
**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
(State or Other Jurisdiction
of Incorporation or Organization)

200 Connell Drive, Suite 1500
Berkeley Heights, New Jersey
(Address of principal executive offices)

91-1707622
(I.R.S. Employer
Identification No.)

07922
(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

| | <u>Page</u> |
|--|-------------|
| <u>Part I.</u> | |
| <u>Financial Information</u> | |
| <u>Item 1.</u> | <u>3</u> |
| <u>Financial Statements (Unaudited)</u> | |
| <u>Item 2.</u> | <u>14</u> |
| <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | |
| <u>Item 3.</u> | <u>22</u> |
| <u>Quantitative and Qualitative Disclosures About Market Risk</u> | |
| <u>Item 4.</u> | <u>22</u> |
| <u>Controls and Procedures</u> | |
| <u>Part II.</u> | |
| <u>Other Information</u> | |
| <u>Item 1.</u> | <u>23</u> |
| <u>Legal Proceedings</u> | |
| <u>Item 1A.</u> | <u>23</u> |
| <u>Risk Factors</u> | |
| <u>Item 2.</u> | <u>24</u> |
| <u>Unregistered Sales of Equity Securities and Use of Proceeds</u> | |
| <u>Item 3.</u> | <u>24</u> |
| <u>Defaults Upon Senior Securities</u> | |
| <u>Item 4.</u> | <u>24</u> |
| <u>Mine Safety Disclosures</u> | |
| <u>Item 5.</u> | <u>24</u> |
| <u>Other Information</u> | |
| <u>Item 6.</u> | <u>24</u> |
| <u>Exhibits</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)

| | <u>December 31,</u> <u>2017</u> | <u>September 30,</u> <u>2018</u> |
|---|------------------------------------|-------------------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 23,910 | \$ 18,973 |
| Prepaid expenses and other current assets | 2,064 | 1,696 |
| Total current assets | <u>25,974</u> | <u>20,669</u> |
| Property and equipment, net | 29 | 38 |
| Total assets | <u>\$ 26,003</u> | <u>\$ 20,707</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 1,558 | \$ 1,411 |
| Accrued and other current liabilities | 2,555 | 2,592 |
| Total current liabilities | <u>4,113</u> | <u>4,003</u> |
| Other liabilities | 124 | 106 |
| Total liabilities | <u>4,237</u> | <u>4,109</u> |
| 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. | - | - |
| 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 | <u>21,766</u> | <u>16,598</u> |
| Total liabilities and stockholders' equity | <u>\$ 26,003</u> | <u>\$ 20,707</u> |

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 September 30, | | Nine Months Ended 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 | <u>\$ (1,883)</u> | <u>\$ (2,066)</u> | <u>\$ (5,617)</u> | <u>\$ (5,273)</u> |

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, 2017 | September 30, 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 | <u>8,305,484</u> | <u>8,461,048</u> |

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 |
| | <u>\$ 2,064</u> | <u>\$ 1,696</u> |

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 |
| | <u>\$ 2,555</u> | <u>\$ 2,592</u> |

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

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 subsets. 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 | <u>\$ 958</u> | <u>\$ 1,205</u> | <u>\$ 247</u> | <u>26</u> |

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 | | Difference | |
|---|---------------------------|-------------|-------------------|----------|
| | September 30, | | | |
| | 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 September 30, | | Difference | |
|--------------------------|-------------------------------------|--------|------------|----|
| | 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 September 30, | | Difference | |
|--|--|-----------------|-------------------|----------|
| | 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 September 30, | | Difference | |
|-------------------------|------------------------------------|---------------|----------------|------------|
| | 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 | <u>\$ 901</u> | <u>\$ 828</u> | <u>\$ (73)</u> | <u>(8)</u> |

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 September 30, | | Difference | |
|--------------------------|------------------------------------|---------------|---------------|-----------|
| | 2017 | 2018 | \$ | % |
| Total income tax benefit | <u>\$ 793</u> | <u>\$ 985</u> | <u>\$ 192</u> | <u>24</u> |

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):

| | 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 Pharmaceuticals, 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

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

CLINICAL COLLABORATION AGREEMENT

This Clinical Collaboration Agreement (“Agreement”), effective as of the 21 day of August, 2018 (“Effective Date”), is entered into by and between The University of Texas M. D. Anderson Cancer Center, with a place of business located at 1515 Holcombe Blvd., Houston, TX 77030, USA (“MD Anderson”), a member institution of The University of Texas System (“System”) and Cyclacel Limited, with a place of business located at 1 James Lindsay Place, Dundee, Scotland, DD1 5JJ, United Kingdom, (“Cyclacel”) (MD Anderson and Cyclacel each a “Party,” and collectively, the “Parties”).

WITNESSETH

Whereas, Cyclacel is clinical-stage biopharmaceutical using cell cycle control, transcriptional regulation and DNA damage response biology to develop innovative, targeted medicines for cancer and other proliferative diseases and is involved in the field of research and development of such pharmaceutical products, including the sponsorship of clinical trials.

Whereas, MD Anderson is a comprehensive cancer research, treatment, and prevention center, with scientists and technicians in substantive fields relating to cancer research.

Whereas, the Parties hereby wish to establish a clinical collaboration, as further described herein, (“Collaboration”) whereby Cyclacel will provide support for one or more clinical research studies to be conducted by MD Anderson pursuant to this Agreement using Cyclacel’s drug candidates, including CYC065 and CYC140 (each, a “Cyclacel Drug Candidate,” and collectively, the “Cyclacel Drug Candidates”), each such study a “Study,” and all such Studies the “Studies”).

Whereas, MD Anderson and Cyclacel shall have the right to carry out any obligation set out in this Agreement through an Affiliate, where an “Affiliate” means any individual, MD Anderson, partnership or other entity which directly or indirectly, at present or in the future, controls, is controlled by or is under common control of a Party, and “control” will mean direct or indirect beneficial ownership of at least fifty per cent (50%) of the voting share capital in such MD Anderson or other business entity, or to hold the effective power to appoint or dismiss members of the management.

Now therefore, in consideration of the premises and the mutual covenants and conditions hereinafter recited, the Parties do hereby agree as follows:

1 Subject and Scope of Agreement

- 1.1 The Parties intend that the scope of the Collaboration will consist of the Studies included in Appendix I, attached hereto, the details of which are to be mutually agreed upon by the Parties. Cyclacel and MD Anderson agree to jointly design and write the Protocols for the Studies based on a first draft provided by Cyclacel. MD Anderson will use reasonable efforts to conduct the work under each Study. Studies may be changed as agreed upon by the Parties in writing.
-

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

- 1.2 The Agreement is a Collaboration agreement which shall govern the performance of Studies by MD Anderson and one or more Principal Investigator(s), as defined below, on the basis of Study specific documents (“Study Orders”) as agreed upon by the Parties. Once the Parties have agreed to the precise nature of each Study to be performed, MD Anderson shall review the Protocol for such Study as proposed by Cyclacel. It is understood between the Parties that the sample size of each Study will not exceed [***] Subjects unless otherwise agreed in writing by the Parties. “Subject” shall mean, as the term is defined in the U.S. Code of Federal Regulations 21 CFR §312.3(b), a human who participates in the Study, either as a recipient of the investigational new drug or as a control. Once the Protocol has been agreed and has been approved by MD Anderson’s Institutional Review Board (“Institutional Review Board” or “IRB”) under Section 2.2 below, (i) Cyclacel, as Study sponsor, shall obtain regulatory approval for the Study as required by FDA; and (ii) the detailed provisions for performance of the Study by the Parties including by MD Anderson and the MD Anderson principal investigator(s) responsible for the performance of such Study (“Principal Investigator(s)” or “Investigator(s)”), shall be set out in a Study Order to be agreed between the Parties but substantially in the form attached as Appendix III to this Agreement which shall detail the specifics of the Study to be performed under such Study Order including, without limitation, (i) the detailed Protocol, (ii) the Principal Investigator, (iii) identify any project-specific resources or support provided by Cyclacel including quantities of Cyclacel Drug Candidate and timing of delivery. Any changes to the Protocol must be agreed upon in writing in advance by Cyclacel unless necessary to protect the safety, rights or welfare of the Subjects.
- 1.3 In the event of any conflict of terms of this Agreement and the terms of a Study Order, the terms of this Agreement shall govern, unless the Study Order specifically and expressly supersedes this Agreement with respect to a specific term, and then only with respect to the particular Study Order and specific term. If there is any discrepancy or conflict between the terms contained in a Protocol and this Agreement and/or the relevant Study Order, the terms of the Protocol shall govern and control with respect to clinical and/or scientific matters and the terms of the Agreement and/or the relevant Study Order shall govern and control with respect to all other matters, e.g., legal and financial matters.

