

Cyclacel Pharmaceuticals, Inc.
Form 10-Q
November 13, 2018

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, 2018

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

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

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

200 Connell Drive, Suite 1500

07922

Berkeley Heights, New Jersey

(Address of principal executive offices) (Zip Code)

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See 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

Emerging growth company

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

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 9, 2018 there were 12,497,447 shares of the registrant's common stock outstanding.

TABLE OF CONTENTS

| | Page |
|--|-------------|
| <u>Part I. Financial Information</u> | |
| <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>22</u> |
| <u>Item 4. Controls and Procedures</u> | <u>22</u> |
| <u>Part II. Other Information</u> | |
| <u>Item 1. Legal Proceedings</u> | <u>23</u> |
| <u>Item 1A. Risk Factors</u> | <u>23</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>24</u> |
| <u>SIGNATURE PAGE</u> | <u>25</u> |

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

| | December 31, 2017 | September 30, 2018 |
|--|----------------------|-----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 23,910 | \$ 18,973 |
| Prepaid expenses and other current assets | 2,064 | 1,696 |
| Total current assets | 25,974 | 20,669 |
| Property and equipment, net | 29 | 38 |
| Total assets | \$ 26,003 | \$ 20,707 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 1,558 | \$ 1,411 |
| Accrued and other current liabilities | 2,555 | 2,592 |
| Total current liabilities | 4,113 | 4,003 |
| Other liabilities | 124 | 106 |
| Total liabilities | 4,237 | 4,109 |
| Stockholders' equity: | | |
| Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 31, 2017 and September 30, 2018; 6% Convertible Exchangeable preferred stock; 335,273 shares issued and outstanding at December 31, 2017 and September 30, 2018. | - | - |
| Aggregate preference in liquidation of \$4,006,512 as of December 31, 2017 and September 30, 2018. | | |
| Series A convertible preferred stock, \$0.001 par value; 264 shares issued and outstanding at December 31, 2017 and September 30, 2018. | - | - |

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

| | | |
|---|------------|------------|
| Common stock, \$0.001 par value; 100,000,000 shares authorized at December 31, 2017 and September 30, 2018; 11,997,447 shares issued and outstanding at December 31, 2017 and September 30, 2018. | 12 | 12 |
| Additional paid-in capital | 365,057 | 365,160 |
| Accumulated other comprehensive loss | (794) | (796) |
| Accumulated deficit | (342,509) | (347,778) |
| Total stockholders' equity | 21,766 | 16,598 |
| Total liabilities and stockholders' equity | \$ 26,003 | \$ 20,707 |

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

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, | |
|---|-------------------------------------|------------|------------------------------------|------------|
| | 2017 | 2018 | 2017 | 2018 |
| Revenues: | | | | |
| Total revenues | \$— | \$— | \$— | \$— |
| Operating expenses: | | | | |
| Research and development | 958 | 1,205 | 3,491 | 3,185 |
| General and administrative | 1,154 | 1,250 | 3,802 | 3,898 |
| Total operating expenses | 2,112 | 2,455 | 7,293 | 7,083 |
| Operating loss | (2,112) | (2,455) | (7,293) | (7,083) |
| Other income (expense): | | | | |
| Foreign exchange gains (losses) | (22) | 1 | (65) | (42) |
| Interest income | 30 | 85 | 59 | 238 |
| Other income, net | 28 | - | 907 | 632 |
| Total other income | 36 | 86 | 901 | 828 |
| Loss before taxes | (2,076) | (2,369) | (6,392) | (6,255) |
| Income tax benefit | 219 | 301 | 793 | 985 |
| Net loss | (1,857) | (2,068) | (5,599) | (5,270) |
| Dividend on convertible exchangeable preferred shares | (50) | (50) | (151) | (151) |
| Beneficial conversion feature of Series A convertible stock | (3,638) | - | (3,638) | - |
| Conversion of Series A convertible preferred stock | (3,373) | - | (3,373) | - |
| Net loss applicable to common shareholders | \$(8,918) | \$(2,118) | \$(12,761) | \$(5,421) |
| Basic and diluted earnings per common share: | | | | |
| Net loss per share – basic and diluted | \$(0.91) | \$(0.18) | \$(2.06) | \$(0.45) |
| Weighted average common shares outstanding | 9,835,441 | 11,997,447 | 6,200,783 | 11,997,447 |

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

CYCLACEL PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In \$000s)

(Unaudited)

| | Three Months Ended | | Nine Months Ended | |
|--|--------------------|-------------|-------------------|-------------|
| | September 30, | | September 30, | |
| | 2017 | 2018 | 2017 | 2018 |
| Net loss | \$ (1,857) | \$ (2,068) | \$ (5,599) | \$ (5,270) |
| Translation adjustment | (4,882) | 2,263 | (13,435) | 5,559 |
| Unrealized foreign exchange gain on intercompany loans | 4,856 | (2,261) | 13,417 | (5,562) |
| Comprehensive loss | \$ (1,883) | \$ (2,066) | \$ (5,617) | \$ (5,273) |

