

Cyclacel Pharmaceuticals, Inc.  
Form 10-Q  
November 13, 2017

**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, 2017**

**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 (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 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 " Smaller reporting filer x  
(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 x

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

Emerging growth company

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

As of November 13, 2017 there were 11,904,521 shares of the registrant's common stock outstanding.

**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**

**CYCLACEL PHARMACEUTICALS, INC.**

**INDEX**

	<b>Page</b>
<b><u>Part I. Financial Information</u></b>	
<u>Item 1. Financial Statements (Unaudited)</u>	<u>3</u>
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>14</u>
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>23</u>
<u>Item 4. Controls and Procedures</u>	<u>24</u>
<b><u>Part II. Other Information</u></b>	
<u>Item 1. Legal Proceedings</u>	<u>24</u>
<u>Item 1A. Risk Factors</u>	<u>24</u>
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>24</u>
<u>Item 3. Defaults Upon Senior Securities</u>	<u>24</u>
<u>Item 4. Mine Safety Disclosures</u>	<u>24</u>
<u>Item 5. Other Information</u>	<u>24</u>
<u>Item 6. Exhibits</u>	<u>25</u>
<b><u>SIGNATURE PAGE</u></b>	<b><u>26</u></b>

Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****CYCLACEL PHARMACEUTICALS, INC.****CONSOLIDATED BALANCE SHEETS****(In \$000s, except share and per share amounts)****(Unaudited)**

	December 31, 2016	September 30, 2017
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 16,520	\$ 26,025
Prepaid expenses and other current assets	3,097	1,792
Total current assets	19,617	27,817
Property, plant and equipment (net)	45	34
Total assets	\$ 19,662	\$ 27,851
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,497	\$ 1,973
Accrued and other current liabilities	2,762	2,292
Total current liabilities	5,259	4,265
Other liabilities	130	128
Total liabilities	5,389	4,393
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 31, 2016 and September 30, 2017; 6% Convertible Exchangeable preferred stock; 335,273 shares issued and outstanding at December 31, 2016 and September 30, 2017. Aggregate preference in liquidation of \$4,006,512 at December 31, 2016 and September 30, 2017.	—	—
Series A convertible preferred stock; 0 shares and 664 shares issued and outstanding at December 31, 2016 and September 30, 2017, respectively.	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized at December 31, 2016 and September 30, 2017; 4,256,829 and 11,697,021 shares issued and	4	12

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form 10-Q

outstanding at December 31, 2016 and September 30, 2017, respectively.

Additional paid-in capital	350,051		364,843	
Accumulated other comprehensive loss	(743	)	(762	)
Accumulated deficit	(335,039	)	(340,635	)
Total stockholders' equity	14,273		23,458	
Total liabilities and stockholders' equity	\$ 19,662		\$ 27,851	

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,	
	2016	2017	2016	2017
Revenues:				
Grant revenue	\$205	\$-	\$566	\$-
Operating expenses:				
Research and development	2,409	958	7,545	3,491
General and administrative	1,273	1,154	4,002	3,802
Total operating expenses	3,682	2,112	11,547	7,293
Operating loss	(3,477 )	(2,112 )	(10,981 )	(7,293 )
Other income (expense):				
Foreign exchange gains (losses)	51	(22 )	369	(65 )
Interest income	8	30	31	59
Other income, net	18	28	56	907
Total other income	77	36	456	901
Loss before taxes	(3,400 )	(2,076 )	(10,525 )	(6,392 )
Income tax benefit	454	219	1,573	793
Net loss	(2,946 )	(1,857 )	(8,952 )	(5,599 )
Dividend on convertible exchangeable preferred shares	(50 )	(50 )	(150 )	(151 )
Beneficial conversion feature of Series A convertible preferred stock	-	(3,638 )	-	(3,638 )
Conversion of Series A convertible preferred stock	-	(3,373 )	-	(3,373 )
Net loss applicable to common shareholders	\$(2,996 )	\$(8,918 )	\$(9,102 )	\$(12,761 )
Basic and diluted earnings per common share:				
Net loss per share – basic and diluted	\$(0.86 )	\$(0.91 )	\$(2.89 )	\$(2.06 )
Weighted average common shares outstanding	3,473,696	9,835,441	3,145,730	6,200,783

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		Nine months Ended	
	September 30,		September 30,	
	2016	2017	2016	2017
Net loss	\$ (2,946 )	\$ (1,857 )	\$ (8,952 )	\$ (5,599 )
Translation adjustment	4,839	(4,882 )	19,604	(13,435)
Unrealized foreign exchange gain on intercompany loans	(4,860 )	4,856	(19,766)	13,417
Comprehensive loss	\$ (2,967 )	\$ (1,883 )	\$ (9,114 )	\$ (5,617 )

