended December 31, 2014.

*Other income (expense)*

The following table summarizes other income (expense) for the nine months ended September 30, 2014 and 2015 (in \$000 except percentages):

	Nine months Ended September 30,		Difference	
	2014	2015	\$	%
Change in valuation of financial instruments associated with stock purchase agreement	\$ (115 )	\$ (51 )	\$64	(56 )
Change in valuation of liabilities measured at fair value	20	—	(20 )	(100 )
Foreign exchange losses	(23 )	(354 )	(331)	1,439
Interest income	5	5	—	—
Other income, net	26	95	69	265
Total other income (expense)	\$ (87 )	\$ (305 )	\$(218)	251

Total other income (expense) decreased by approximately \$0.2 million, from a loss of approximately \$0.1 million for the nine months ended September 30, 2014, to a loss of \$0.3 million for the nine months ended September 30, 2015.

*Change in valuation of financial instruments associated with stock purchase agreement*

The remaining fair value of the right to sell additional shares under the November 2013 Purchase Agreement with Aspire was recognized during the quarter ended September 30, 2015 when we sold all remaining shares of common stock that were subject to the agreement, at which time the agreement automatically terminated by its terms. Prior to termination, the fair value was remeasured each reporting period. The Company recognized an expense of approximately \$0.1 million for each of the nine months ended September 30, 2014 and 2015, respectively.

*Change in valuation of liabilities measured at fair value*

The Company recognized income of approximately \$20,000 during the nine months ended September 30, 2014 as a result of the Company's fair value determination of the liability associated with an agreement with Scottish Enterprise, or SE, at September 30, 2014. The SE agreement terminated in July 2014.

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*Foreign exchange losses*

Foreign exchange losses decreased by \$0.3 million, from a loss of approximately \$23,000 for the nine months ended September 30, 2014, to a loss of \$0.4 million for the nine months ended September 30, 2015. Foreign exchange losses are reported in the consolidated statement of operations as a separate line item within other income (expense).

*The future*

Other income (expense) for the year ended December 31, 2015 will continue to be impacted by changes in foreign exchange rates. There will be no impact from the change in valuation of financial instruments associated with the stock purchase agreement for the remainder of 2015 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.

As 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 the income tax benefit for the nine months ended September 30, 2014 and 2015 (in \$000s except percentages):

	Nine months Ended		Difference	
	September 30, 2014	September 30, 2015	\$	%
Total income tax benefit	\$ 2,135	\$ 1,646	\$(489)	(23)

The total income tax benefit, primarily composed of research and development tax credits recoverable, decreased by approximately \$0.5 million to \$1.6 million for the nine months ended September 30, 2015 from \$2.1 million for the nine months ended September 30, 2014. The level of tax credits recoverable is linked directly to qualifying research and development expenditure incurred in any one year.

*The future*

We expect to continue to be eligible to receive United Kingdom research and development tax credits for the foreseeable future and will elect to do so. The amount of tax credits we will receive is entirely dependent on the amount of eligible expenses we incur. We expect our qualifying research and development expenditure will decrease for the year ended December 31, 2015 in comparison to the year ended December 31, 2014.

**Liquidity and Capital Resources**

The following is a summary of our key liquidity measures at December 31, 2014 and September 30, 2015 (in \$000s except percentages):

	December 31, 2014	September 30, 2015	\$ Difference	% Difference
Cash and cash equivalents	\$ 24,189	\$ 22,728	\$ (1,461 )	(6 )
Working capital:				
Current assets	\$ 29,000	\$ 26,794	(2,206 )	(8 )
Current liabilities	(7,493 )	(5,263 )	2,230	(30 )
Working capital	\$ 21,507	\$ 21,531	\$ 24	1

At September 30, 2015, we had cash and cash equivalents of \$22.7 million compared to \$24.2 million at December 31, 2014.

We have relied primarily on the proceeds from sales of common and preferred equity securities, as well as the exercise of warrants, to finance our operations and internal growth. Additional funding has come through interest on investments, licensing revenue, government grants, the sale of product rights, and research and development tax credits.