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

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

| | Nine Months Ended September 30, | |
|---|------------------------------------|------------|
| | 2017 | 2018 |
| Operating activities: | | |
| Net loss | \$(5,599) | \$(5,270) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 25 | 22 |
| Stock-based compensation | 200 | 255 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other assets | 1,464 | 320 |
| Accounts payable and other current liabilities | (1,350) | 8 |
| Net cash used in operating activities | (5,260) | (4,665) |
| Investing activities: | | |
| Purchase of property, plant and equipment | (11) | (33) |
| Net cash used in investing activities | (11) | (33) |
| Financing activities: | | |
| Proceeds from issuance of common stock, net of issuance costs | 14,751 | - |
| Payment of preferred stock dividend | (151) | (151) |
| Net cash provided by (used in) financing activities | 14,600 | (151) |
| Effect of exchange rate changes on cash and cash equivalents | 176 | (88) |
| Net increase (decrease) in cash and cash equivalents | 9,505 | (4,937) |
| Cash and cash equivalents, beginning of period | 16,520 | 23,910 |
| Cash and cash equivalents, end of period | \$26,025 | \$18,973 |
| Supplemental cash flow information: | | |
| Cash received during the period for: | | |
| Interest | 60 | 238 |
| Taxes | 1,815 | 1,158 |

Non cash financing activities:

| | | |
|--------------------------------------|----|----|
| Accrual of preferred stock dividends | 50 | 50 |
|--------------------------------------|----|----|

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

CYCLACEL PHARMACEUTICALS, INC.

NOTES TO 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, 2018, 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, 2018, the consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2018 and 2017 and the consolidated statements of cash flows for the nine months ended September 30, 2018 and 2017, and all related disclosures contained in the accompanying notes are unaudited. The consolidated balance sheet as of December 31, 2017 is derived from the audited consolidated financial statements included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2017 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, 2018, and the results of operations and comprehensive loss for the three and nine months ended September 30, 2018 and cash flows for the nine months ended September 30, 2018, have been made. The interim results for the three and nine months ended September 30, 2018 are not necessarily indicative of the results to be expected for the year ending

December 31, 2018 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, 2017 that are included in the Company's Annual Report on Form 10-K filed with the SEC.

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 approximately \$19.0 million as of September 30, 2018 will be sufficient to fund its operating expenses and capital expenditure requirements through to the second quarter of 2020.

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 sources of liquidity;
- 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 second quarter of 2020 is dependent on its ability to raise additional capital to finance its operations. The Company will need to raise substantial additional capital to pursue its transcriptional regulation program evaluating CYC065 in patients with advanced cancers, the DNA damage response and CYC140 programs. 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 development candidates, if available, or be forced to cancel or delay or reduce the scope of its current development programs, including any potential regulatory filings related to the SEAMLESS study of sapacitabine, 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.

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.

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 months and nine months ended September 30, 2017 and 2018.

Revenue recognition

On January 1, 2018, the Company adopted new guidance on revenue recognition, which has been codified within Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers* ("ASC 606"). The accounting policy applicable from January 1, 2018 and further details on the transition are described below. The comparative financial information for the three and nine months ended September 30, 2017 and as of December 31, 2017 has not been restated and is prepared in accordance with the accounting policies that are described in Note 2 to the financial statements included in the Company's Annual Report on Form 10-K.

With effect from January 1, 2018, the Company recognizes revenue using the five step model provided in ASC 606:

- (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.

The transaction price includes fixed payments and an estimate of variable consideration, including milestone payments. The Company determines the variable consideration to be included in the transaction price by estimating the most likely amount that will be received and then applies a constraint to reduce the consideration to the amount which is probable of being received. When applying the constraint, the Company considers:

· Whether achievement of a development milestone is highly susceptible to factors outside the entity's influence, such as milestones involving the judgment or actions of third parties, including regulatory bodies;

· Whether the uncertainty about the achievement of a milestone is not expected to be resolved for a long period of time;

· Whether the Company can reasonably predict that a milestone will be achieved based on previous experience; and.

· The complexity and inherent uncertainty underlying the achievement of a milestone.

The transaction price is allocated to each performance obligation based on the relative selling price of each performance obligation. The best estimate of the selling price is determined after considering all reasonably available information, including market data and conditions, entity-specific factors such as the cost structure of the deliverable and internal profit and pricing objectives.

The revenue allocated to each performance obligation is recognized as or when the Company satisfies the performance obligation.

The Company recognizes a contract asset, when the value of satisfied (or part satisfied) performance obligations is in excess of the payment due to the Company, and deferred revenue when the amount of unconditional consideration is in excess of the value of satisfied (or part satisfied) performance obligations. Once a right to receive consideration is unconditional, that amount is presented as a receivable.