2 Responsibilities and Compliance

- 2.1 Each Study shall be subject to review and approval of the Study protocol (“Protocol”) as required by the IRB and/or any relevant authorities prior to commencement of the Study.
 - 2.2 The scope of the Study to be performed shall be set forth in the Protocol(s) referenced in the Study Order, which shall be incorporated by reference into such Study Order. These Protocol(s) shall be considered final after being agreed to by MD Anderson and Cyclacel, including approval by MD Anderson’s IRB. The Principal Investigator shall submit the Protocol and reports of the ongoing conduct of the Study to the IRB as required by the IRB, obtain written approval from the IRB, and inform the IRB of Study closure.
 - 2.3 Cyclacel is the regulatory “sponsor” of the Studies. Cyclacel shall be responsible for IND filing and will supervise monitoring for each Study. Cyclacel shall be responsible, directly or through third parties, for the preparation, filing and maintenance of all regulatory documents with respect to the Studies. The Parties shall reasonably share and exchange relevant Study information with the aim of ensuring that regulatory compliance is obtained for the Studies. Investigator shall timely have completed, signed and delivered to Cyclacel all forms, documents and regulatory documentation required by applicable law to be completed in connection with the initiation of each Study. For purposes of this Section 2.3, Investigator agrees to disclose to Cyclacel, in a timely fashion and in writing on an appropriate form, any financial arrangement or interest involving any Investigator or sub-investigator who performs services pursuant to this Agreement, or any spouse or dependent child of such person (“Investigator Personnel”) that is required to be disclosed pursuant to applicable law. Investigator shall update such disclosure as necessary to maintain its accuracy and completeness during the term of this Agreement and for any other period required by applicable law. To the extent that samples are required to be analyzed and tested as part of a Study pursuant to the Protocol, such samples shall be shipped to Cyclacel, analyzed and tested by Cyclacel or a designee in accordance with the Protocol at Cyclacel’s cost and expense. Cyclacel shall promptly provide the results and data generated from such Study samples to MD Anderson. Promptly upon MD Anderson’s request, Cyclacel shall return such samples to MD Anderson. Cyclacel and/or its designee shall not have the right to use such samples for any purpose other than testing for the Study and shall not further distribute or disclose such samples.
-

Portions of this Exhibit, indicated by the mark “[],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.***

- 2.4 MD Anderson represents that each Principal Investigator shall use reasonable efforts to conduct a Study in accordance with (a) the terms and conditions of this Agreement and the relevant Study Order, (b) the provisions of the Protocol, (c) applicable Good Clinical Practice requirements as incorporated by FDA regulations (“GCP”), and (d) any and all applicable orders and mandates of relevant authorities and IRB, and applicable MD Anderson policies. MD Anderson shall use diligent efforts to conduct the Study in accordance with specific and detailed performance milestones to be agreed between the Parties and to be set out in the Study Order. If such mutually agreed upon performance milestones are not met, MD Anderson and Cyclacel shall promptly discuss a strategy to cure the performance issues. If MD Anderson has not cured such performance issues within ninety (90) days of such discussion, Cyclacel shall have the right to expand the affected Study to other sites. The costs incurred at other sites shall not be part of this Agreement, shall not affect any aspect of this Agreement and shall be borne solely by Cyclacel. MD Anderson shall use reasonable efforts to enroll a total of approximately 170 Subjects in the Studies within three (3) years of the Effective Date.
 - 2.5 MD Anderson and Cyclacel shall comply with all federal, state, and local laws and regulations as well as ethical codes applicable to the conduct of each such Study.
 - 2.6 MD Anderson and/or Principal Investigator shall forward to Cyclacel evidence of approval of each Study by MD Anderson’s IRB. Cyclacel shall serve as “sponsor” within the meaning of such term under applicable laws and regulations and shall promptly forward to MD Anderson evidence of approval of the Study by relevant regulatory authorities (or exemption from such regulatory authority/ies review and approval).
 - 2.7 If, in the course of a Study at MD Anderson, a Subject is injured by such Subject’s participation in the Study, MD Anderson and/or Principal Investigator shall inform Cyclacel of any such injury by fax or email in case of serious and unexpected adverse reactions and/or serious and unexpected adverse events arising from the use of Study Drug Candidate(s) within the timelines stipulated in the Protocol, or if such is not stipulated in the Protocol, within ten (10) business days following MD Anderson or Principal Investigator becoming aware of such event.
 - 2.8 MD Anderson represents that: (a) it has not been debarred by the FDA pursuant to its authority under Sections 306(a) and (b) of the U.S. Food, Drug, and Cosmetic Act (21 U.S.C. § 335(a) and (b)) and is not the subject of any investigation or proceeding which may result in debarment by the FDA, and to the extent applicable, it shall not use any Principal Investigator or Study team member in the performance of a Study that has been so debarred or subject to any such investigation or proceeding, and; (b) it is not included in the List of Excluded Individuals/Entities (maintained by the U.S. Department of Health and Human Services Office of Inspector General) or the List of Parties Excluded from Federal Procurement and Non-procurement maintained by the U.S. General Services Administration, and is not the subject of any investigation or proceeding which may result in inclusion in any such list, and to the extent applicable, it shall not use any Principal Investigator or Study team member in the performance of a Study that is so included or the subject of any such investigation or proceeding. MD Anderson agrees to promptly notify Cyclacel in writing if it becomes aware of any such debarment, exclusion, investigation or proceeding of MD Anderson or, to the extent applicable, any Principal Investigator or Study team member.
-

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

- 2.9 MD Anderson and Cyclacel shall comply with all applicable federal, state and local laws pertaining to confidentiality and disclosure of all information or records obtained and reviewed in the course of the Study, and shall permit access to such information or records only as authorized by a relevant Study subject, the IRB, and as authorized by law. Each Party agrees to comply with all provisions of the Health Insurance Portability and Accountability Act (“HIPAA”) regulations (45 C.F.R. Parts 160 and 164) as to the protection and security of Protected Health Information (“PHI”). Prior to participation of each subject in a Study, MD Anderson will ensure that (a) it has obtained a signed written informed consent document from the subject (“Consent”) and (b) it has obtained a signed, written, HIPAA authorization that adequately discloses the circumstances under which the subject’s personal data might be disclosed, as applicable, and documents the subject’s express written authorization for use and disclosure of the subject’s PHI for Study purposes, as applicable, pursuant to the HIPAA regulations (“Authorization”). MD Anderson agrees to supply Cyclacel with evidence of IRB approval of the Study, a copy of the Consent form which is IRB-approved, and a copy of any modified Consent form later approved by the IRB and used by MD Anderson. To the extent permitted by the IRB, the Consent form and related Authorizations shall provide for (i) access to the Subject’s medical records by Cyclacel, its designees, and applicable regulatory agencies such as the FDA and (ii) use of de-identified Data for any purpose consistent with applicable law that Cyclacel deems appropriate. MD Anderson shall submit to Cyclacel for comment all forms of Consent forms prior to enrolling Subjects. Cyclacel will only obtain, access, use and disclose the individually identifiable health information of each Study subject in accordance with and to the extent permitted by the IRB, Consent and the Authorization document and in accordance with this Agreement and applicable laws. Cyclacel shall not transmit any information or records from a Study outside the USA except in a de-identified form.
- 2.10 MD Anderson and Cyclacel will promptly notify each other upon identifying any aspect of a Protocol, including information discovered during site monitoring visits, or Study results that may adversely affect the safety, well-being, or medical care of the Subjects, or that may affect the willingness of Subjects to continue participation in a Study, influence the conduct of the Study, or that may alter the IRB’s approval to continue the Study. MD Anderson will promptly notify the IRB of any such events. When Study subject safety or medical care could be directly affected by Study results, then notwithstanding any other provision of this Agreement, MD Anderson will send Subjects a written communication about such results.
- 2.11 Cyclacel shall promptly provide MD Anderson with any materials and documentation and all pre-clinical data reports and summaries in Cyclacel’s possession and necessary, in Cyclacel’s reasonable judgement, for MD Anderson’s conduct of the Studies.
- 2.12 MD Anderson represents and certifies: (i) that it has the legal authority to enter into this Agreement for the Studies and (ii) to the best of its knowledge, that the terms of the Studies and this Agreement do not conflict with and do not result in a breach under any agreement to which MD Anderson is a party that would have a material adverse effect on its ability to perform its obligations under this Agreement. During the term of this Agreement, MD Anderson will not enter into any agreement to provide services that would in any way result in a breach of this Agreement and materially impair its ability to complete the Studies in a timely fashion.
-