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,	
	2016	2017
Operating activities:		
Net loss	\$ (8,952 )	\$ (5,599 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	109	25
Stock-based compensation	614	200
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	629	1,464
Accounts payable and other current liabilities	464	(1,350 )
Net cash used in operating activities	(7,136 )	(5,260 )
Investing activities:		
Purchase of property, plant and equipment	—	(11 )
Net cash used in investing activities	—	(11 )
Financing activities:		
Proceeds from issuance of common stock, net of issuance costs	5,241	14,751
Payment of preferred stock dividend	(150 )	(151 )
Net cash provided by financing activities	5,091	14,600
Effect of exchange rate changes on cash and cash equivalents	(366 )	176
Net increase / (decrease) in cash and cash equivalents	(2,411 )	9,505
Cash and cash equivalents, beginning of period	20,440	16,520
Cash and cash equivalents, end of period	\$ 18,029	\$ 26,025
Supplemental cash flow information:		
Cash received during the period for:		
Interest	31	60
Taxes	1,965	1,815
Non cash financing activities:		
Accrual of preferred stock dividends	50	50

Receivable from issuance of common stock	1,518	—
--	-------	---

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

Table of Contents

**CYCLACEL PHARMACEUTICALS, INC.**

**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS**

**1. Company Overview**

*Nature of Operations*

Cyclacel Pharmaceuticals, Inc. (“Cyclacel” or “the Company”), is a clinical-stage biopharmaceutical company using cell cycle control, transcriptional regulation and DNA damage response biology to develop innovative, targeted medicines for cancer and other proliferative diseases. Cyclacel is a pioneer company in the field of cell cycle biology with a vision to improve patient healthcare by translating cancer biology into medicines.

As of September 30, 2017, 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.

**2. Summary of Significant Accounting Policies**

*Basis of Presentation*

The consolidated balance sheet as of September 30, 2017, the consolidated statements of operations, comprehensive loss and cash flows, and all related disclosures contained in the accompanying notes are unaudited. The consolidated balance sheet as of December 31, 2016 is derived from the audited consolidated financial statements included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2016 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, 2017, the results of operations and comprehensive loss for the three and nine months ended September 30, 2017 and cash flows for the nine months ended September 30, 2017, have been made. The interim results for the three and nine months ended September 30, 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017 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, 2016 that are included in the Company's Annual Report on Form 10-K filed with the SEC.

### *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 the fair value of warrants issued during the reporting period, clinical trial accruals, research and development expenditures, stock-based compensation expense and the recognition of revenue, each of which Cyclacel reviews 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.

### *Risks and Uncertainties*

Drug candidates developed by the Company typically will require approvals or clearances from the Food and Drug Administration ("FDA"), European Medicines Agency ("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 was denied approval or clearance or such approval was delayed, or is unable to obtain the necessary financing to complete the development and approval processes, 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 certain of 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.

Table of Contents

*Going Concern*

Management considers that there are no conditions or events, in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern for a period of at least one year from the date the financial statements are issued. The Company expects that its cash of \$26.0 million as of September 30, 2017, will be sufficient to fund its operating expenses and capital expenditure requirements through to the end of 2019.

This evaluation is based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued, including:

- a. The Company's current financial condition, including its liquidity sources;
- b. The Company's conditional and unconditional obligations due or anticipated within one year;
- c. The funds necessary to maintain the Company's operations considering its current financial condition, obligations, and other expected cash flows; and
- d. Other conditions and events, when considered in conjunction with the above, that may adversely affect the Company's ability to meet its obligations.

The future viability of the Company beyond the end of 2019 is dependent on its ability to raise additional capital to finance its operations. The Company will need to raise substantial additional capital to pursue the transcriptional regulation program evaluating CYC065, a CDK inhibitor, in patients with advanced cancers, or the DNA damage response program evaluating a sequential regimen of sapacitabine and CDK inhibitors, in patients with BRCA positive, advanced solid cancers. Additional funding may not be available to the Company on favorable terms, or at all. If the Company is unable to obtain additional funds, it will need to reduce operating expenses, enter into a collaboration or other similar arrangement with respect to development and/or commercialization rights to its CDK inhibitors or sapacitabine, if available, or be forced to delay or reduce the scope of its CDK inhibitors and sapacitabine development programs, including any potential regulatory filings related to the SEAMLESS study, and/or limit or cease its operations. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies.

*Segments*

The Company is managed and operated as one business which is focused on using cell cycle, transcriptional regulation, and DNA damage response biology to develop innovative, targeted medicines for cancer and other proliferative diseases. The entire business is managed by a single management team that reports to the Chief Executive Officer. The Company does not operate separate lines of business with respect to any of its products or product candidates and the Company does not prepare discrete financial information with respect to separate products or

product candidates or by location. Accordingly, the Company views its business as one reportable operating segment with development operations in two geographic areas, namely the United States and the United Kingdom.

### ***Cash and Cash Equivalents***

The Company considers all highly liquid investments with an original maturity of three months or less at the time of initial purchase to be cash equivalents. The objectives of the Company's cash management policy are to safeguard and preserve funds, to maintain liquidity sufficient to meet Cyclacel's cash flow requirements and to attain a market rate of return.

The Company's cash and cash equivalents balance at September 30, 2017 was \$26.0 million and it maintains its cash accounts both within the United States and the United Kingdom. Cash held in the United States is insured by the Federal Deposit Insurance Corporation ("FDIC") up to \$250,000 per account. The Company has cash balances exceeding the balance insured by the FDIC that totalled approximately \$24.3 million at September 30, 2017. Cash held in the United Kingdom is insured by the UK Government Financial Services Compensation Scheme ("FSCS") up to £75,000 per account. The Company has cash balances exceeding the balance insured by the FSCS that totalled approximately \$1.4 million at September 30, 2017.