With effect from January 1, 2018, grant revenue, if new grants are obtained, will be presented as a reduction of research and development expenses.

Accounting standards adopted in the period

The Company has adopted Accounting Standards Update (“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 adoption of this standard did not have a material impact on the company’s consolidated financial statements.

The Company has adopted 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 adoption of this standard did not have a material impact on the company’s consolidated financial statements.

The Company has adopted 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. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts.

The Company has adopted the guidance on using a modified retrospective approach with the cumulative effect of initially applying the guidance recognized as of January 1, 2018. The adoption of this standard did not have a material impact on the Company’s consolidated financial statements and it did not have a cumulative effect requiring adjustment to opening retained earnings.

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 will report grant revenue, if new grants are obtained in a nonreciprocal transaction, as a reduction of the corresponding research and development expense. Historically grants have been reported in revenue, but 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.

The Company also expects to recognize revenue associated with contingent milestone-based payments at the time the contingent event is likely 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 when milestones are recognized as revenues is unlikely to be affected.

Recently Issued Accounting Pronouncements

In July 2017, the FASB issued 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. A down round feature is a provision in a financial instrument that reduces the strike price of an issued financial instrument if the issuer sells shares of its stock for an amount less than the currently stated strike price of the issued financial instrument or issues an equity-linked financial instrument with a strike price below the currently stated strike price of the issued financial instrument. ASU 2017-11 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 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 in ASU 2016-02 may 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 August 2018, the FASB issued ASU 2018-11, Leases, which, in addition to the existing requirements to transition, permits an entity to adopt the new lease accounting guidelines by recognizing a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption without restating prior periods. The Company is currently evaluating the impact of the guidance on the consolidated financial statements. We anticipate adopting this as of January 1, 2019 without recasting prior periods. We anticipate that the adoption of the guidance will have a material impact on the Company's consolidated balance sheet due to the recognition of a lease liability and corresponding right-of-use asset.

3. Revenue

Revenue recognized in the three and nine months ended September 30, 2017 and 2018 was \$0. Deferred revenue as of December 31, 2017 and September 30, 2018 was \$150,000 and is included in Accrued and other current liabilities on the accompanying balance sheets. We expect to recognize this deferred revenue by the end of 2018.

The aggregate transaction price that is allocated to performance obligations that are unsatisfied (or partially unsatisfied) as of September 30, 2018 was \$0.

4. Net Loss per Common Share

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

The following potentially dilutive securities have not been included in the computation of diluted net loss per share for the three and nine months ended September 30, 2017 and 2018, as the result would be anti-dilutive:

| September 30, | September 30, |
|---------------|---------------|
| 2017 | 2018 |

| | | |
|--|-----------|-----------|
| Stock options | 381,786 | 836,850 |
| Convertible preferred stock | 1,698 | 1,698 |
| Series A preferred stock | 332,000 | 132,000 |
| Common stock warrants | 7,590,000 | 7,490,500 |
| Total shares excluded from calculation | 8,305,484 | 8,461,048 |

5. Prepaid Expenses and Other Current Assets

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

| | December 31, 2017 | September 30, 2018 |
|--|----------------------|-----------------------|
| Research and development tax credit receivable | \$ 1,054 | \$ 816 |
| Prepayments and VAT receivable | 772 | 798 |
| Other current assets | 238 | 82 |
| | \$ 2,064 | \$ 1,696 |

6. Accrued and Other Liabilities

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

| | December 31, 2017 | September 30, 2018 |
|-------------------------------------|----------------------|-----------------------|
| Accrued research and development | \$ 1,645 | \$ 1,968 |
| Accrued legal and professional fees | 248 | 320 |
| Other current liabilities | 662 | 304 |
| | \$ 2,555 | \$ 2,592 |

Other current liabilities at December 31, 2017 and September 30, 2018 include \$150,000 of deferred revenue in respect of payment received in advance of achieving a milestone under the ManRos agreement.

7. Stock Based Compensation

ASC 718 requires compensation expense associated with share-based awards to be recognized over the requisite service period, which for the Company is the period between the grant date and the date the award vests or becomes exercisable. Most of the awards granted by the Company (and still outstanding) vest ratably over one to four years. The Company recognizes all share-based awards under the straight-line attribution method, assuming that all granted awards will vest. Forfeitures are recognized in the periods when they occur.

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, 2017 and 2018 as shown in the following table (in \$000s):

| | Three Months Ended | | Nine Months Ended | |
|--------------------------------|--------------------|-------|-------------------|--------|
| | September 30, | | September 30, | |
| | 2017 | 2018 | 2017 | 2018 |
| General and administrative | \$ 48 | \$ 66 | \$ 146 | \$ 188 |
| Research and development | 17 | 22 | 54 | 67 |
| Stock-based compensation costs | \$ 65 | \$ 88 | \$ 200 | \$ 255 |

2018 Plan

In May 2018, the Company's stockholders approved the 2018 Equity Incentive Plan (the "2018 Plan"), under which Cyclacel may make equity incentive grants to its officers, employees, directors and consultants. The 2018 Plan replaces the 2015 Equity Incentive Plan (the "2015 Plan").