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

3 Personnel, Materials and Equipment

- 3.1 Except as set forth in this Agreement, MD Anderson shall provide all reasonable necessary personnel, facilities, and resources to accomplish its responsibilities under this Agreement and the relevant Study Order.
 - 3.2 Cyclacel agrees to promptly provide, or arrange to provide, MD Anderson with the required quantities of CYC065, CYC140 or other mutually agreed Cyclacel Drug Candidate that will be utilized and/or required in accordance with the provisions of the Protocol applicable to the Study, Collaboration Funding solely applicable to the Study, and/or support services to the extent required for the conduct of a Study as specified in the Protocol or this Agreement. Any Cyclacel Drug Candidate provided by Cyclacel will be used solely in accordance with the applicable Study and the Protocol. MD Anderson will not use such Cyclacel Drug Candidate outside of the scope of the Study. Except to a Subject, MD Anderson will not transfer the Cyclacel Drug Candidate to any third party for any purpose.
 - 3.3 It is recognized that the design of some Studies includes administration to the Subject of a Cyclacel Drug Candidate in combination with another drug (“Other Drug”). If the cost of Other Drug is not reimbursed under insurance or in any other manner, Cyclacel shall reimburse MD Anderson the costs associated with MD Anderson obtaining such Other Drug within thirty (30) days of receipt of an invoice from MD Anderson for such cost. The indication that is the subject of each Study, including if applicable, for the combination of the Other Drug and a Cyclacel Drug Candidate, shall be referred to as “Study Indication”.
 - 3.4 Cyclacel will deliver the Cyclacel Drug Candidate DAP (INCOTERMS 2010) to MD Anderson’s, or its designee’s, location as specified by MD Anderson (“Delivery” with respect to such Cyclacel Drug Candidate). Title and risk of loss for the Cyclacel Drug Candidate shall transfer from Cyclacel to MD Anderson at Delivery. MD Anderson will, or will cause its designee to: (i) take delivery of the Cyclacel Drug Candidate supplied hereunder and if applicable, promptly ship the Cyclacel Drug Candidate to the Study sites for use in the Study, in compliance with cGMP, GCP and other applicable statutes. After receipt, MD Anderson is solely responsible, at its own cost, for subsequent handling, storage, transportation, warehousing and distribution of Cyclacel Drug Candidate supplied by Cyclacel hereunder. MD Anderson shall ensure that all such activities are conducted in compliance with cGMP, GCP and other applicable law.
 - 3.5 MD Anderson or its designated agent shall, within ten (10) business days following receipt of a shipment of Cyclacel Drug Candidate hereunder, carry out a Visual Inspection (as defined below) of such shipment in association with the certificate of conformity and certificate of analysis. If following Visual Inspection MD Anderson determines in its sole discretion (exercised reasonably) that the shipment is defective or deficient it shall promptly notify Cyclacel in writing rejecting the shipment and specifying in detail the reasons therefor (“Notice of Rejection”). If MD Anderson does not notify Cyclacel in this manner within such ten (10) day period, such shipment of Cyclacel Drug Candidate shall be deemed to have been accepted by MD Anderson. For the purposes of this Agreement, “Visual Inspection” shall mean:
 - 3.5.1 comparing the shipment against the documentation accompanying the shipment to verify that the delivery date, identity, quantity and exterior shipment labelling comply;
 - 3.5.2 verifying that the certificate of analysis for the shipment states that the Cyclacel Drug Candidate conforms in all material respects to the applicable specifications and GMP;
 - 3.5.3 visually inspecting the exterior of the shipment to verify that the shipment appears to be in good condition;
-

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

3.5.4 verifying that the temperature of the shipment has remained within specification by reviewing the data logger information;
3.5.5 for the avoidance of doubt, Visual Inspection does not include laboratory analysis.

- 3.6 Upon completion of the applicable Study, any unused quantities of the applicable Cyclacel Drug Candidates (whether returned by Subjects, remaining at the conclusion of the Study, or otherwise) shall, at the direction of Cyclacel, be returned to Cyclacel or disposed of properly by MD Anderson. If Cyclacel requests that such quantities of Study Drug Candidates be destroyed, MD Anderson shall promptly destroy the same and provide to Cyclacel a certificate evidencing such destruction. If, within thirty (30) days after completion of the applicable Study, Cyclacel does not provide MD Anderson with its decision regarding whether to have the Cyclacel Drug Candidate returned or destroyed, MD Anderson shall have the right to destroy the Cyclacel Drug Candidate.
- 3.7 Decisions regarding the strategy and course of further clinical development progression of a Cyclacel Drug Candidate alone or in combination after completion of each Study shall be at the sole discretion and responsibility of Cyclacel, but in consultation with MD Anderson. Following completion of each Study the Parties and their clinical representatives including the Principal Investigator for the Study shall meet to discuss the results in good faith. If it is concluded in good faith that the results are positive, Cyclacel shall use its Commercially Reasonable Efforts to further develop and commercialize the Cyclacel Drug candidate for the Study Indication. In this Section 3.7 “Commercially Reasonable Efforts” shall mean efforts and resources commonly used by Cyclacel to develop and commercialize a product owned by it or to which it has rights, which product is at a similar stage in its development or product life and is of similar market potential to the product for the Study Indication in question and taking into account the patent and other proprietary position of the product.
- 3.8 From time to time during the term, either Party (the “Transferring Party”) may supply the other Party (the “Receiving Party”) with proprietary materials of the Transferring Party (other than Cyclacel Drug Candidate) (“Proprietary Materials”) for use in the Study as further listed in the Study Order. In connection therewith, each Receiving Party hereby agrees that: (a) the Receiving Party will not use the Proprietary Materials for any purpose other than exercising its rights or performing its obligations hereunder; (b) it will use such Proprietary Materials only in compliance with all applicable laws; (v) it will not transfer any such Proprietary Materials to any Third Party without the prior written consent of the Transferring Party; (d) it will not acquire any rights of ownership, or title in or to such Proprietary Materials as a result of such supply by the Transferring Party; and (e) upon the expiration or termination of this Agreement or a Study Order, if requested by the Transferring Party, it will destroy or return any such Proprietary Materials that are not the subject of the grant of a continuing license hereunder.
- 3.9 Nothing in this Agreement shall be construed to limit the freedom of MD Anderson or of any Principal Investigator or Study team member to engage in similar clinical trials or research performed independently under other grants, contracts, or agreements with parties other than Cyclacel.
-

*Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

4 Financials

4.1 Any costs and expenses incurred by Cyclacel in the performance of its own roles and responsibilities shall be exclusively borne by Cyclacel including clinical supply of the Cyclacel Drug Candidates, as well as costs for the Other Drug if they cannot be reimbursed (as provided in Section 3.3) and any additional laboratory costs as requested by Cyclacel at Cyclacel's sole discretion. Cyclacel will reimburse MD Anderson as specified in Sections 3.3, 4.2 and 4.3.