### ***Fair Value of Financial Instruments***

Financial instruments consist of cash equivalents, accounts payable and accrued liabilities. The carrying amounts of cash equivalents, accounts payable and accrued liabilities approximate their respective fair values due to the nature of the accounts, notably their short maturities.

Table of Contents

***Comprehensive Income (Loss)***

All components of comprehensive income (loss), including net income (loss), are reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income (loss) and other comprehensive income (loss), including foreign currency translation adjustments, are reported, net of any related tax effect, to arrive at comprehensive income (loss). No taxes were recorded on items of other comprehensive income (loss). There were no reclassifications out of other comprehensive income (loss) during the three and nine months ended September 30, 2016 and 2017.

***Recently Issued Accounting Pronouncements***

In July 2017, the FASB issued Accounting Standards Update (“ASU”) No. 2017-11, Accounting for Certain Financial Instruments with Down Round Features (“ASU 2017-11”), which simplifies the accounting for certain financial instruments with down-round features. ASU 2017-11 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted, including adoption in an interim period. ASU 2017-11 should be adopted retrospectively for each prior reporting period presented or retrospectively as of the beginning of the year of adoption. The Company anticipates this standard will not have a material impact on its consolidated financial statements.

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

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

In February 2016, the FASB issued guidance on accounting for leases in ASU No. 2016-02. The guidance requires that lessees recognize a lease liability, which is a lessee’s obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which is an asset that represents the lessee’s right to use, or

control the use of, a specified asset for the lease term at the commencement date. The guidance is effective for fiscal years beginning after December 15, 2018. Early application is permitted. The guidance must be adopted on a modified retrospective transition approach for leases existing, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The Company is currently evaluating the impact of the guidance on the consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) (“ASU 2014-09”), which supersedes existing revenue recognition guidance. The standard’s core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The standard defines a five-step process to achieve this principle; (1) identify the contract with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when, or as, the Company satisfies a performance obligation. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. The guidance is effective for annual periods beginning after December 15, 2017 and for interim periods within those fiscal years. ASU 2014-09 was amended by multiple accounting standards updates from 2014-2016.

The Company anticipates this standard will not have a material impact on its consolidated financial statements. While the Company is continuing to assess all potential impacts of the standard, the Company currently believes the most significant impact relates to its accounting for revenues related to grants received from government agencies or nonprofit organizations and revenues from contingent “milestone” based payments. Under the new standard, the Company expects to report grant revenue, if new grants are obtained, in other income (or in some cases as a contra-expense). Historically, grants have been reported in revenue. As the grantor is not likely to be receiving a good or service in exchange for the payment, the grant cannot be reported in revenue under ASU 2014-09. The Company also expects to recognize revenue associated with contingent milestone-based payments at the time the contingent event is probable to be met, rather than when the milestone is achieved. However, given the limited number of potential milestones owed to Cyclacel, and the inherent risk involved in developing drugs, the timing of revenue recognition associated with contingent milestones is unlikely to be impacted.



Table of Contents

ASU 2014-09 permits two methods of adoption: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the modified retrospective method). The Company currently intends to use the modified retrospective method when it adopts the new accounting standard, and does not anticipate recording a material adjustment to opening accumulated deficit as of the date of adoption.

**3. 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 (adjusted for conversion and beneficial conversion feature of preferred stock) 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 nine months ended September 30, 2016 and 2017, as the result would be anti-dilutive:

	<b>September 30,</b>	<b>September 30,</b>
	<b>2016</b>	<b>2017</b>
Stock options	393,723	381,786
6% Convertible Exchangeable preferred stock	1,698	1,698
Series A convertible preferred stock	-	332,000
Common stock warrants	-	7,590,000
Total shares excluded from calculation	395,421	8,305,484

**4. Prepaid Expenses and Other Current Assets**

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

	December 31,	September 30,
	2016	2017
Research and development tax credit receivable	\$ 1,730	\$ 845
Prepayments	867	365
VAT receivable	327	376

Other current assets	173	206
	\$ 3,097	\$ 1,792

**5. Accrued and Other Current Liabilities**

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

	December 31, 2016	September 30, 2017
Accrued research and development	\$ 2,138	\$ 1,881
Accrued legal and professional fees	194	227
Other current liabilities	430	184
	\$ 2,762	\$ 2,292

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 awards granted by the Company (and still outstanding) vest ratably over one to four years and have a maximum life of ten years from the date of grant.

Effective January 1, 2016, the Company recognizes all share-based awards under the straight-line attribution method, assuming that all granted awards will vest. Forfeitures will be recognized in the periods when they occur. 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, 2016 and 2017 as shown in the following table (in \$000s):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2017	2016	2017
General and administrative	\$ 113	\$ 48	\$ 376	\$ 146
Research and development	79	17	238	54
Stock-based compensation costs before income taxes	\$ 192	\$ 65	\$ 614	\$ 200

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. On May 30, 2017, the Company's stockholders approved the amendment of the 2015 Plan to increase the number of shares of common stock available for such equity incentive grants. The 2015 Plan replaces the 2006 Equity Incentive Plan. As of September 30, 2017, there were approximately 612,500 reserved awards available to be granted under the 2015 plan.

There were 12,000 options granted during the nine months ended September 30, 2017.