The 2018 Plan allows for the issuance of up to 1,500,000 shares of the Company's common stock pursuant to various types of award grants, including stock options and restricted stock units. In addition, the 2018 Plan allows up to 709,889 additional shares to be issued if awards outstanding under the 2018 Plan are cancelled or expire on or after the date of the Company's 2018 annual meeting of stockholders.

As of September 30, 2018, the Company has reserved 1,657,500 shares of the Company's common stock under the 2018 Plan, including shares that were available under the 2015 Plan and carried forward to the 2018 Plan. Stock option awards granted under the Company's equity incentive plans have a maximum life of 10 years and generally vest over a one to four-year period from the date of grant.

There were 306,304 options granted during the nine months ended September 30, 2018. These options had grant date fair values ranging between \$1.17-\$1.29 per option. Of these options, approximately 174,272 are performance based and will vest upon the fulfillment of certain clinical objectives. The Company determined that the satisfaction of one of the objectives was probable as of September 30, 2018, but that the other vesting criteria related to these awards were not probable as of September 30, 2018. As such, the Company recognized compensation cost for these grants under the expectation that 25% of these awards will vest.

There were 170,853 options granted during the year ended December 31, 2017. Of these options, 158,853 are performance based, which will vest upon the fulfillment of certain clinical objectives. The Company determined that the satisfaction of one of the objectives was probable as of September 30, 2018, but that the other vesting criteria related to these awards were not probable as of September 30, 2018. As such, the Company recognized compensation cost for these grants under the expectation that 25% of these awards will vest.

There were no stock options exercised during each of the nine months ended September 30, 2017 and 2018, respectively. The Company does not expect to be able to benefit from the deduction for stock option exercises that may occur because the company has tax loss carryforwards from prior periods that would be expected to offset any potential taxable income.

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, 2017 | 535,617 | 11.10 | 8.23 | — |
| Granted | 306,304 | 1.51 | | |
| Cancelled/forfeited | (5,071) | 129.31 | | |
| Options outstanding at September 30, 2018 | 836,850 | 6.87 | 8.26 | — |
| Unvested at September 30, 2018 | (653,697) | 2.52 | 8.79 | — |
| Vested and exercisable at September 30, 2018 | 183,153 | 22.41 | 6.38 | — |

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

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 \$13.7 million, after deducting underwriting discounts, commissions and other estimated offering expenses. The Class A Units and Class B Units have no stand-alone rights and the shares of common stock, Series A Preferred Stock and the Class A and Class B Warrants comprising those units were immediately separable.

The common stock, Class A Warrants and Class B Warrants (together the “Warrants”) and Series A Preferred Stock are freestanding financial instruments. The Warrants are classified within equity 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.

Warrants

As of September 30, 2018, there were 7,490,500 warrants to purchase the Company’s common stock 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 and nine months ended September 30, 2018.

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 year ended December 31, 2017, 8,608 shares of the Series A Preferred Stock were converted into 4,304,000 shares of common stock. As of September 30, 2018, 264 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 264 shares of Series A Preferred Stock issued and outstanding at September 30, 2018, are convertible into 132,000 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.

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, 2018, 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.

Subsequent Events

On September 6, 2018, the Board of Directors declared a quarterly cash dividend in the amount of \$0.15 per share on the Company's Preferred Stock. The cash dividend was paid on November 1, 2018 to the holders of record of the Preferred Stock as of the close of business on October 15, 2018.

On October 4, 2018, the Company entered into a Common Stock Sales Agreement, or the Sales Agreement, with H.C. Wainwright & Co., LLC, or Wainwright, as sales agent, pursuant to which Wainwright may sell shares of our common stock, par value \$0.001 per share, having an aggregate offering price of up to \$5,000,000, by any method that is deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. Shares sold under the Sales Agreement will be offered and sold pursuant to the Company's previously filed and effective Registration Statement on Form S-3 and a prospectus supplement and accompanying base prospectus. The Company will pay Wainwright a commission of 3.0% of the gross sales price per share sold.

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.

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, 2017, 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

During 2018, our primary focus has been on our transcriptional regulation program where we are evaluating CYC065, our cyclin dependent kinase, or CDK, inhibitor and our DNA damage response, or DDR, program where we are evaluating sapacitabine in combination with our CDK inhibitor seliciclib in Phase 1/2 studies in patients with solid tumors. Additionally in our SEAMLESS study of sapacitabine in Acute Myeloid Leukemia, or AML, stratified and exploratory subgroup analyses have been completed and have defined a patient population who may benefit from treatment with the experimental arm. We have begun discussing the SEAMLESS data with certain regulatory authorities.