We believe that existing funds together with cash generated from operations and recent financing activities are sufficient to satisfy our planned working capital, capital expenditures and other financial commitments beyond the availability of mature data for

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final analysis of the SEAMLESS Phase 3 trial. However, we do not currently have sufficient funds to complete development and commercialization of any of our drug candidates. Current business and capital market risks could have a detrimental effect on the availability of sources of funding and our ability to access them in the future which may delay or impede our progress of advancing our drugs currently in the clinical pipeline to approval by the FDA or other international regulatory authority for commercialization.

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

Cash provided by (used in) operating, investing and financing activities for the nine months ended September 30, 2014 and 2015, is summarized as follows (in \$000s):

	Nine months Ended September 30,	
	2014	2015
Net cash used in operating activities	\$(15,034)	\$(11,784)
Net cash used in investing activities	\$(14 )	\$(9 )
Net cash provided by financing activities	\$10,815	\$10,426

Cash flows generated from discontinued operations have been combined with the cash flows from continuing operations within each of the Operating, Investing and Financing activities sections.

*Operating activities*

Net cash used in operating activities decreased by \$3.2 million, from \$15.0 million for the nine months ended September 30, 2014 to \$11.8 million for the nine months ended September 30, 2015. The decrease in cash used in operating activities is primarily because of decreased expenditures related to the SEAMLESS trial after enrollment in the trial was completed in December 2014.

*Investing activities*

Net cash used in investing activities decreased from approximately \$14,000 for the nine months ended September 30, 2014 to approximately \$9,000 for the nine months ended September 30, 2015. Net cash used in investing activities

was primarily payments purchases of property, plant and equipment of approximately \$0.3 million and \$32,000 for the nine months ended September 30, 2015 and 2014, respectively, partially offset by payments received from the termination and settlement agreement with Sinclair of approximately \$0.1 million and approximately \$23,000 for the nine months ended September 30, 2015 and 2014, respectively.

#### *Financing activities*

Net cash provided by financing activities was \$10.5 million for the nine months ended September 30, 2015, primarily as a result of approximately \$9.2 million in net proceeds from the issuance of common stock in March 2015, and \$1.4 million in proceeds from the issuance of common stock under the Purchase Agreement with Aspire entered into in November 2013.

Net cash provided by financing activities was \$10.8 million for the nine months ended September 30, 2014, primarily as a result of approximately \$9.3 million in proceeds from the issuance of common stock in April 2014, and \$1.7 million in proceeds from the issuance of common stock under the Purchase Agreement with Aspire.

#### *Operating Capital and Capital Expenditure Requirements*

To date, we have not generated significant product revenue but have financed our operations and internal growth through private placements, registered direct financings, licensing revenue, collaborations, interest on investments, government grants and research and development tax credits. We have recognized grant revenues of \$1.3 million during the nine months ended September 30, 2015 from the Biomedical Catalyst of the United Kingdom government. We have also recognized \$1.6 million in research and development tax credits, which are reported as income tax benefits on the consolidated statements of operations, from the HMRC, during the nine months ended September 30, 2015. On July 10, 2015, we entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement with Cantor, under which we may, from time to time, sell up to an aggregate of \$8.35 million of our shares of common stock.

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

We currently anticipate that our cash and cash equivalents will be sufficient to fund our operations for at least the next 12 months. We cannot be certain that any of our programs will be successful or that we will be able to raise sufficient funds to complete the development and commercialize any of our product candidates, should they succeed. Additionally, we plan to continue to evaluate in-licensing and acquisition opportunities to gain access to new drugs or drug targets that would fit with our strategy. Any such transaction would likely increase our funding needs in the future.

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

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

· the costs associated with establishing manufacturing and commercialization capabilities;

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

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

· the costs and timing of seeking and obtaining FDA, EMA and other regulatory approvals;

· the effect of competing technological and market developments; and

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

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

**Critical Accounting Policies**

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and related disclosure of contingent assets and liabilities. We review our estimates on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates. We believe the judgments and estimates required by the following accounting policies to be critical in the preparation of our consolidated financial statements.

### ***Clinical Trial Accounting***

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

### ***Research and Development Expenditures***

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

### ***Revenue Recognition***

#### ***Collaboration, supply and licensing agreements***

In June 2015, we entered into a collaboration, licensing and supply agreement with ManRos for the exclusive development and commercialization of our oral seliciclib capsules by ManRos as a treatment for CF.