In 2016, the Company granted certain performance based options. As of September 30, 2017, 184,924 such options remain outstanding. These options will vest upon the fulfillment of certain clinical outcome conditions and will terminate automatically if they have not vested by December 31, 2020. The Company determined that the satisfaction of the vesting criteria was not probable as of September 30, 2017 and, as a result, did not record any expense related to these awards for the three and nine months ended September 30, 2017.

There were no stock options exercised during the nine months ended September 30, 2016 and 2017, respectively. 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, 2017 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, 2017.

*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, 2016	389,379	\$ 25.80	5.83	\$ 121
Granted	12,000	\$ 4.38		
Cancelled/forfeited	(19,593 )	\$ 108.73		
Options outstanding at September 30, 2017	381,786	\$ 20.87	5.24	\$ —
Unvested at September 30, 2017	(236,962 )	\$ 5.06	4.41	\$ —
Vested and exercisable at September 30, 2017	144,824	\$ 46.73	6.60	\$ —

Table of Contents

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.

Volatility is based on the Company's historical volatility over the same period as the expected term for a given award.

**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 certain 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 up-front fee, to reimburse Daiichi Sankyo for certain enumerated expenses, and to make milestone payments and pay royalties on a country-by-country basis. The up-front 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 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 any sapacitabine-based products in Japan, within certain limitations, Daiichi Sankyo must be notified

and given a right of first refusal, with such right 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**

### *July 2017 Underwritten Public Offering*

On July 21, 2017, the Company issued (i) 3,154,000 Class A Units for \$2 per unit, each consisting of one share of the Company's common stock, and a warrant to purchase one share of common stock (the "Class A Warrants"), and (ii) 8,872 Class B Units, each consisting of one share of the Company's Series A Convertible Preferred Stock, par value \$0.001 per share (the "Series A Preferred Stock"), convertible into 500 shares of Common Stock at the initial conversion price, and a warrant to purchase a number of shares of common stock equal to \$1,000.00 divided by the conversion price (the "Class B Warrants") for \$1,000 per unit. The net proceeds to the Company after the underwriters' exercise in full of the over-allotment option were approximately \$13,700,000, after deducting underwriting discounts, commissions and other estimated offering expenses. The Class A Units and Class B Units have no stand-alone rights and the shares of common stock, Series A Preferred Stock and the Class A and Class B Warrants comprising those units were immediately separable.

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

## Table of Contents

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

### *June 2016 At Market Issuance*

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 the Company was authorized to issue and sell shares of its common stock, from time to time, through FBR, acting as its sales agent. Under the FBR Sales Agreement, FBR was authorized to sell such shares of common stock by any method that is deemed to be an “at the market offering”. The Company was not obligated to make any sales of common stock under the FBR Sales Agreement, and the Company was required to pay FBR a commission of 3.0% of the gross proceeds of the sale of any shares of common stock sold through FBR. In the nine months ended September 30, 2017, the Company sold 183,118 shares of common stock under the FBR Sales agreement for net proceeds of approximately \$1.1 million, and the FBR Sales Agreement terminated automatically by its terms.

## Warrants

As of September 30, 2017, there were 7,590,000 warrants outstanding, each with an exercise price of \$2.00. All such warrants were issued in connection with the July 2017 Underwritten Public Offering and are immediately exercisable. The Warrants expire in 2024. Subject to limited exceptions, a holder of warrants will not have the right to exercise any portion of its warrants if the holder (together with such holder’s affiliates, and any persons acting as a group together with such holder or any of such holder’s affiliates) would beneficially own a number of shares of common stock in excess of 4.99% (or, at the election of the purchaser, 9.99%) of the shares of our Common Stock then outstanding after giving effect to such exercise.

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

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

There was no exercise of warrants during the three months ended September 30, 2016 and 2017 respectively.

### Series A Preferred Stock

8,872 shares of the Company's Series A Preferred Stock were issued in the July 2017 Underwritten Public Offering. During the three months ended September 30, 2017, 8,208 shares of the Series A Preferred Stock were converted into 4,104,000 shares of common stock. As of September 30, 2017, 664 shares of the Series A Preferred Stock remain issued and outstanding.

Each share of Series A Preferred Stock is convertible at any time at the option of the holder thereof, into a number of shares of common stock determined by dividing \$1,000 by the initial conversion price of \$2.00 per share, subject to a 4.99% blocker provision, or, upon election by a holder prior to the issuance of shares of Series A Preferred Stock, 9.99%, and is subject to adjustment for stock splits, stock dividends, distributions, subdivisions and combinations. The 664 shares of Series A Preferred Stock issued and outstanding at September 30, 2017, are convertible into 332,000 shares of common stock.

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

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





Table of Contents

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

6% Convertible Exchangeable Preferred Stock

As of September 30, 2017, there were 335,273 shares of the Company's 6% Convertible Exchangeable Preferred Stock ("6% Preferred Stock") issued and outstanding at an issue price of \$10.00 per share. Dividends on the 6% Preferred Stock are cumulative from the date of original issuance at the annual rate of 6% of the liquidation preference of the 6% 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 6% Preferred Stock has a liquidation preference of \$10.00 per share, plus accrued and unpaid dividends.

The Company may automatically convert the 6% Preferred Stock into common stock if the per share closing price of the Company's common stock has exceeded \$2,961, which is 150% of the conversion price of the 6% 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 6% 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 6% Preferred Stock in whole or in part, out of funds legally available at the redemption price of \$10.00 per share.