Transcriptional Regulation Program

CDKs are a family of enzymes first discovered as regulators of the cell cycle, but that 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 certain specific CDKs 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 FDA approval in March 2015 of a CDK inhibitor for palbociclib, and more recently in 2017, ribociclib and abemaciclib, 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 that malfunctions in about two-thirds of human cancers. Under his guidance, Cyclacel's drug discovery and development programs concentrated on the CDK2/9 isoforms, which operate as key components of the p53 pathway. These efforts resulted in bringing two molecules into clinical trials: seliciclib, a first-generation CDK inhibitor, and CYC065, a second-generation CDK inhibitor, which has benefited from the Company's clinical experience with seliciclib.

CYC065 has been evaluated in a first-in-human, Phase 1 trial in patients with advanced solid tumors and a recommended Phase 2 dose established. The study demonstrated that CYC065 durably suppresses Mcl-1, a member of the Bcl-2 family of survival proteins. CYC065 is under investigation in combination with other anticancer drugs, including Bcl-2 inhibitors such as venetoclax. Preclinical data show that CYC065 may benefit adults and children with hematological malignancies, including acute myeloid leukemias (AML), acute lymphocytic leukemias (ALL), and in particular leukemias with rearrangement of the Mixed Lineage Leukemia gene (MLL-r), chronic lymphocytic leukemias (CLL), B-cell lymphomas, multiple myelomas, and patients with certain solid tumors, including breast and uterine cancers, and neuroblastomas.

Seliciclib, our first-generation CDK inhibitor, is being evaluated in an all-oral Phase 1/2 combination study with our sapacitabine in patients with BRCA mutations, and has been evaluated to date in approximately 450 patients.

DNA Damage Response, or DDR, Program

Many cancers have defects in the way in which cells monitor and repair damaged DNA, collectively termed DNA damage response, or DDR. These deficiencies in DDR pathways render cells more susceptible to DNA damage. Many traditional cancer treatments, such as DNA-damaging chemotherapy and radiotherapy, are based on this finding. However, such treatments are often accompanied by significant and unwanted side effects. Developing treatments which target specific DDR deficiencies to preferentially kill cancer cells, while minimizing the impact on normal cells, has potential for more selective, better tolerated therapies to improve survival in multiple cancers.

We have focused on developing treatments targeting DNA damage pathways for several years. For example, 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 more susceptible to cell death induced by sapacitabine.

We are evaluating sapacitabine in a Phase 1/2 combination study with seliciclib in patients with BRCA mutations. A Phase 1b/2 investigator-sponsored clinical trial has been initiated to evaluate the safety and effectiveness of sapacitabine in combination with olaparib in patients with BRCA mutant breast cancer. The trial will be conducted at the Dana-Farber Cancer Institute with collaborators Cyclacel and AstraZeneca providing sapacitabine investigational drug and the approved PARP-inhibitor olaparib, respectively.

CYC140

CYC140 is a novel, small molecule, selective polo-like-kinase 1 (PLK1) inhibitor which is ready to start investigation in cancer patients. CYC140 is differentiated from other PLK1 inhibitors, demonstrating potent and selective target inhibition and high activity in xenograft models of human cancers when dosed orally at non-toxic doses and is the subject of a translational biology program focused on acute leukemias and esophageal cancer.

MD Anderson Clinical Collaboration

On October 1, 2018, the Company entered into a Clinical Collaboration Agreement, or CCA with The University of Texas MD Anderson Cancer Center, or MD Anderson. The main objective of the CCA is to clinically evaluate the safety and efficacy of three Cyclacel medicines in patients with hematological malignancies, including chronic lymphocytic leukemias, acute myeloid leukemias, myelodysplastic syndromes and other advanced leukemias. Under the terms of the CCA, MD Anderson will conduct four clinical studies with a total projected enrollment of up to 170 patients. The four protocols will study CYC065, CYC140 and sapacitabine either as single agents or in combination with approved drugs. The CCA shall remain in effect for the duration of the period during which payments are due to MD Anderson.

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

Results of Operations

Three Months Ended September 30, 2017 and 2018

Results of Continuing Operations

Revenues

Revenues for the three months ended September 30, 2017 and 2018 were \$0 and \$0.

The future

Recognition of any further revenue from milestones under a collaboration, licensing and supply agreement with ManRos Therapeutics SA is dependent on the clinical progress of the program, which we do not control.