The agreement contains multiple deliverables, including but not limited to know-how, technical assistance, and drug supply. We determined that each of the deliverables was separable under ASC 605-25. Of note, we believe that seliciclib is a widely researched compound with a safety profile that has spanned many years. Accordingly, other market participants could obtain standalone value from having access to our seliciclib know-how, even absent us providing any further technical assistance related to this know-how. This is because many contract research organizations or others with drug development experience could utilize the know-how to design and execute later stage clinical trials without any assistance from us.

The ManRos agreement contains an upfront, nonrefundable license payment and a series of milestones, one of which we earned in the third quarter of 2015. We have elected not to apply the optional accounting policy for recognizing substantive milestones when earned. Instead, we are allocating all arrangement consideration – both nonrefundable upfront fees and any milestone payments – to the separable elements based on a relative selling price method.

In applying the relative selling price method, we determined that we do not have vendor-specific objective evidence or third party evidence as to the price at which separable elements would be sold on a standalone basis. Accordingly, we made our best estimate of the standalone selling price for each of the separable elements. In estimating the standalone selling price of the know-how transfer deliverable, we looked to observable prices at which similar compounds licensed for the CF therapeutic area were licensed in recent market transactions. We adjusted those prices considering the estimated potential market opportunities of those comparable compounds with seliciclib, which is an older compound that will be losing composition of matter patent protection in 2016.

Nonetheless, after applying the relative selling price method, nearly all of the arrangement consideration was allocated to the transfer of seliciclib know-how deliverable. Accordingly, in the three and nine months ended September 30, 2015, we recognized revenue of \$0.3 million, representing substantially all of the upfront and milestone payments received to date.

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*Stock-based Compensation*

We grant stock options, restricted stock units and restricted stock to officers, employees, directors and consultants under the Company's 2015 Equity Incentive Plan, or 2015 Plan, which was approved on May 22, 2015. Awards granted prior to the adoption of the 2015 Plan were granted under the Amended and Restated Equity Incentive Plan, or 2006 Plan, which was originally approved on March 16, 2006 and subsequently amended and restated as of April 14, 2008 and May 23, 2012.

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

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

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**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 chief executive officer and principal financial and accounting officer, we conducted an evaluation of the effectiveness, as of September 30, 2015, 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 chief executive officer and principal financial and accounting officer have concluded that, as of September 30, 2015, 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 September 30, 2015 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.

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**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, 2014. 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 authorities prior to their commencement may subsequently be considered insufficient for approval at the time of application for regulatory approval. Thus, our SPA regarding our SEAMLESS trial does not guarantee marketing approval or approval of our sapacitabine oral capsules for the treatment of AML.*

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

In addition, the FDA may revise previous guidance or decide to ignore previous guidance at any time during the course of clinical activities or after the completion of clinical trials. The FDA may raise issues relating to, among other things, safety, study conduct, bias, deviation from the protocol, statistical power, patient completion rates, changes in scientific or medical parameters, or internal inconsistencies in the data prior to making its final decision.

The FDA may also seek the guidance of an outside advisory committee prior to making its final decision. Even with successful clinical safety and efficacy data, including such data from a clinical trial conducted pursuant to an SPA, we may be required to conduct additional, expensive clinical trials to obtain regulatory approval.

*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 Institutional Review Board, or IRB, and regulatory approvals to commence a clinical trial;

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

negative or inconclusive results from clinical trials, such as the recommendations of the DSMB regarding 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;



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- 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 the development of our drug candidates or generate revenue, and our development costs could increase significantly. Adverse events have been observed in our clinical trials and may force us to stop development of our product candidates or prevent regulatory approval of our product candidates.***

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

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

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

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

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

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

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

We do not have the ability to independently conduct clinical trials required to obtain regulatory approvals for our drug candidates. We must rely on third parties, such as contract research organizations, data management companies, contract clinical research associates, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials. In addition, we rely on third parties to assist with our preclinical development of drug candidates. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, or if the third parties need to be replaced or 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.

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 as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete our obligations under any arrangement;
- a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors; and

collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our drug candidates.