The 6% 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 6% Preferred Stock. The Debentures, if issued, will mature 25 years after the Exchange Date and have terms substantially similar to those of the 6% Preferred Stock. No such exchanges have taken place to date.

On September 7, 2017, the Board declared a quarterly cash dividend in the amount of \$0.15 per share on the 6% Preferred Stock. The cash dividend was paid on November 1, 2017 to the holders of record of the 6% Preferred Stock as of the close of business on October 13, 2017.

## **9. Subsequent Events**

On October 17 2017, 400 shares of Series A preferred stock were converted into 200,000 shares of common stock. 264 shares of Series A preferred stock remain outstanding and are convertible into 132,000 shares of common stock. On October 23 2017, 7,500 warrants connected with the July 2017 Underwritten Public Offering were exercised, resulting in cash proceeds of \$15,000.

## **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 Exchange Act of 1933 as amended 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, 2016, 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 2017, our focus has been on our transcriptional regulation program, pursuant to which we are evaluating our cyclin dependent kinase, or CDK, inhibitor and our DNA damage response, or DDR, program, in which we are evaluating sapacitabine in combination with our CDK inhibitor seliciclib in solid tumors in a Phase I study. Additionally, we are completing the analysis of data from SEAMLESS, the Phase 3 study in acute myeloid leukemia, or “AML”.

### ***Transcriptional Regulation Program, CDK inhibitors***

We are progressing clinical development of our CDK inhibitor CYC065 in an ongoing, first-in-human, Phase 1 trial in patients with advanced solid tumors.

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

In general, cell cycle regulation is less well controlled in cancer cells than in normal cells, which explains in part why cancer cells divide uncontrollably. Different CDKs are responsible for control of different aspects of proliferation, and

when dysregulated, can be drivers of particular cancer sub-sets. Modulating CDK activity with targeted therapies is an attractive strategy to reinforce cell cycle control and decrease the rate of abnormal proliferation of cancer cells. The first Food and Drug Administration or “FDA” approval in March 2015 of a CDK4/6 inhibitor for palbociclib, and in 2017, ribociclib and abemaciclib, all for a type of breast cancer, has led to great interest in the development of this class of drugs as oncology therapeutics.

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

CYC065 is being evaluated in an on-going Phase 1 first-in-human clinical trial. The objective of Part 1 of the clinical trial was to assess the safety and recommended dosing for Phase 2 (RP2D) of CYC065 in advanced cancer patients, based on determination of the biologically effective dose through measurement of CYC065’s effects on the Mcl-1 biomarker. Part 1 is now complete and the RP2D has been selected, Part 2 of the study will focus on patients with advanced solid tumors with amplification of cyclin E, or CCNE, Mcl-1 and/or MYC. The trial is being conducted at the Dana Farber Cancer Institute in Boston.

Table of Contents

Seliciclib, is being evaluated in an all-oral Phase 1 combination study with our sapacitabine in patients with BRCA mutations. In total seliciclib has been evaluated to date in approximately 450 patients with various liquid and solid cancers.

Similar to the approved CDK4/6 inhibitors, abemaciclib, palbociclib, and ribociclib, CYC065 may be most useful in combination with other anticancer agents. CDK2/9 inhibitors, such as CYC065 may be useful as treatments for patients with either liquid or solid tumors, in combination with Bcl-2 antagonists, such as venetoclax, or HER2 inhibitors, such as trastuzumab.

***DNA Damage Response, or DDR, Program***

In our DNA damage response program we are evaluating sapacitabine in combination with our first-generation CDK inhibitor seliciclib in solid tumors.

Cancer cells with modified DNA damage response, or DDR, mechanisms can accumulate additional genetic changes and continue to proliferate. Cancer cells that are deficient in such DDR pathways are more susceptible to DNA damage, a property exploited by traditional cancer treatments, such as DNA-damaging chemotherapy and radiotherapy. However, such treatments are often associated with significant and unwanted side effects. Developing treatments which target specific DDR deficiencies to preferentially kill cancer cells, while minimizing the impact on normal cells, is a promising strategy which could result in more selective, better tolerated therapies with the aim of improving survival in various types of cancer.

We have focused on developing treatments targeting DNA damage pathways, such as evaluating sapacitabine in a Phase 1 combination study with seliciclib in patients with BRCA mutations. Sapacitabine is an oral nucleoside analogue prodrug whose metabolite, CNDAC, generates single-strand DNA breaks, or SSB, either leading to arrest of the cell cycle at G2 phase or development of double-strand DNA breaks, or DSB. Repair of CNDAC-induced DSB is dependent on the homologous recombination, or HR repair pathway. BRCA mutations in cancer cells are a cause of HR deficiency, making such cancer cells susceptible to cell death induced by sapacitabine.

In addition to these development programs, we are completing analysis of data from SEAMLESS, the Phase 3 study in AML, in the elderly, in an alternating schedule with decitabine and closing the last remaining clinical trial sites. Dependent on the outcome of this analysis, we will seek meetings with regulatory authorities to discussing potential regulatory submissions. In parallel we also plan to present SEAMLESS data at an oral presentation at the 59th American Society of Hematology Annual Meeting in Atlanta, Georgia.