4.2 Cyclacel shall pay MD Anderson for research staff, including study nurse, compensation in the amount of \$[***] per contract year for three (3) years following the Effective Date payable as follows:

Effective Date: \$[***]

1st anniversary of Effective Date: \$[***]

2nd anniversary of Effective Date: \$[***]

4.3 If the cumulative total amount of Evaluable Subjects enrolled according to each Protocol on all four Studies exceeds a total of [***] Subjects, then Cyclacel will pay MD Anderson \$[***] for each additional Evaluable Subject. "Evaluable Subject" means a Subject properly enrolled in the Study and who has completed Study procedures as required by the Protocol and whose case report forms ("CRFs") have been completed.

4.4 If any given Study has more than [***] Evaluable Subjects enrolled, Cyclacel will pay MD Anderson \$[***] for each additional Evaluable Subject.

4.5 The items the subject of Sections 3.3, 4.2 and 4.3 are collectively, "Collaboration Funding". Payment for Collaboration Funding shall be due within thirty (30) days of Cyclacel's receipt of an invoice from MD Anderson. If the Parties extend the term of this Agreement by mutual agreement as set forth herein, the Parties shall negotiate in good faith the amount of future Study funding commitments by applicable to such extended term.

4.6 Cyclacel shall pay to MD Anderson the milestone payments listed in Appendix II relative to the total number of Subjects actually dosed in the three-year period (each, a "Milestone Payment"), upon achievement of the milestones listed in Section 4.6 below, regardless of whether the milestone event is achieved by Cyclacel or an Affiliate, or a licensee of Cyclacel.

4.7 Milestone event:

- Upon a Cyclacel Drug Candidate achieving first commercial Sale [***] for a Study Indication described in Study Work Order or Appendix I (this Milestone Payment will be paid up to four times);
 - Upon a Cyclacel Drug Candidate achieving first commercial Sale [***] for a Study Indication described in Study Work Order or Appendix I (this Milestone Payment will be paid up to four times);
 - Upon a Cyclacel Drug Candidate achieving first commercial Sale [***] for a Study Indication described in Study Work Order or Appendix I (this Milestone Payment will be paid up to four times);
 - Cumulative \$[***] in Sales of either or all Cyclacel Drug Candidates for Study Indications described in Study Work Order or Appendix I;
 - Cumulative \$[***] in Sales of either or all Cyclacel Drug Candidates for Study Indications described in Study Work Order or Appendix I;
 - Cumulative \$[***] in Sales of either or all Cyclacel Drug Candidates for Study Indications described in Study Work Order or Appendix I.
-

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

- 4.8 Cyclacel shall notify MD Anderson in writing immediately upon achievement of any of the foregoing milestones. Each of the foregoing Milestone Payments shall be made by Cyclacel to MD Anderson (and following receipt of an invoice from MD Anderson) within forty-five (45) calendar days of achieving the milestone event and shall not reduce the amount of any other payment provided for in this Agreement.
 - 4.9 The cumulative Sales milestones are each payable only once in respect of the Sales for all Study Indications in countries where the Cyclacel Drug Candidate is protected by valid and non-expired composition of matter patents.
 - 4.10 The amount paid in respect of milestones earned shall be subject to a cap such that in a given calendar year Cyclacel pays MD Anderson no more than [***].
 - 4.11 For purposes of this Agreement, “Sales” shall mean “Net Sales” which mean the gross amount invoiced by Cyclacel, its Affiliates, or licensees for sale of Cyclacel Drug Candidate for a Study Indication to third parties, less the following deductions attributable solely to sales of such Cyclacel Drug Candidate:
 - 4.11.1 normal and customary trade, cash and quantity discounts actually given, credits, price adjustments or allowances for damaged products, returns or rejections of products;
 - 4.11.2 chargeback payments and rebates (or the equivalent thereof) for the Cyclacel Drug Candidate granted to group purchasing organizations, managed health care organizations or to federal, state/provincial, local and other governments, including their agencies, or to trade customers;
 - 4.11.3 reasonable and customary freight, shipping insurance and other transportation expenses directly related to the sale of the Cyclacel Drug Candidate (if actually borne by Cyclacel, its Affiliates or licensees without reimbursement from any third party);
 - 4.11.4 required distribution commissions/fees payable to any third party providing distribution services to Cyclacel or its Affiliates;
 - 4.11.5 sales, value-added, excise taxes, tariffs and duties, and other taxes and government charges directly related to the sale, to the extent that such items are included in the gross invoice price of the Cyclacel Drug Candidate and actually borne by Cyclacel, its Affiliates or licensees or without reimbursement from any third party (but not including taxes assessed against the income derived from such sale).
 - 4.12 In circumstances where Cyclacel, its Affiliates or licensees further develop and commercialize a Cyclacel Drug Candidate for a Study Indication, within thirty (30) calendar days following each anniversary after completion of the last Study and until the first Milestone Payment for such Study Indication is paid, Cyclacel will, will require its Affiliate, or in the case of a licensee use reasonable efforts to require license to, deliver to MD Anderson a written progress report as to Cyclacel’s (and any Affiliate’s and licensees) efforts and accomplishments during the preceding year in relation to such development and commercialization together with commercialization plans for the upcoming year.
-

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

- 4.13 Commencing with the first sale of a Cyclacel Drug Candidate for a Study Indication by Cyclacel, an Affiliate or licensee of Cyclacel, Cyclacel shall make a written report to MD Anderson within one hundred and twenty (120) days of each Cyclacel fiscal year which ends in December, reporting the amount of all Sales received in respect of Cyclacel Drug Candidates for the Study Indication. Cyclacel shall keep accurate records and books of accounting in accordance with good accounting practice with respect to the patenting and commercialization of Study Drug Candidate (including by it, its Affiliates and licensees). Cyclacel agrees to permit a representative of MD Anderson during normal business hours to inspect any or all parts of the books, ledgers and records kept by Cyclacel which are relevant to a determination of the accuracy of any report required to be rendered to MD Anderson. If any amounts due MD Anderson are determined to have been underpaid in an amount equal to or greater than five percent (5%) of the total amount due during the period so examined, then Cyclacel will pay the cost of the examination plus accrued interest at the highest allowable rate.
- 4.14 If Cyclacel or its Affiliate licenses its rights to the Cyclacel Drug Candidates for a Study Indication, Cyclacel will diligently collect all amounts due Cyclacel from licensees.
- 4.15 All payments made pursuant to this Agreement shall be made in U.S. Dollars by wire payable to the Study Center at:

[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]

Such payments shall be made free and clear of any deduction or withholding, except that Sponsor may deduct or withhold (i) any taxes, surcharges or other governmental charges or levies that Sponsor is required by Applicable Law to deduct or withhold and (ii) any monies that are the subject of a bona fide dispute between MD Anderson and Cyclacel. All amounts paid to MD Anderson by Cyclacel, are expressed to be inclusive of any value added taxes or other similar taxes or levies that might be imposed by a governmental authority on amounts paid by Cyclacel pursuant hereto.