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 CYC065, CYC140 and sapacitabine. We have also incurred costs in the advancement of product candidates toward clinical and preclinical 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 organizations;

Preclinical studies and laboratory supplies and materials;

Technology license costs;

Stock-based compensation; 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, 2017 and 2018 (in \$000s except percentages):

| | Three Months Ended September 30, | | Difference | |
|--|-------------------------------------|----------|------------|-------|
| | 2017 | 2018 | \$ | % |
| Transcriptional Regulation (CYC065) | \$ 232 | \$ 680 | \$448 | 193 |
| DNA Damage Response (sapacitabine and seliciclib) | 89 | 24 | (65) | (73) |
| Sapacitabine (SEAMLESS and manufacturing) | 561 | 316 | (245) | (44) |
| Other research and development programs and expenses | 76 | 185 | 109 | 143 |
| Total research and development expenses | \$ 958 | \$ 1,205 | \$247 | 26 |

Total research and development expenses represented 45% and 49% of our operating expenses for the three months ended September 30, 2017 and 2018, respectively.

Research and development expenses increased by \$0.2 million from \$1.0 million for the three months ended September 30, 2017 to \$1.2 million for the three months ended September 30, 2018. Research and development expenses relating to transcriptional regulation increased by \$0.5 million from \$0.2 million for the three months ended September 30, 2017 to \$0.7 million for the three months ended September 30, 2018, primarily due to progression of the clinical evaluation of CYC065. Research and development expenses relating to sapacitabine decreased by \$0.3 million from \$0.6 million for the three months ended September 30, 2017 to \$0.3 million for the three months ended September 30, 2018, primarily as a result of a reduction in expenses associated with the SEAMLESS Phase 3 trial and related costs.

The future

We anticipate that overall research and development expenses for the year ended December 31, 2018 will increase compared to the year ended December 31, 2017, as we progress the clinical development of CYC065. 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 the outcome of discussions with regulatory authorities.

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, 2017 and 2018 (in \$000s except percentages):

| | Three Months Ended September 30, | | Difference | |
|---|-------------------------------------|----------|------------|---|
| | 2017 | 2018 | \$ | % |
| Total general and administrative expenses | \$ 1,154 | \$ 1,250 | \$ 96 | 8 |

Total general and administration expenses represented 55% and 51% of our operating expenses for the three months ended September 30, 2017 and 2018, respectively. General and administrative activity has been consistent year over year resulting in expenses remaining relatively flat at \$1.2 million and \$1.3 million for the nine months ended September 30, 2017 and 2018, respectively.

The future

We expect general and administrative expenses for the year ended December 31, 2018 compared to our expenses for the year ended December 31, 2017 to remain relatively flat.

Other income, net

The following table summarizes other income for the three months ended September 30, 2017 and 2018 (in \$000 except percentages):

| | Three Months Ended | | Difference | |
|---------------------------------|--------------------|-------|------------|-------|
| | September 30, | | \$ | % |
| | 2017 | 2018 | | |
| Foreign exchange gains (losses) | \$ (22) | \$ 1 | \$23 | 105 |
| Interest income | 30 | 85 | 55 | 183 |
| Other income, net | 28 | - | (28) | (100) |
| Total other income | \$ 36 | \$ 86 | \$50 | 139 |

Total other income increased by approximately \$50,000 from \$36,000 for the three months ended September 30, 2017 to \$86,000 for the three months ended September 30, 2018. The increase in other income is primarily related to increased yields on cash held on deposit, offset by royalties receivable under a December 2005 Asset Purchase Agreement, or APA, whereby Xcyte Therapies, Inc., or Xcyte (a business acquired by the Company in March 2006) sold certain assets and intellectual property to ThermoFisher Scientific Company, or TSC (formerly Invitrogen Corporation) through an APA and other related agreements. The assets and technology were not part of the Company's product development plan following the transaction between Xcyte and Cyclacel in March 2006. Accordingly, the company recognized \$28,000 and \$0 of other income arising from sales related to this transaction during the three months ended September 30, 2017 and 2018, respectively

Foreign exchange gains (losses)

Foreign exchange losses decreased by approximately \$23,000, from a loss of \$22,000 for the three months ended September 30, 2017, to a gain of \$1,000 for the three months ended September 30, 2018.

The future

Other income (expense), net for the year ended December 31, 2018, will continue to be impacted by changes in foreign exchange rates and the receipt of income under the APA. As we are not in control of sales made by TSC, we are unable to estimate the level and timing of income under the APA, if any.

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

Income tax benefit

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

The following table summarizes total income tax benefit for the three months ended September 30, 2017 and 2018 (in \$000s except percentages):

| | Three Months Ended | | Difference | |
|--------------------------|--------------------|--------|------------|----|
| | September 30, 2017 | 2018 | \$ | % |
| Total income tax benefit | \$ 219 | \$ 301 | \$ 82 | 37 |

The total income tax benefit, which comprised of research and development tax credits recoverable, increased by \$0.1 million from an income tax benefit of \$0.2 million for the three months ended September 30, 2017 to an income tax

benefit of \$0.3 million for the three months ended September 30, 2018. The level of tax credits recoverable is linked directly to qualifying research and development expenditure incurred in any one year and the availability of trading losses.