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

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

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collaboration with our current or future third-party manufacturers or on our own, for any of our drug candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA and other regulatory bodies must review and approve. If we are unable to successfully increase the manufacturing capacity for a drug candidate, whether for late stage clinical trials or for commercial sale, or are unable to secure alternative third-party suppliers to our current suppliers, the drug development, regulatory approval or commercial launch of any related drugs may be delayed or blocked, or there may be a shortage in supply. Even if any third party manufacturer makes improvements in the manufacturing process for our drug candidates, we may not own, or may have to share, the intellectual property rights to such innovation. Any performance failure on the part of manufacturers could delay late stage clinical development or regulatory approval of our drug, the commercialization of our drugs, or our ability to sell our commercial products, producing additional losses and depriving us of potential product revenues.

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

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

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

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

Obtaining an NDA approval is expensive and is a complex, lengthy and uncertain process. The FDA approval process for a new drug involves completion of preclinical studies and the submission of the results of these studies to the FDA, together with proposed clinical protocols, manufacturing information, analytical data and other information in an IND, which must become effective before human clinical trials may begin. Clinical development typically involves

three phases of study: Phase 1, 2 and 3. The most significant costs associated with clinical development are the pivotal or suitable for registration late Phase 2 or Phase 3 clinical trials, as they tend to be the longest and largest studies conducted during the drug development process. After completion of clinical trials, an NDA may be submitted to the FDA. In responding to an NDA, the FDA may refuse to file the application, or if accepted for filing, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. In addition, failure to comply with the FDA and other applicable foreign and U.S. regulatory requirements may subject us to administrative or judicially imposed sanctions. These include warning letters, civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production and refusal to approve either pending NDAs, or supplements to approved NDAs.

There is substantial time and expense invested in preparation and submission of an NDA or equivalents in other jurisdictions and regulatory approval is never guaranteed. Depending on the final data from our SEAMLESS study, we may meet with regulatory authorities in the United States and the European Union to discuss registration submissions for sapacitabine for the AML indication. In light of the futility cross reported by the SEAMLESS DSMB, there can be no assurance that data from SEAMLESS will be sufficient to submit registration submissions or that regulatory authorities will accept or validate any such submissions.

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

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

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

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

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

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

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

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

- issue warning letters;

mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;

require us or our collaborators to enter into a consent decree or permanent injunction, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;

- impose other administrative or judicial civil or criminal penalties;

- withdraw regulatory approval;

refuse to approve pending applications or supplements to approved applications filed by us or our potential future collaborators;

- impose restrictions on operations, including costly new manufacturing requirements; or

- seize or detain products.



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

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

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

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

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

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

- developing drug candidates;

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

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

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

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

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

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

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

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

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

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for our products, it is less likely that they will be widely used. Market acceptance and sales of 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 for. We cannot be certain that reimbursement will be available for product candidates that we develop. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any of our product candidates.

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

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

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

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

There are existing products in the marketplace that compete with our products. Companies may develop new products that compete with our products. Certain of these competitors and potential competitors have longer operating histories, substantially greater product development capabilities and financial, scientific, marketing and sales resources. Competitors and potential competitors may also develop products that are safer, more effective or have other potential advantages compared to our products. In addition, research, development and commercialization efforts by others could render our products obsolete or non-competitive. Certain of our competitors and potential competitors have broader product offerings 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

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

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

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

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

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

Our commercialization efforts in the United States are subject to various federal and state laws pertaining to promotion and healthcare fraud and abuse, including federal and state anti-kickback, fraud, and false claims laws. Anti-kickback laws make it illegal for a manufacturer to offer or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase of a product. The federal government has published many regulations relating to the anti-kickback statutes, including numerous safe harbors or exemptions for certain arrangements. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payers including Medicare and Medicaid, claims for reimbursed products or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services.

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

In addition, we may be required to prepare and report product pricing-related information to federal and state governmental authorities, such as the Department of Veterans Affairs and under the Medicaid program. The calculations used to generate the

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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. Because 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. 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 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.

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



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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 we have coverage outside of the United States for lesser amounts that vary by country. As such, our insurance coverage may not reimburse us or

may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to product liability. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash resources and adversely affect our business.

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

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

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

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

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**Risks Related to Our Business and Financial Condition**

***Raising additional capital in the future may not be available to us on reasonable terms, if at all, when or as we require additional funding. If we issue additional shares of our common stock or other securities that may be convertible into, or exercisable or exchangeable for, our common stock, our existing stockholders would experience further dilution. If we fail to obtain additional funding, we may be unable to complete the development and commercialization of our lead drug candidate, sapacitabine, or continue to fund our research and development programs.***

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

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

As widely reported, global credit and financial markets have experienced extreme disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not continue to occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current financial markets deteriorate, or do not improve, it may make any necessary financing more difficult, more costly, and more dilutive. Failure to secure

any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price, and could require us to delay or abandon clinical development or other operating or strategic plans for our business.