5 Confidential Information

- 5.1 In conjunction with each Study, the Parties may wish to disclose confidential information to each other. For purposes of this Agreement, “Confidential Information” means confidential, non-public information, know-how and data (technical or non-technical) that is disclosed in writing, orally, graphically, in machine readable form, or in any other manner by or on behalf of a disclosing Party to a receiving Party or its Affiliates for purposes of this Agreement or any Study Order (“Purpose”). For clarity, Confidential Information excludes Data as defined under Section 7.4 as there are separate provisions of this Agreement governing Data. Confidential Information may be disclosed in any form (e.g. oral, written, graphic, electronic or sample) by or on behalf of disclosing Party or its Affiliates, or may be otherwise accessible to receiving Party or its Affiliates. Exchanges of Confidential Information directly between the Affiliates are also covered by this Agreement
-

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

- 5.2 Without disclosing Party’s prior written consent, and subject always to Section 5.5, receiving Party will: (a) not use any part of or the whole of the Confidential Information for any purpose other than the Purpose; (b) restrict the dissemination of Confidential Information to individuals within its own organization and disclose the Confidential Information only to those of its officers, employees and Affiliates who have a legitimate need to have access to the Confidential Information, who will be bound by confidentiality and non-use commitments no less restrictive than those of this Agreement, and who will have been made aware of the confidential nature of the Confidential Information; (c) protect the Confidential Information by using the same degree of care, but not less than a reasonable degree of care, to prevent the unauthorized use, dissemination, or publication of the Confidential Information as receiving Party uses to protect its own confidential information of a like nature; (d) preserve the confidentiality of the Confidential Information, not disclose it to any third party, and take all necessary and reasonable precautions to prevent such information from being accessible to any third party; (e) not combine any part of or the whole of the Confidential Information with any other information; and (f) promptly notify the disclosing Party upon becoming aware of evidence or suspicion of any unauthorized use or disclosure of the Confidential Information. The foregoing obligations will exist for a period of seven (7) years from the date of completion of the last Study in relation to which the Confidential Information is disclosed or used.
- 5.3 The obligations of confidentiality and non-use listed in this Article 5 will not apply to information: (a) which is in the public domain or public knowledge at the time of disclosure, or which subsequently enters the public domain through no fault of receiving Party; (b) which was rightfully in the possession of receiving Party at the time of disclosure by disclosing Party; (c) which is independently developed by receiving Party without use of disclosing Party’s Confidential Information; (d) which the receiving Party receives legally from any third party and which is not subject to an obligation of confidentiality; (e) receiving Party is required to disclose pursuant to applicable law or the order of a court or other tribunal; provided, however, that receiving Party will make reasonable efforts, if legally permissible, to notify disclosing Party prior to the disclosure of any part of or the whole of the Confidential Information and allow disclosing Party the opportunity to contest and avoid such disclosure, and provided, further, that receiving Party will disclose only that portion of such Confidential Information that it is legally required to disclose; (f) is communicated to the receiving party’s IRB or other scientific committee; (g) is required to be disclosed in order to obtain informed consent from patients or subjects who may wish to enroll in the Study, provided, however, that the information will be disclosed only to the extent necessary and will not be provided in answer to unsolicited inquiries by telephone or to individuals who are not eligible to be Subjects; (h) is disclosed to a Subject for the safety or well-being of the Subject; or (j) is required to be disclosed in publicly filed financial or other public statements under rules governing a stock exchange provided that to the extent possible the Party making such filing shall provide the other Party a copy of the proposed text for such filing not less than two (2) business days prior to the proposed filing to enable such other Party to review the same and provide comments.
- 5.4 For the purposes of this Article 5, any combination of features disclosed to the receiving Party will not be deemed to be within the foregoing exceptions merely because individual features are. Moreover, specific disclosures made to the receiving Party will not be deemed to be within the foregoing exceptions merely because they are embraced by general disclosures.
-

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

- 5.5 The receiving Party shall also have the right to use and/or disclose Confidential Information in the following circumstances:
- (i) to its actual or potential investment bankers; (ii) to existing and potential investors in connection with an offering or placement of securities for purposes of obtaining financing for its business and to actual and prospective lenders for the purpose of obtaining financing for its business; and (iii) to a bona fide potential acquirer or merger partner for the purposes of evaluating entering into a merger or acquisition and (iv) disclose Confidential Information to its legal advisers for the purpose of seeking legal advice, provided, however, any such persons must be obligated to abide by confidentiality and non-use obligations as least as strict as set forth in Section 5 to hold in confidence and not make use of such Confidential Information for any purpose other than those permitted by this Agreement; and
- 5.6 All Confidential Information disclosed to receiving Party pursuant to this Agreement will be and remain the disclosing Party’s property. Nothing contained herein will be construed as granting to receiving Party any proprietary right on or in relation to any part of or the whole of the Confidential Information, or any right to use any of the Confidential Information except for purposes of this Agreement and the Collaboration. Receiving Party will return to disclosing Party all documents and other materials which constitute Confidential Information, as well as all copies thereof, promptly upon request or upon termination of this Agreement (whichever is earlier); provided, however, that receiving Party may keep one copy of the Confidential Information received under this Agreement in its secure files in accordance with the terms of this Agreement for the sole purpose of maintaining a record of the Confidential Information received hereunder and for compliance with this Agreement and/or applicable laws.
- 5.7 MD Anderson will not disclose any “Protected Health Information” (as such term is defined under HIPAA) to Cyclacel under this Agreement and Cyclacel will not require MD Anderson to disclose any Protected Health Information. Notwithstanding the foregoing, if Cyclacel comes into knowledge or possession of any Protected Health Information by or through MD Anderson or any information that could be used to identify any Subject or other MD Anderson patients or research subjects, Cyclacel will maintain any such Protected Health Information or other information confidential in accordance with laws and regulations as applicable to MD Anderson, including without limitation HIPAA, will use any such Protected Health Information solely to the extent permitted by applicable laws, the IRB and the Consent/Authorization of the patient/research subject, and will not use or disclose any such Protected Health Information or other information in any manner that would constitute a violation of any applicable laws or regulation if such use or disclosure was made by MD Anderson.
- 5.8 Improper use or disclosure of the Confidential Information by receiving Party is likely to cause substantial harm to disclosing Party. Therefore, in the event of a breach, threatened breach, or intended breach of this Agreement by receiving Party, in addition to any other rights and remedies available to it at law or in equity, disclosing Party will be entitled to seek preliminary and final injunctions enjoining and restraining such breach, threatened breach, or intended breach.
- 6 Clinical Data / Monitoring**
- 6.1 Oral reports or interim written status reports of the progress of the Studies will be provided by the Principal Investigator to Cyclacel no less than once per three (3) months during the course of a Study. Significant developments arising out of Studies will be communicated promptly to Cyclacel.
-

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

- 6.2 As applicable to and appropriate for a Study, Cyclacel may monitor the conduct of a Study in accordance with Good Clinical Practice requirements of FDA Regulations, and may visit MD Anderson for the purpose of such monitoring. Any such monitoring visits shall be scheduled in coordination with MD Anderson and/or Principal Investigator during normal administrative business hours, and shall be subject to compliance with MD Anderson’s reasonable measures for confidentiality, safety and security, and shall also be subject to compliance with generally applicable premises rules at MD Anderson.
- 6.3 MD Anderson and Principal Investigator shall, during a Study, permit inspections by responsible legal and regulatory authorities with respect to such Study. To the extent permitted by law and to the extent practicable, MD Anderson shall notify Cyclacel of such inspection. Upon notification of an impending inspection concerning the Study by the FDA or other regulatory authority, MD Anderson shall, to the extent permitted by law to the extent practicable notify Cyclacel immediately and shall permit representatives of Cyclacel to be present during such inspection.
- 6.4 Cyclacel and MD Anderson agree to maintain adequate and accurate records as required under Applicable Law relating to the disposition of the Cyclacel Drug Candidate and the treatment of the Subjects. Investigator specifically agrees to timely prepare and maintain complete, accurately written medical records, accounts, notes, reports, and data of all Studies performed under this Agreement, including patient CRFs, for each Subject. All Study Information will be furnished to Cyclacel or a representative of Cyclacel in a de-identified format. “Study Information” means all results, data, documents and information generated by MDACC as a result of conducting the Study, but shall not include Inventions, laboratory notebooks, source documents, patient records, business and compliance documents or any other documents that MD Anderson is required to retain per Applicable Law or its policies. Cyclacel has the right to review Subject records to verify entries in the CRFs during normal administrative business hours, and subject to compliance with MD Anderson’s reasonable measures for confidentiality, safety and security, and shall also be subject to compliance with generally applicable premises rules at MD Anderson. Cyclacel shall not at any time disclose the name of any subject or any information which identifies a Subject to a third party unless specifically required to do so by Applicable Law or the FDA. Cyclacel, MD Anderson and Investigator agree to comply with applicable FDA reporting requirements, including those related to adverse event reporting and all reporting requirements set forth in the Protocol or as required by applicable law.
- 6.5 Cyclacel and MD Anderson agree to maintain the records described in Section 6.4 above for the time period required by applicable laws. Prior to destroying or otherwise disposing of any such records, MD Anderson will provide Cyclacel a reasonable opportunity to reimburse MD Anderson to retain such records for a longer period of time or take possession of the records at Cyclacel’s own expense.