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 and having sufficient trading losses. We expect our qualifying research and development expenditure to increase for the year ended December 31, 2018 in comparison to the year ended December 31, 2017.

Nine Months Ended September 30, 2017 and 2018

Results of Continuing Operations

Revenues

Revenues for the nine months ended September 30, 2017 and 2018 were \$0 and \$0.

The future

Recognition of any further revenue from milestones under a collaboration, licensing and supply agreement with ManRos Therapeutics is dependent on the clinical progress of the program, which we do not control.

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 and PLK inhibitors and sapacitabine. We have also incurred costs in the advancement of product candidates toward clinical and

preclinical 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 nine months ended September 30, 2017 and 2018 (in \$000s except percentages):

| | Nine Months Ended September 30, | | Difference | |
|--|------------------------------------|----------|------------|-------|
| | 2017 | 2018 | \$ | % |
| Transcriptional Regulation (CYC065) | \$ 737 | \$ 1,786 | \$1,049 | 142 |
| DNA Damage Response (sapacitabine and seliciclib) | 324 | 84 | (240) | (74) |
| Sapacitabine (SEAMLESS and manufacturing) | 2,212 | 798 | (1,414) | (64) |
| Other research and development programs and expenses | 218 | 517 | 299 | 137 |
| Total research and development expenses | \$ 3,491 | \$ 3,185 | \$(306) | (9) |

Total research and development expenses represented 48% and 45% of our operating expenses for the nine months ended September 30, 2017 and 2018, respectively.

Research and development expenses decreased by \$0.3 million from \$3.5 million for the nine months ended September 30, 2017 to \$3.2 million for the nine months ended September 30, 2018. Research and development expenses relating to transcriptional regulation increased by \$1.1 million from \$0.7 million for the nine months ended September 30, 2017 to \$1.8 million for the nine months ended September 30, 2018, as the clinical evaluation CYC065 progresses. Research and development expenses relating to sapacitabine decreased by \$1.4 million from \$2.2 million for the nine months ended September 30, 2017 to \$0.8 million for the nine months ended September 30, 2018, primarily as a result of a reduction in expenditures associated with the SEAMLESS Phase 3 trial and related costs.

The future

We anticipate that overall research and development expenses for the year ended December 31, 2018 will increase compared to the year ended December 31, 2017, as we progress the clinical development of CYC065. 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 the outcome of discussions with regulatory authorities.

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, 2017 and 2018 (in \$000s except percentages):

| | Nine Months Ended | | Difference | |
|---|-------------------|----------|------------|---|
| | September 30, | | | |
| | 2017 | 2018 | \$ | % |
| Total general and administrative expenses | \$ 3,802 | \$ 3,898 | \$ 96 | 3 |

Total general and administration expenses represented 52% and 55% of our operating expenses for the nine months ended September 30, 2017 and 2018, respectively. General and administrative activity has been consistent year over year resulting in expenses remaining relatively flat at \$3.8 million and \$3.9 million for the nine months ended September 30, 2017 and 2018, respectively.

The future

We expect general and administrative expenditures for the year ended December 31, 2018 compared to our expenditures for the year ended December 31, 2017 to remain relatively flat.

Other income, net

The following table summarizes other income, net for the nine months ended September 30, 2017 and 2018 (in \$000 except percentages):

| | Nine Months Ended | | Difference | |
|-------------------------|-------------------|----------|------------|-------|
| | September 30, | | \$ | % |
| | 2017 | 2018 | | |
| Foreign exchange losses | \$ (65) | \$ (42) | \$ 23 | 35 |
| Interest income | 59 | 238 | 179 | 303 |
| Other income, net | 907 | 632 | (275) | (30) |
| Total other income | \$ 901 | \$ 828 | \$(73) | (8) |

Total other income decreased by approximately \$0.1 million, from \$0.9 million for the nine months ended September 30, 2017 to \$0.8 million for the nine months ended September 30, 2018. The decrease in other income is primarily related to royalty payments receivable under a December 2005 APA, whereby Xcyte sold certain assets and intellectual property to TSC through an APA and other related agreements. We have no knowledge of TSC's activities and cannot predict when we may receive income under the APA, if any.

Foreign exchange losses

Foreign exchange losses decreased by approximately \$23,000, from a loss of \$65,000 for the nine months ended September 30, 2017, to a loss of \$42,000 for the nine months ended September 30, 2018.

The future

Other income (expense), net for the year ended December 31, 2018 will continue to be impacted by changes in foreign exchange rates and the receipt of income under the APA. As we are not in control of sales made by TSC we are unable to estimate the level and timing of income under the APA, if any.