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

On July 21, 2017, the Company issued (i) 3,154,000 Class A Units for \$2 per unit, each consisting of one share of the Company's common stock, and a warrant to purchase one share of common stock (the "Class A Warrants"), and (ii) 8,872 Class B Units, each consisting of one share of the Company's Series A Convertible Preferred Stock, par value \$0.001 per share (the "Series A Preferred Stock"), and a warrant to purchase a number of shares of common stock equal to \$1,000.00 divided by the conversion price (the "Class B Warrants") for \$1,000 per unit. The net proceeds to the Company were approximately \$13,700,000, after deducting underwriting discounts, commissions and other estimated offering expenses. The Class A Units and Class B Units have no stand-alone rights and the shares of common stock, Series A Preferred Stock and the Class A and Class B Warrants comprising those units were immediately separable.

### Subsequent Events

On October 17 2017, 400 shares of Series A preferred stock were converted into 200,000 shares of common stock. 264 shares of Series A preferred stock remain outstanding and are convertible into 132,000 shares of common stock. On October 23 2017, 7,500 warrants connected with the July 2017 Underwritten Public Offering were exercised, resulting in cash proceeds of \$15,000.

### Results of Operations

#### *Three Months Ended September 30, 2016 and 2017*

#### *Revenues*

The following table summarizes the components of our revenues for the three months ended September 30, 2016 and 2017 (in \$000s, except percentages):

	Three Months Ended September 30,		Difference	
	2016	2017	\$	%
Grant revenue	\$ 205	\$ -	\$(205)	(100)





Table of Contents

We recognized \$0.2 million and \$0 in grant revenue for the three months ended September 30, 2016 and 2017, respectively, from the European Union and the Biomedical Catalyst of the United Kingdom government.

*The future*

We will not recognize further grant revenue for the CYC140 program, as the grant from the Biomedical Catalyst of the United Kingdom government ended in November 2016. Although we may apply for additional grants in 2017, we will not recognize grant revenue for the remainder of 2017 and we are not certain of our ability to obtain grant revenue in 2018.

***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 our CDK inhibitors, sapacitabine 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, 2016 and 2017 (in \$000s except percentages):

	Three Months Ended September 30,		Difference	
	2016	2017	\$	%
Sapacitabine	\$ 1,510	\$ 603	\$(907 )	(60)
Other costs related to research and development programs, management and exploratory research	899	355	(544 )	(61)
Total research and development expenses	\$ 2,409	\$ 958	\$(1,451)	(60)

Total research and development expenses represented 65% and 45% of our operating expenses for the three months ended September 30, 2016 and 2017, respectively.

Research and development expenditures decreased by \$1.5 million from \$2.4 million for the three months ended September 30, 2016 to \$1.0 million for the three months ended September 30, 2017. Research and development expenses relating to sapacitabine decreased by \$0.9 million from \$1.5 million for the three months ended September 30, 2016 to \$0.6 million for the three months ended September 30, 2017, primarily as a result of a reduction in expenditures associated with the SEAMLESS Phase 3 trial as clinical sites are closed.

Table of Contents*The future*

We anticipate that overall research and development expenditures for the year ended December 31, 2017 will decrease compared to the year ended December 31, 2016, as we close the remaining clinical study sites for SEAMLESS. The timing and extent of any future SEAMLESS expenditure, including the possibility of registration submissions to regulatory authorities in Europe and the U.S., are dependent upon final clinical data and regulatory authority input.

***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, 2016 and 2017 (in \$000s except percentages):

	Three Months Ended		Difference	
	September 30,		\$	%
	2016	2017		
Total general and administrative expenses	\$ 1,273	\$ 1,154	\$(119)	(9)

Total general and administration expenses represented 35% and 55% of our operating expenses for the three months ended September 30, 2016 and 2017, respectively. General and administrative expenses remained relatively flat at \$1.3 million and \$1.2 million for the three months ended September 30, 2016 and 2017.

*The future*

We expect general and administrative expenditures for the year ended December 31, 2017 compared to our expenditures for the year ended December 31, 2016 to remain relatively flat.

***Other income (expense), net***

Edgar Filing: Cyclacel Pharmaceuticals, Inc. - Form 10-Q

The following table summarizes other income (expense) for the three months ended September 30, 2016 and 2017 (in \$000 except percentages):

	Three Months Ended September 30,		Difference	
	2016	2017	\$	%
Foreign exchange gains (losses)	\$ 51	\$ (22 )	\$(73)	(143 )
Interest income	8	30	22	275
Other income, net	18	28	(10)	(56 )
Total other income	\$ 77	\$ 36	\$(41)	(53 )

*Foreign exchange gains (losses)*

Foreign exchange gains (losses) decreased by approximately \$73,000 from a gain of \$51,000 for the three months ended September 30, 2016, to a loss of \$22,000 for the three months ended September 30, 2017.

*The future*

Other income (expense), net for the year ended December 31, 2017 will continue to be impacted by changes in foreign exchange rates and the receipt of income under the Asset Purchase Agreement, or APA, with Life Technologies Corporation, or LTC, (formerly Invitrogen Corporation), in respect of certain assets and intellectual property owned by Xcyte Therapies, Inc., or Xcyte, and sold to LTC in December 2005. The assets and technology were not part of our product development plan following the transaction between Xcyte and Cyclacel in March 2006. As we are not in control of sales made by LTC we are unable to estimate the level and timing of income under the APA, if any.