7 Data & Inventions

- 7.1 In this Section 7 (i) “Invention” means any invention or discovery, whether patentable or not, that is conceived and first reduced to practice during performance of a Study and which directly arises from the conduct of the Study; and (ii) “Research and Academic Purposes” includes, but is not limited to, all forms of research funded by MD Anderson itself, or under a grant, or in collaboration with another not-for-profit entity but expressly excludes any research funded by or in collaboration with a for-profit commercial entity.
-

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

- 7.2 MD Anderson shall promptly disclose to Cyclacel, on a confidential basis, any Inventions. MD Anderson hereby assigns to Cyclacel all its right, title and interest in and to all Inventions and it agrees to take further reasonable acts as may be reasonably required to convey ownership in all Inventions to Cyclacel, including executing, or causing its employees (including the Investigator), officers or agents to execute, any documents necessary to effectuate the foregoing, each of the foregoing, at Cyclacel’s sole cost and expense.
- 7.3 All right, title and interest in and to Inventions shall be owned solely by Cyclacel and shall be assigned to Cyclacel. Cyclacel shall grant and hereby grants to MD Anderson a non-exclusive, worldwide, perpetual, irrevocable, fully paid-up license to use Inventions for Research and Academic Purposes.
- 7.4 All data and results generated in the conduct of the Studies (“Data”) shall be promptly disclosed by MD Anderson to Cyclacel and will be owned by Cyclacel subject to MD Anderson’s right to use Data for Research and Academic Purposes as specified in Section 7.3, as well as for publication purposes. The Parties will keep the Data confidential until the earlier of (a) publication of the Data by MD Anderson, as provided in Section 12, or (b) publication of the Data by Cyclacel. Cyclacel shall promptly provide MD Anderson with a copy of any Data generated by, or on behalf of Cyclacel in connection with a Study.
- 7.5 Cyclacel shall have the first right to prepare, file, prosecute, maintain, enforce and defend all U.S. and foreign Patents, registrations and other forms of intellectual property in Inventions at the sole cost and expense of Cyclacel. Cyclacel shall keep MD Anderson reasonably informed of all such filings and the prosecution of such filings.
- 7.6 MD Anderson represents and certifies that its employees and agents (including the Investigator) are obliged to convey to MD Anderson all right, title and interest to Inventions.
- 7.7 MD Anderson shall provide assurance that no federal funding will be used by MD Anderson for the Studies.

8 Term and Termination

- 8.1 This Agreement will be effective as of the Effective Date and will remain in effect for so long as any payments are due to MD Anderson hereunder.
 - 8.2 A Party will have the right to terminate this Agreement if the other Party commits a material breach of the Agreement and fails to cure such breach within ninety (90) days of receiving notice from the non-breaching Party of such breach. Any expiration or termination of this Agreement under this Section 8 will not affect any then existing Study Orders, and any such Study Orders will continue after the expiration or termination of this Agreement in accordance with their respective provisions. Upon any expiration or termination of this Agreement, provisions of this Agreement that are incorporated by reference into any then outstanding Study Orders and all other provisions of the Agreement relevant to the conduct of a Study Order or regulating the relationship of the Parties in relation thereto will survive termination of this Agreement and will continue to apply to such Study Orders until termination or expiration of each such Study Orders.
-

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

- 8.3 A Party may terminate a Study Order: (a) if the other Party commits a material breach of the Study Order and fails to cure such breach within thirty (30) days of receiving notice from the non-breaching Party of such breach; or (b) due to health and safety concerns related to the Cyclacel Drug Candidate or procedures in the Study (including regulatory holds due to the health and safety of the Subjects). The Parties agree that any termination of a Study Order shall allow for: (i) the wind down of the Study to ensure the safety of Subjects; and (ii) Cyclacel’s final reconciliation of Data related to the Study in addition to Cyclacel’s final monitoring visit. All reasonable fees associated with the wind-down activities and final monitoring visit shall be paid by Cyclacel. Termination of one or more Study Orders will not automatically result in the termination of this Agreement or termination of any other Study Orders. Upon termination of a Study Order, MD Anderson will immediately return at Cyclacel’s cost any unused quantities of Cyclacel Drug Candidate provided by Cyclacel for such Study as directed by Cyclacel.
- 8.4 In case any regulatory or legal authorization necessary for the conduct of the Study is (i) finally rejected or (ii) withdrawn, the relevant Study Order shall terminate automatically at the date of receipt of such final rejection. Termination, relinquishment, expiration or cancellation of this Agreement or a Study Order will not affect the rights and obligations of the Parties that have accrued prior to termination relinquishment, expiration or cancellation, including, without limitation, any and all damages arising from any breach hereunder, and any provisions of this Agreement or a particular Study Order that by their nature extend beyond expiration or termination will survive the expiration or termination of this Agreement and/or that particular Study Order. In particular, the provisions of Sections 2-15as applicable will survive any expiration or termination of this Agreement.
- 8.5 In the event the Parties cannot reach agreement on a new Principal Investigator pursuant to Section 8.2 or such new Principal Investigator does not agree to the terms of this Agreement and the relevant Study Order, either Party may terminate such Study Order upon notice to the other Party.
- 8.6 In addition, in order to accommodate the review and approval of this Agreement by the Office of General Counsel of UT System (the “OGC”), for a period of sixty (60) days following the Effective Date (the “Limited Unilateral Termination Period”), MD Anderson will have the right to terminate this Agreement without cause upon ten (10) days’ notice to Cyclacel; provided, however, that (i) a termination by MD Anderson will be effective if notice of termination is sent by MD Anderson any time within the Limited Unilateral Termination Period even if the ten day notice period extends beyond the Limited Unilateral Termination Period and (ii) the Limited Unilateral Termination Period will expire on the earlier to occur of (x) the end of the sixty days, or (y) written notice to Cyclacel from MD Anderson that the Agreement has been approved by the OGC.
- 8.7 For each Study, Cyclacel shall make all payments due for Study performance reasonably incurred or obligated in good faith hereunder which have accrued up to the date of termination of a Study Order or this Agreement, or, in case of a termination of this Agreement or the relevant Study Order pursuant to Section 7.5, up to the date of receipt of such final rejection.
- 8.8 If at the time of any termination of a Study Order or this Agreement MDACC and Cyclacel shall conclude, based upon an evaluation of the risks to the Subjects, that some or all of the Subjects should not immediately be withdrawn from Cyclacel Drug Candidate treatment, the Parties will cooperate to safely withdraw Subjects from Cyclacel Drug Candidate treatment over a mutually agreeable period of time.
-