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

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

We must demonstrate that our drug candidates satisfy rigorous standards of safety and efficacy for their intended uses before the FDA, 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 other regulatory authorities 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, MDS, NSCLC and CLL. A combination of sapacitabine and seliciclib is currently in a Phase 1 clinical trial. We cannot be certain that the clinical development of these or any other drug candidates in preclinical testing or clinical development will be successful, that we will receive the regulatory approvals required to commercialize them or that any of our other research and drug discovery programs will yield a drug candidate suitable for investigation through clinical trials. Our commercial revenues from our product candidates currently in development, if any, will be derived from sales of drugs that will not become marketable for several years, if at all.

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

We have incurred operating losses in each year since beginning operations in 1996 due to costs incurred in connection with our research and development activities and selling, general and administrative costs associated with our operations, and we may never achieve profitability. As of December 31, 2014 and September 30, 2015, our accumulated deficit was \$308.8 million and \$319.8 million, respectively. Our net loss was \$14.6 million and \$11.0 million for the nine months ended September 30, 2014 and 2015. Our drug candidates are in the mid-stages of clinical testing and we must conduct significant additional clinical trials before we can seek the regulatory approvals necessary to begin commercial sales of our drugs. We expect to incur continued losses for several years as we continue our research and development of our drug candidates, seek regulatory approvals and commercialize any approved drugs. If our drug candidates are unsuccessful in clinical trials or we are unable to obtain regulatory approvals, or if our drugs are unsuccessful in the market, we will not be profitable. If we fail to become and remain profitable, or if we are unable to fund our continuing losses, particularly in light of the current economic conditions, you could lose all or part of your investment.

***If we fail to comply with the continued listing requirements of the NASDAQ Global 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 Global Market. We must satisfy NASDAQ's continued listing requirements, including, among other things, a minimum stockholders' equity of \$10.0 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 Global 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 August 4, 2015, we received approval from The NASDAQ Stock Market LLC, or NASDAQ, to transfer the listing of our common stock from the NASDAQ Global Market to the NASDAQ Capital Market. This transfer will be effective at the opening of business on August 6, 2015. Our common stock will continue to trade under the symbol "CYCC." The NASDAQ Capital Market is a continuous trading market that operates in substantially the same manner as the NASDAQ Global Market and requires listed companies to meet certain financial requirements and comply with NASDAQ's corporate governance requirements.

As previously reported, we were notified by NASDAQ on February 2, 2015 that we were no longer in compliance with the minimum bid price requirement of \$1.00 per share for continued listing as set forth in NASDAQ Listing Rule 5450(a)(1). In anticipation of not meeting the minimum bid price requirement by August 3, 2015, the end of its initial 180-day grace period, we had previously applied to transfer the listing of its stock to the NASDAQ Capital Market. The Company currently meets the NASDAQ Capital Market initial listing criteria, except for the bid price requirement. Upon transfer to the NASDAQ Capital Market, we are being afforded an additional 180-day grace period to regain compliance with NASDAQ's minimum bid price requirement. In order to regain compliance, the minimum bid price per share of the Company's common stock must be at least \$1.00 for at least ten consecutive business days during the second 180-day grace period, which will end on February 2, 2016.

If we do not regain compliance within the allotted compliance period(s), including any extensions that may be granted by NASDAQ, NASDAQ will provide notice that our shares of common stock will be subject to delisting. We would then be entitled to appeal NASDAQ's determination to a NASDAQ Hearings Panel and request a hearing. We intend to consider available options to resolve the noncompliance with the minimum bid price requirement. No determination regarding our response has been made at this time. There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or will otherwise be in compliance with other NASDAQ listing criteria. There can also be no assurance that any application to NASDAQ will be approved or that any appeal would be granted by the NASDAQ Hearings Panel.