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.

Table of Contents*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, 2016 and 2017 (in \$000s except percentages):

	Three Months Ended		Difference	
	September 30, 2016	2017	\$	%
Total income tax benefit	\$ 454	\$ 219	\$(235)	(52)

The total income tax benefit, which is comprised of research and development tax credits recoverable, decreased by \$0.2 million from an income tax benefit of \$0.5 million for the three months ended September 30, 2016 to an income tax benefit of \$0.2 million for the three months ended September 30, 2017. The level of tax credits recoverable is linked directly to qualifying research and development expenditure incurred in any one year.

*The future*

We expect to continue to be eligible to receive United Kingdom research and development tax credits for the foreseeable future and will 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, 2017 in comparison to the year ended December 31, 2016.

*Nine Months Ended September 30, 2016 and 2017***Results of Continuing Operations***Revenues*

The following table summarizes the components of our revenues for the nine months ended September 30, 2016 and 2017 (in \$000s, except percentages):

	Nine Months		Difference	
	Ended September 30,			
	2016	2017	\$	%
Grant revenue	\$ 566	\$ -	\$(566)	(100)

We recognized \$0.6 million and \$0 in grant revenue for the nine months ended September 30, 2016 and 2017, respectively, from the European Union and the Biomedical Catalyst of the United Kingdom government.

*The future*

We will not recognize further grant revenue for the CYC140 program, as the grant from the Biomedical Catalyst of the United Kingdom government ended in November 2016. Although we may apply for additional grants in 2017, we will not recognize grant revenue for the remainder of 2017 and we are not certain of our ability to obtain grant revenue in 2018.

***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 our CDK inhibitors, sapacitabine 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:

Table of Contents

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 nine months ended September 30, 2016 and 2017 (in \$000s except percentages):

	Nine Months Ended September 30,		Difference	
	2016	2017	\$	%
Sapacitabine	\$ 5,206	\$ 2,331	\$(2,875)	(55)
Other costs related to research and development programs, management and exploratory research	2,339	1,160	(1,179)	(50)
Total research and development expenses	\$ 7,545	\$ 3,491	\$(4,054)	(54)

Total research and development expenses represented 65% and 48% of our operating expenses for the nine months ended September 30, 2016 and 2017, respectively.

Research and development expenditures decreased by \$4.1 million from \$7.5 million for the nine months ended September 30, 2016 to \$3.5 million for the nine months ended September 30, 2017. Research and development expenses relating to sapacitabine decreased by \$2.9 million from \$5.2 million for the nine months ended September 30, 2016 to \$2.3 million for the nine months ended September 30, 2017, primarily as a result of a reduction in expenditures associated with the SEAMLESS Phase 3 trial as clinical sites are closed.

*The future*

We anticipate that overall research and development expenditures for the year ended December 31, 2017 will decrease compared to the year ended December 31, 2016, as we close the remaining clinical study sites for SEAMLESS. The timing and extent of any future SEAMLESS expenditure, including the possibility of registration submissions to regulatory authorities in Europe and the U.S., are dependent upon final clinical 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 nine months ended September 30, 2016 and 2017 (in \$000s except percentages):

	Nine Months Ended		Difference	
	September 30,		\$	%
	2016	2017		
Total general and administrative expenses	\$ 4,002	\$ 3,802	\$(200)	(5)

Total general and administration expenses represented 35% and 52% of our operating expenses for the nine months ended September 30, 2016 and 2017, respectively. General and administrative expenses remained flat at \$4.0 million and \$3.8 million for the nine months ended September 30, 2016 and 2017, respectively.



Table of Contents*The future*

We expect general and administrative expenditures for the year ended December 31, 2017 compared to our expenditures for the year ended December 31, 2016 to remain relatively flat.

***Other income (expense), net***

The following table summarizes other income (expense) for the nine months ended September 30, 2016 and 2017 (in \$000 except percentages):

	Nine Months Ended		Difference	
	September 30,		\$	%
	2016	2017		
Foreign exchange gains / (losses)	\$ 369	\$ (65 )	\$(434)	(118 )
Interest income	31	59	28	90
Other income, net	56	907	851	1,520
Total other income	\$ 456	\$ 901	\$445	98

Total other income increased by approximately \$0.4 million, from \$0.5 million for the nine months ended September 30, 2016 to \$0.9 million for the nine months ended September 30, 2017. The increase in other income is primarily related to income received under the APA with LTC, in respect of certain assets and intellectual property owned by Xcyte, and sold to LTC in December 2005. The assets and technology were not part of our product development plan following the transaction between Xcyte and Cyclacel in March 2006. We have no knowledge of LTC's activities and cannot predict when we may receive income under the APA, if any.

*Foreign exchange gains*

Foreign exchange gains decreased by approximately \$0.4 million, from a gain of \$0.4 million for the nine months ended September 30, 2016, to a loss of \$65,000 for the nine months ended September 30, 2017.

*The future*

Other income (expense), net for the year ended December 31, 2017 will continue to be impacted by changes in foreign exchange rates and the receipt of income under the APA. As we are not in control of sales made by LTC we are unable to estimate the level and timing of income under the APA, if any.