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

9 Indemnification

- 9.1 Cyclacel agrees to defend, indemnify, and hold harmless MD Anderson, System each Principal Investigator and its/their Regents, trustees, officers, directors, staff, employees, students, faculty members, and its/their Affiliates and other parties as may be listed on a Study Order (“Indemnified Party/ies”): (a) from and against any and all liability, claims, lawsuits, losses, demands, damages, costs, and expenses (“Indemnified Losses”) resulting from (i) the design or manufacture of the Cyclacel Drug Candidate or defects in the Cyclacel Drug Candidate (including failure to manufacture the Cyclacel Drug Candidate in accordance with current Good Manufacturing Practices in the United States of America), (ii) the use of the Data or results of the Study (iii) Cyclacel’s negligence or intentional misconduct in connection with a Study or this Agreement, (iv) Cyclacel’s breach of any representations and/or warranties provided hereunder, and (v) Cyclacel’s failure to comply with applicable law or regulation; (b) from and against any Indemnified Losses arising from an injury to a Subject caused by the Cyclacel Drug Candidate or any procedure required by the Protocol. The completion or termination of a Study shall not affect’s Cyclacel’s obligation to indemnify with respect to any claim or suit based upon the aforementioned Indemnified Losses. Notwithstanding the foregoing, Cyclacel will not be responsible for any Indemnified Losses to the extent that they arise from (i) non-adherence to the Protocol by any of the Indemnified Parties (except permitted deviations for health and safety reasons); or (ii) negligence, intentional misconduct, or malpractice of the Indemnified Parties, it being understood that the proper administration of the Cyclacel Drug Candidate in accordance with the Protocol (including permitted deviations for health and safety reasons) shall not constitute negligence, intentional misconduct, or malpractice for the purposes of this Agreement.
- 9.2 To the extent authorized by the constitution and laws of the State of Texas, MD Anderson, agrees to indemnify, and hold harmless Cyclacel and its/their officers, directors, staff, employees, students, and its/their Affiliates (also, “Indemnified Party”): from and against any and all Indemnified Losses resulting from (i) non-adherence to the Protocol by MD Anderson, each Principal Investigator and its/their Regents, trustees, officers, directors, staff, employees, students, faculty members, and its/their Affiliates (except permitted deviations for health and safety reasons); or (ii) the negligence, intentional misconduct, or malpractice of MD Anderson, each Principal Investigator and its/their Regents, trustees, officers, directors, staff, employees, students, faculty members, and its/their Affiliates in conducting the Study, it being understood that the proper administration of the Cyclacel Drug Candidate in accordance with the Protocol (including permitted deviations for health and safety reasons) shall not constitute negligence, intentional misconduct, or malpractice for the purposes of this Agreement. The completion or termination of a Study shall not affect MD Anderson’s obligation to indemnify with respect to any claim or suit based upon the aforementioned Indemnified Losses. Notwithstanding the foregoing, MD Anderson will not be responsible for any Indemnified Losses to the extent that they arise from the negligence, intentional misconduct, or malpractice of Cyclacel or its/their officers, directors, staff, employees, students, and its/their Affiliates.
- 9.3 Subject to the statutory duties of the Texas State Attorney General, any Indemnified Party shall: (a) notify the indemnifying Party in writing as soon as is reasonably possible after receipt of notice of any and all claims, lawsuits, and demands, or any action, suit, or proceeding giving rise to the right of indemnification; (b) permit the indemnifying Party to retain counsel to represent the named Indemnified Party; and (c) permit the indemnifying Party to retain control of any such claims, lawsuits, and demands, including the right to make any settlement, except that the indemnifying Party shall not make any settlement or take any other action which would be deemed to confess wrongdoing by any of the Indemnified Parties without the prior written consent of the applicable Indemnified Party.
-

*Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

10 Subject Injury Medical Costs

10.1 Cyclacel shall assume responsibility for reasonable medical expenses incurred by a Subject for reasonable and necessary treatment if the Subject experiences an illness, adverse event or injury that is proven to result from the administration of the Cyclacel Drug Candidate or any procedure required by the Protocol that the Subject would not have undergone were it not for such Subject's participation in the Study. Cyclacel shall not be responsible for expenses to the extent that they are (i) the result of a foreseeable side effect as expressly and specifically indicated in the Protocol, (ii) covered by the Subject's medical or hospital insurance, or any similar third-party payor providing such medical or hospital coverage (excluding Medicare, to the extent required by law), (iii) attributable to a failure of MD Anderson, or any of its personnel conducting the Study, to adhere to the terms of the Protocol, provided, however, that emergency medical care shall not be deemed a violation of the Protocol, (iv) attributable to the negligence or misconduct of MD Anderson or any of the personnel conducting the Study, including the Principal Investigator, or (v) attributable to a pre-existing abnormal medical condition or underlying disease of the Subject, or (vi) treatment that would have been provided to the Subject in the ordinary course notwithstanding participation of the Study.

11 Insurance

11.1 During the term of any Study Order under this Agreement, Cyclacel shall maintain in full force and effect insurance for its liabilities arising from the Study with limits of not less than \$[***] per loss and \$[***] annual aggregate. Cyclacel shall provide MD Anderson with evidence of such insurance upon request.

11.2 MD Anderson is self-insured pursuant to The University of Texas Professional Medical Liability Benefit Plan under the authority of Chapter 59, Texas Education Code. MD Anderson has and will maintain in force during the term of this Agreement adequate insurance or financial resources to cover its obligations pursuant to this Agreement.

12 Publications

12.1 Publication or public disclosure of Study results may be based on the entire Study or Study interim results but shall occur only after Study results have been provided to Cyclacel with an opportunity to review. In light of the critical importance of such results to Cyclacel's survival and success and the Parties extensive history of joint publications, the Parties will jointly agree in good faith with respect to the Study manuscript, abstracts/presentations at meetings and such publication and the journal submission strategy.

12.2 Any such communication, presentation or publication by MD Anderson shall not contain Confidential Information, other than Study Information, Study results or Data. Investigator may not disclose to third parties or otherwise make public the raw data or CRFs obtained in the Study with respect to any proposed publication or presentation of the Study.

12.3 With respect to any proposed publication or presentation of the Study results pursuant to Section 12.1 above, Investigator will submit to Cyclacel a copy of the proposed publication or presentation and the name of the scientific journal or forum to which the proposed publication or presentation will be submitted at least sixty (60) days prior to the submission thereof for publication or presentation. Investigator shall comply with Cyclacel's request to delete references to Confidential Information, other than Study information, Study results or Data, in any such publication or presentation, and agrees to delay publication or presentation of the same for up ninety (90) additional days, in order to permit Cyclacel to obtain patent protection or other similar protection as Cyclacel deems it necessary.

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

- 12.4 MD Anderson and/or Principal Investigator shall give Cyclacel acknowledgment for its sponsorship of a Study in all applicable Study publications. Authorship and acknowledgements for scientific publications shall be consistent with the principles embodied in the International Committee of Medical Journal Editors (“ICMJE”) Uniform Requirements for Manuscripts.
- 12.5 Cyclacel shall register the Study if required by, and in accordance with, Section 801 of the Food and Drug Administration Amendments Act of 2007 on www.clinicaltrials.gov and on any other database required by laws or regulations in accordance with applicable standards regarding scope, form and content and in accordance with ICMJE guidelines such that the Study will be eligible for publication in those publications.

13 Use of Name/Public Statements/Disclosure

- 13.1 Except as expressly set forth in this Agreement, each Party agrees that it will not at any time during the term of this Agreement or following termination of this Agreement use any name of the other Party or any other names, insignia, mark(s), symbol(s), or logotypes associated with the other Party or any variant or variants thereof in any advertising, or promotional materials without the prior written consent of the other Party.
- 13.2 Except as expressly set forth in this Agreement, to the extent required by law or regulation, or to the extent necessary for MD Anderson for the recruitment of subjects to any Study hereunder, the Parties agree to make no public presentations about any Cyclacel Drug Candidate or any Study conducted under this Agreement. Any advertisements directed at recruitment of study subjects for a Study must comply with all applicable laws, rules and regulations (including the need for IRB review), the confidentiality obligations herein, and shall not include the trademarked insignia, symbol(s), or logotypes, or any variant or variants thereof, of the other Party. Except as required by law or for regulatory purposes, neither Party will use the name (including trademark or other identifier) of the other Party or such other Party’s employee or staff member (except in an acknowledgment of sponsorship) in publications, advertising, press releases or for any other commercial purpose without the written approval of the other Party. Cyclacel will not state or imply in any publication, advertisement, or other medium that any Cyclacel Drug Candidate or service bearing any of Cyclacel’s names or trademarks and/or manufactured, sold or distributed by Cyclacel has been tested, approved, or endorsed by MD Anderson.
- 13.3 Either Party may use the name of the other Party in any document filed with any governmental authority or regulatory agency applicable to a Study, and to comply with any applicable legal or regulatory requirements. Further, each Party is permitted to disclose the other Party’s name, the title of the Study, the name of the Principal Investigator, and an overall Study Budget amount projected to be paid/actual total amount paid for conducting the Study, provided that this information is presented together as part of mandatory disclosure in accordance with and to the extent required applicable law.

