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

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016

OR

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

Commission file number 000-50626

CYCLACEL PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**91-1707622**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

200 Connell Drive, Suite 1500

Berkeley Heights, New Jersey **07922**

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(908) 517-7330**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

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

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

CYCLACEL PHARMACEUTICALS, INC.

INDEX

Table of Contents

EXPLANATORY NOTE

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

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

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

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

Table of Contents

CYCLACEL PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

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

(Unaudited)

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

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

Table of Contents

CYCLACEL PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In $000s)

(Unaudited)

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

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

Table of Contents

CYCLACEL PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In $000s)

(Unaudited)

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

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

Table of Contents

CYCLACEL PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Nature of Operations

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

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

As of June 30, 2016, substantially all efforts of the Company to date have been devoted to performing research and development, conducting clinical trials, developing and acquiring intellectual property, raising capital and recruiting and training personnel.

Capital Resources

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

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

Basis of Presentation

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

Reverse Stock Split

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

Table of Contents

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

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

Risks and Uncertainties

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

Foreign Currency and Currency Translation

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

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

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

Segments

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

Cash and Cash Equivalents

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

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

Fair Value of Financial Instruments

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

Table of Contents

Revenue Recognition

Collaboration, supply and licensing agreements

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

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

Grant revenue

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

Clinical Trial Accounting

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

Research and Development Expenditures

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

Income Taxes

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

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

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

Stock-based Compensation

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

Table of Contents

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

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

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

Net Loss Per Common Share

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

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

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

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

Comprehensive Income (Loss)

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

Accounting Standards Adopted in the Period

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

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

Table of Contents

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

Recent Accounting Pronouncements Not Yet Effective

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

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

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

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

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

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

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

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

Table of Contents

3. FAIR VALUE

Fair Value Measurements

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

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

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

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

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

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

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

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

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

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

4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

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

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

5. ACCRUED AND OTHER CURRENT LIABILITIES

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

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

Table of Contents

6. STOCK BASED COMPENSATION

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

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

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

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

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

2015 Plan

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

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

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

2006 Plan

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

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

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

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

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

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

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

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

Restricted Stock Units

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

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

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

7. COMMITMENTS AND CONTINGENCIES

Distribution, Licensing and Research Agreements

The Company has entered into licensing agreements with academic and research organizations. Under the terms of these agreements, the Company has received licenses to technology and patent applications. The Company is required to pay royalties on future sales of products employing the technology or falling under claims of patent applications.

Table of Contents

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

8. STOCKHOLDERS' EQUITY

Preferred Stock

As of June 30, 2016, there were 335,273 shares of the Company's 6% Convertible Exchangeable Preferred Stock ("Preferred Stock") issued and outstanding at an issue price of $10.00 per share. Dividends on the Preferred Stock are cumulative from the date of original issuance at the annual rate of 6% of the liquidation preference of the Preferred Stock, payable quarterly on the first day of February, May, August and November, commencing February 1, 2005. Any dividends must be declared by the Company's Board and must come from funds that are legally available for dividend payments. The Preferred Stock has a liquidation preference of $10.00 per share, plus accrued and unpaid dividends.

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

The Company may automatically convert the Preferred Stock into common stock if the closing price of the Company's common stock has exceeded $2,961.00 per share, which is 150% of the conversion price of the Preferred Stock, for at least 20 trading days during any 30-day trading period, ending within five trading days prior to notice of automatic conversion.

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

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

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

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

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

Common Stock

June 2016 At Market Issuance

On June 23, 2016, the Company entered into the FBR Sales Agreement, under which the Company may, from time to time, sell through FBR up to an aggregate of $4.0 million in shares of the Company's common stock. Under the FBR Sales Agreement FBR may sell the shares of common stock by any method that is deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the "Securities Act"). The Company will pay FBR a commission of 3.0% of the gross sales price per share sold. The Company is not obligated to make any sales of common stock under the FBR Sales Agreement. The Company has not made any sales

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

17

Table of Contents

July 2015 Controlled Equity Offering SM

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

March 2015 Public Offering

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

November 2013 Stock Purchase Agreement

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

Common Stock Warrants

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

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

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

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

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, including, without limitation, Management's Discussion and Analysis of Financial Condition and Results of Operations, contains "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We intend that the forward-looking statements be covered by the safe harbor for forward-looking statements in the Exchange Act. The forward-looking information is based on various factors and was derived using numerous assumptions. All statements, other than statements of historical fact, that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future are forward-looking statements. Such statements are based upon certain assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate. These forward-looking statements are usually accompanied by words such as "believe," "anticipate," "plan," "seek," "expect," "intend" and similar expressions.

Table of Contents

Forward-looking statements necessarily involve risks and uncertainties, and our actual results could differ materially from those anticipated in the forward looking statements due to a number of factors, including those set forth in Part I, Item 1A, entitled "Risk Factors," of our Annual Report on Form 10-K for the year ended December 31, 2015, as updated and supplemented by Part II, Item 1A, entitled "Risk Factors," of our Quarterly Reports on Form 10-Q, and elsewhere in this report. These factors as well as other cautionary statements made in this Quarterly Report on Form 10-Q, should be read and understood as being applicable to all related forward-looking statements wherever they appear herein. The forward-looking statements contained in this Quarterly Report on Form 10-Q represent our judgment as of the date hereof. We encourage you to read those descriptions carefully. We caution you not to place undue reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless an earlier date is indicated) and we undertake no obligation to update or revise the statements except as required by law. Such forward-looking statements are not guarantees of future performance and actual results will likely differ, perhaps materially, from those suggested by such forward-looking statements. In this report, "Cyclacel," the "Company," "we," "us," and "our" refer to Cyclacel Pharmaceuticals, Inc.

Overview

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

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

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

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

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

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

Recent Events

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

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

Table of Contents

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

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

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

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

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

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

Results of Operations

Three Months Ended June 30, 2015 and 2016

Results of Continuing Operations

Revenues

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

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

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

The future

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

Research and development expenses

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

- Clinical trial and regulatory-related costs;
- Payroll and personnel-related expenses, including consultants and contract research;

20

Table of Contents

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

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

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

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

The future

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

General and administrative expenses

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

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

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

The future

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

Other income (expense), net

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

Three Months Ended June 30,	Difference