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 nine months ended September 30, 2016 and 2017 (in \$000s except percentages):

	Nine Months Ended		Difference	
	September 30,		\$	%
	2016	2017		
Total income tax benefit	\$ 1,573	\$ 793	\$(780)	(50)

The total income tax benefit, which comprised of research and development tax credits recoverable, decreased by \$0.8 million from an income tax benefit of \$1.6 million for the nine months ended September 30, 2016 to an income tax benefit of \$0.8 million for the nine months ended September 30, 2017. 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, 2017 in comparison to the year ended December 31, 2016.

*Liquidity and Capital Resources*

The following is a summary of our key liquidity measures as of September 30, 2016 and 2017 (in thousands):

	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	2016	2017
Cash and cash equivalents	\$ 18,029	\$ 26,025
Working capital:		
Current assets	22,579	27,817
Current liabilities	(5,570 )	(4,265 )
Total working capital	\$ 17,009	\$ 23,552

Since our inception, we have relied primarily on the proceeds from sales of common and preferred equity securities to finance our operations and internal growth. Additional funding has come through research and development tax credits, government grants, the sale of product rights, interest on investments, licensing revenue, and a limited amount of product revenue from operations discontinued in September 2012. We have incurred significant losses since our inception. The increase in the cash balance during the year is primarily as a result of the approximately \$13.7 million in net proceeds from the July 2017 underwritten public offering. As of September 30, 2017, we had an accumulated deficit of \$340.6 million.

*Cash Flows*

Cash used in operating, investing and financing activities for the nine months ended September 30, 2016 and 2017 is summarized as follows (in thousands):

	Nine months ended September 30,	
	2016	2017
Net cash used in operating activities	\$ (7,136 )	\$ (5,260 )
Net cash used in investing activities	—	(11 )
Net cash provided by financing activities	5,091	14,600

*Operating activities*

Net cash used in operating activities decreased by \$1.9 million, from \$7.1 million for the nine months ended September 30, 2016 to \$5.3 million for the nine months ended September 30, 2017. The decrease in cash used by operating activities was primarily the result of a reduction in net loss of \$3.3 million, offset by a change in working capital of \$1.7 million and stock compensation of \$0.4 million.

*Investing activities*

Net cash used in investing activities increased by \$11,000 as a result of capital expenditure on IT equipment.

Table of Contents

*Financing activities*

Net cash provided by financing activities was \$14.6 million for the nine months ended September 30, 2017, primarily as a result of the approximately \$13.7 million in net proceeds from the July 2017 underwritten public offering and approximately \$1.1 million in net proceeds from the issuance of common stock under the FBR Sales Agreement entered into in June 2016 offset by dividend payments of approximately \$0.2 million to the holders of our 6% Preferred Stock. Net cash provided by financing activities was \$5.1 million for the nine months ended September 30, 2016, primarily as a result of approximately \$5.1 million in net proceeds from the issuance of common stock under the FBR Sales Agreement entered into in June 2016 and approximately \$0.2 million in net proceeds from a Controlled Equity Offering<sup>SM</sup> Sales Agreement with Cantor Fitzgerald & Co entered into in July 2015 offset by dividend payments of approximately \$0.2 million to the holders of our 6% Preferred Stock.

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

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

We believe that existing funds together with cash generated from operations, such as the R&D tax credit, and recent financing activities, are sufficient to satisfy our planned working capital, capital expenditures and other financial commitments through 2019. However, we do not currently have sufficient funds to complete development and commercialization of any of our drug candidates. Current business and capital market risks could have a detrimental effect on the availability of sources of funding and our ability to access them in the future, which may delay or impede our progress of advancing our drugs currently in the clinical pipeline to approval by the FDA or EMA for commercialization. Additionally, we plan to continue to evaluate in-licensing and acquisition opportunities to gain access to new drugs or drug targets that would fit with our strategy. Any such transaction would likely increase our funding needs in the future.

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

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

• the costs associated with establishing manufacturing and commercialization capabilities;

- the costs of acquiring or investing in businesses, product candidates and technologies;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs and timing of seeking and obtaining FDA and EMA approvals;
- the effect of competing technological and market developments; and
- the economic and other terms and timing of any collaboration, licensing or other arrangements into which we may enter.

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

### **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.

Table of Contents

**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, 2017, 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, 2017, 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, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Inherent Limitation on the Effectiveness of Internal Controls**

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

**PART II. Other Information**

**Item 1. Legal Proceedings**

None.

**Item 1A. Risk Factors**

There have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the year ended December 31, 2016. For a further discussion of our Risk Factors, refer to Part I, Item 1A, "Risk Factors," of our Annual Report on Form 10-K for the year ended December 31, 2016.

**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.

**Item 5. Other Information**

None.



Table of Contents

**Item 6. Exhibits**

- 3.1 Certificate of Designation of Series A Preferred Stock, incorporated herein by reference to Exhibit 3.5 to the Company's Registration Statement on Form S-1 (No. 333-218305) effective July 28, 2017.
- 4.1 Form of Warrant to purchase shares of Cyclacel Pharmaceuticals Inc. Common Stock, incorporated herein by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1 (No. 333-218305) effective July 28, 2017.
- 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, 2017, 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.

Table of Contents

**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 13, 2017 By: /s/ Paul McBarron

Paul McBarron

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