Further declines in the trading price of our common shares may cause us to fail to meet certain of the other continuing listing standards of NASDAQ, which could result in the delisting of our shares of common stock. If our shares cease to be traded on the NASDAQ or on another national securities exchange, the price at which you may be able to sell your common shares of the Company may be significantly less than their current trading price or you may not be able to sell them at all.

***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:

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- fund research and development and clinical trials connected with our research;
  - fund clinical trials and seek regulatory approvals;
- build or access manufacturing and commercialization capabilities;
- implement additional internal control systems and infrastructure;

commercialize and secure coverage, payment and reimbursement of our drug candidates, if any such candidates receive regulatory approval;

- maintain, defend and expand the scope of our intellectual property; and
  - hire additional management, sales and scientific personnel.

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

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

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

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

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

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

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

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



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*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 advanced development of seliciclib, or additional programs. Because we have to prioritize our development candidates as a result of budget constraints, we may not be able to fully realize the value of our product candidates in a timely manner, if at all.

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

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

### **Risks Related to our Intellectual Property**

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

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

Sapacitabine is protected by (i) United States-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); (ii) 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 (iii) a United States-granted patent claiming a specified method of administration of sapacitabine with patent exclusivity until July 2030. An amorphous form of sapacitabine is covered in granted, composition of matter patents that expired in 2014 in the United States and expired in 2012 outside of the United States. The amorphous sapacitabine form was used in early Phase 1 clinical trials. We have used one of the stable, crystalline forms 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.

Selaciclib is protected by granted composition of matter patents that expire in 2016. Additional patents and applications claim certain medical uses of selaciclib, 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

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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.***

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.

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

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

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

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

-

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

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

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

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

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

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

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***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees 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.

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.



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**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 have concluded that our internal control over financial reporting was effective as of December 31, 2014.

*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, 2014, 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, 2014 because we are a smaller reporting company. In the event our independent auditor is required to provide an opinion on such controls in the future, there is a risk that the auditor would conclude that such controls are ineffective.

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

*Our common stock may have a volatile public trading price.*

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

- disclosure of actual or potential clinical results with respect to product candidates we are developing;
  - regulatory developments in both the United States and abroad;
  - developments concerning proprietary rights, including patents and litigation matters;

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

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

- public announcements by our competitors or others; and
- general market conditions and comments by securities analysts and investors.

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

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

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

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

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

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

We have the authority to issue up to 5 million shares of preferred stock and to determine the terms of those shares of stock without any further action by our stockholders. If the Board of Directors exercises this power to issue preferred stock, it could be more difficult for a third party to acquire a majority of our outstanding voting stock and vote the stock they acquire to remove management or directors. Our amended and restated certificate of incorporation and amended and restated bylaws also provides staggered terms for the members of our Board of Directors. Under Section 141 of the Delaware General Corporation Law, our directors may be removed by stockholders only for cause and only

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

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

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

In March 2008 (as subsequently amended, 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.

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***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 September 30, 2015, there were 335,273 shares of our preferred stock issued and outstanding. If the transaction were one in which proceeds were received by the Company for distribution to stockholders, and the terms of the Certificate of Designations governing the preferred stock were strictly complied with, approximately \$4.0 million would be paid to the preferred holders before any distribution to the common stockholders, although the form of transaction could affect how the holders of preferred stock are treated. In such an event, although such a transaction would be subject to the approval of our holders of common stock, we cannot assure our common stockholders that we will be able to negotiate terms that would provide for a price equivalent to, or more favorable than, the price at which our shares of common stock may be trading at such time. Thus, the terms of our preferred stock might hamper a third party's acquisition of our company.

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

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

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

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

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

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of large stockholders to complete a business combination with, or acquisition of, us. These provisions may prevent a business combination or acquisition that would be attractive to stockholders and could limit the price that investors would be willing to pay in the future for our stock.

These provisions also make it more difficult for our stockholders to replace members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt to replace our current management team. Additionally, these provisions may prevent an acquisition that would be attractive to stockholders and could limit the price that investors would be willing to pay in the future for our common stock.

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

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

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

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

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

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

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

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

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

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

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

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

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



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***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 Cantor Fitzgerald & Co., or Cantor.***

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

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

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

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

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

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

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

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

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

**Item 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**

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 September 30, 2015, 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: November 12, 2015 By: /s/ Paul McBarron

Paul McBarron

Chief Operating Officer, Chief Financial Officer and  
Executive Vice President, Finance