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, 2017 and 2018 (in \$000s except percentages):

| | Nine Months Ended | | Difference | |
|--------------------------|-------------------|--------|------------|----|
| | September 30, | | | |
| | 2017 | 2018 | \$ | % |
| Total income tax benefit | \$ 793 | \$ 985 | \$ 192 | 24 |

The total income tax benefit, which comprised of research and development tax credits recoverable, increased by \$0.2 million from an income tax benefit of \$0.8 million for the nine months ended September 30, 2017 to an income tax benefit of \$1.0 million for the nine months ended September 30, 2018. 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 increase for the year ended December 31, 2018 in comparison to the year ended December 31, 2017.

Liquidity and Capital Resources

The following is a summary of our key liquidity measures as of September 30, 2017 and 2018 (in thousands):

| | Nine Months Ended September 30, | |
|---------------------------|------------------------------------|-----------|
| | 2017 | 2018 |
| Cash and cash equivalents | \$ 26,025 | \$ 18,973 |
| Working capital: | | |
| Current assets | \$ 27,817 | \$ 20,669 |
| Current liabilities | (4,265) | (4,003) |
| Total working capital | \$ 23,552 | \$ 16,666 |

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. As of September 30, 2018, we had an accumulated deficit of \$ 347.8 million.

Cash Flows

Cash used in operating, investing and financing activities for the nine months ended September 30, 2017 and 2018 is summarized as follows (in thousands):

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

| | Year Ended September 30, | |
|---|--------------------------|-------------|
| | 2017 | 2018 |
| Net cash used in operating activities | \$ (5,260) | \$ (4,665) |
| Net cash used in investing activities | (11) | (33) |
| Net cash provided by (used in) financing activities | 14,600 | (151) |

Operating activities

Net cash used in operating activities decreased by \$0.6 million, from \$5.3 million for the nine months ended September 30, 2017 to \$4.7 million for the nine months ended September 30, 2018. The decrease in cash used by operating activities was primarily the result of a change in working capital of \$0.3 million and a reduction in net loss of \$0.3 million.

Investing activities

Net cash used in investing activities increased by approximately \$22,000 for the nine months ended September 30, 2018 due to capital expenditures on IT equipment.

Financing activities

Net cash used in financing activities in the nine months ended September 30, 2018 of \$0.2 million relates to payment of dividends to the holders of our Preferred Stock. 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.

Operating Capital and Capital Expenditure Requirements

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

We believe that existing funds together with cash generated from operations, 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 to the second quarter of 2020. 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.

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, 2018, 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, 2018, 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

Beginning January 1, 2018, we implemented ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. There were no significant changes made to our internal controls over financial reporting as a result of the implementation.

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

Except as set forth below, there have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the period ended December 31, 2017. For a further discussion of our Risk Factors, refer to the “Risk Factors” discussion contained in our Annual Report on Form 10-K.

We are subject to export control laws, data protection laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition.

We are subject to laws and regulations governing our international operations, including regulations administered by the government of the United States and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. In addition, various statutes and rules in Europe and elsewhere around the world regulate privacy and data protection, which affect our collection, use, storage, and transfer of information both abroad and in the United States. New laws and regulations are periodically being enacted in this area, which remains in a state of flux. Monitoring and complying with these laws requires substantial financial resources.

In particular, the European Union's General Data Protection Regulation ("GDPR") took effect in May 2018, and will require us to meet new and more stringent requirements regarding the handling of personal data about European Union residents. Failure to meet GDPR requirements could result in penalties of up to 4% of our worldwide revenue. The GDPR is a complex law and the regulatory guidance is still evolving, including with respect to how the GDPR should be applied in the context of clinical studies. Furthermore, many of the countries within the European Union are still in the process of drafting supplementary data protection legislation in key fields where the GDPR allows for national variation, including the fields of clinical study and other health-related information. These variations in European data protection laws may raise our costs of compliance and result in greater legal risks. There is no assurance that we will be completely effective in ensuring our compliance with all applicable legal requirements, including Trade Control and data protection laws such as the GDPR. If we are not in compliance with these laws, we may be subject to penalties, lawsuits and damages claims, disgorgement and other sanctions and remedial measures, orders to stop transferring or using personal data, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity.

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.

Item 6. Exhibits

10.1 Clinical Collaboration Agreement, dated October 1, 2018, by and between Cyclacel Pharamceuticals, Inc. and The University of Texas MD Anderson Cancer Center*

10.2 Common Stock Sales Agreement, dated October 4, 2018, by and between Cyclacel Pharmaceuticals, Inc. and H.C. Wainwright & Co., LLC. (previously filed as Exhibit 1.1 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on October 4, 2018, and incorporated by reference)

31.1 Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a) As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

31.2

Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a) As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

32.1 Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

32.2 Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

101 The following materials from Cyclacel Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the period ended September 30, 2018, 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.

* Certain portions of the Exhibit have been omitted based upon a pending request for confidential treatment filed by us with the SEC . The omitted portions of the Exhibit have been separately filed by us with the SEC.

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, 2018 By: /s/ Paul McBarron
Paul McBarron
Chief Operating Officer, Chief Financial Officer and
Executive Vice President, Finance