14 Principal Investigator

- 14.1 If a designated Principal Investigator resigns from or otherwise leaves MD Anderson, or in the event of the death, chronic illness or other non-availability of the Principal Investigator, MD Anderson shall use reasonable efforts to designate a duly qualified person to act as new Principal Investigator, subject to the reasonable agreement of Cyclacel. If the Parties are unable to agree on a new Principal Investigator or if the new Principal Investigator is unwilling to agree to the terms and conditions of this Agreement and the relevant Study Order, either Party shall be entitled to terminate the respective Study Order in accordance with Section 8.5.
-

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

15 General Provisions

15.1 Cyclacel hereby represents and warrants that:

- (a) It is duly authorized, by all requisite corporate action, to execute and deliver this Agreement and to perform its obligations hereunder and thereunder;
- (b) this Agreement, and the execution and delivery hereof constitute legal, valid and binding obligations of Cyclacel that are enforceable against it in accordance with their terms;
- (c) the execution, delivery and performance of this Agreement by Cyclacel does not violate any agreement or instrument to which Cyclacel is a party or by which Cyclacel is bound and does not violate any applicable law
- (d) it will perform its obligations in accordance with applicable laws.

EXCEPT AS EXPRESSLY PROVIDED HEREIN, NEITHER PARTY MAKES ANY WARRANTIES, EXPRESS OR IMPLIED, CONCERNING THE DATA OR RESULTS OF ANY STUDY OR THE CYCLACEL DRUG CANDIDATE, OR OF THE MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF SUCH DATA, RESULTS OR CYCLACEL DRUG CANDIDATE. NEITHER PARTY SHALL BE LIABLE FOR ANY INDIRECT OR CONSEQUENTIAL DAMAGES SUFFERED BY THE OTHER PARTY AS A RESULT OF PERFORMANCE OF ANY STUDY UNDER THIS AGREEMENT. Notwithstanding the foregoing, Cyclacel represents and warrants that each Cyclacel Drug Candidate hereunder shall have been manufactured in accordance with applicable current Good Manufacturing Practices in the United States and that it has not received any claim that use of any Cyclacel Drug Candidate in the performance of a Study would infringe the rights of any third party Recognising that each Cyclacel Drug Candidate is an investigational drug, and that the results of any study are unpredictable, at the Effective Date Cyclacel represents that it knows of no defects in a Cyclacel Drug Candidate that cause personal injury going beyond known side effects. Cyclacel understands and acknowledges that the development and dissemination of scientific knowledge is a fundamental component of MD Anderson’s mission, and that MD Anderson makes no representations, warranties, or guarantees with respect to any specific results of the Studies.

- 15.2 Assignment. This Agreement and/or any Study Order may not be assigned by either Party except as agreed upon in writing by the other Party provided always that either Party may assign this Agreement in whole or in part to a corporate Affiliate on reasonable prior written notice to the other Party of such assignment on the condition that the assigning Party shall remain liable hereunder for the prompt payment and performance of all obligations of the assignee; (ii) this Agreement may be assigned by a Party to a third party in connection with a sale or transfer of all or substantially all of such Party’s business or assets to which this Agreement relates or in connection with a merger or consolidation transaction involving such third party provided always that such third party gives a written deed of undertaking to the non-affected Party agreeing to abide by all the obligations under this Agreement of the assigning Party. Any assignment or attempt to assign not in accordance with this Section shall be void and without effect.
- 15.3 Independent Contractors. MD Anderson and Cyclacel shall be independent parties and nothing contained in this Agreement shall be construed or implied to create an agency or partnership. No Party shall have the authority to agree to or incur expenses on behalf of another except as may be expressly authorized by this Agreement or a Study Order.
-

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

- 15.4 Notices. Any notice or communication required or permitted to be given or made under this Agreement by one of the Parties hereto to the other shall be in writing and shall be deemed to have been sufficiently given or made for all purposes on the date of mailing by certified mail, postage prepaid, overnight courier service, and/or fax to be followed by mailed original addressed to such other Party at its respective address as referenced in the Study Order.
 - 15.5 Severability. If any one or more of the provisions of this Agreement shall be held to be invalid, illegal or unenforceable, the validity, legality or enforceability of the remaining provisions of this Agreement shall not in any way be affected or impaired thereby.
 - 15.6 Entirety. This Agreement represents the entire agreement of the Parties with respect to the subject matter hereof and it expressly supersedes all previous written and oral communications between the Parties. No amendment, alteration, or modification of this Agreement or any Study Orders attached hereto shall be valid unless executed in writing by authorized signatories of all Parties.
 - 15.7 Waiver. The failure of any Party hereto to insist upon strict performance of any provision of this Agreement or to exercise any right hereunder will not constitute a waiver of that provision or right.
 - 15.8 Force Majeure. In the event that performance of the obligations of a Party hereunder are prevented by events beyond their reasonable control, including, but not limited to, acts of God, regulations or acts of any governmental authority, war, civil commotion, strikes, or other labor disturbances, epidemics, fire, earthquakes, storms or other catastrophes of a similar nature, the affected Party will promptly notify the other Party of such event using the procedure defined herein, and the Parties shall be relieved of their respective obligations hereunder to the extent that the performance of such obligations is actually prevented thereby. During the existence of any such condition, the affected Party shall, nevertheless, use its best efforts to remove the cause thereof and resume performance of its obligations hereunder. The period of performance shall be extended for the Party who is unable to perform due to Force Majeure reasons by a period of time equal to the length of the period during which the Force Majeure reason exists or for a longer period if required to meet the requirements of the Study Protocol.
 - 15.9 Counterparts. It is understood that this Agreement may be executed in one or more counterpart copies, each of equal dignity, which when joined, shall together constitute one Agreement. In the event of execution by exchange of facsimile or electronic signed copies, the Parties agree that, upon being signed by both Parties, this Agreement shall become effective and binding and that facsimile or .pdf signed copies will constitute evidence of this Agreement.
 - 15.10 Export Control. Notwithstanding any other provision of this Agreement, it is understood that the Parties are subject to, and shall comply with, applicable United States laws, regulations, and governmental requirements and restrictions controlling the export of technology, technical data, computer software, laboratory prototypes, and other commodities, information and items (individually and collectively, “Technology and Items”), including without limitation, the Arms Export Control Act, the Export Administration Act of 1979, relevant executive orders, and United States Treasury Department embargo and sanctions regulations, all as amended from time to time (“Restrictions”) and that the Parties’ obligations hereunder are contingent on compliance with applicable Restrictions.
-

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

15.11 Choice of Law. Any disputes or claims arising under this Agreement shall be governed by the laws of the State of Texas. MD Anderson is an agency of the State of Texas and under the constitution and the laws of the State of Texas possesses certain rights and privileges, is subject to certain limitations and restrictions, and only has such authority as is granted to it under the constitution and laws of the State of Texas. Notwithstanding any provision hereof, nothing in this Agreement is intended to be, nor will it be construed to be, a waiver of the sovereign immunity of the State of Texas or a prospective waiver or restriction of any of the rights, remedies, claims, and privileges of the State of Texas. Moreover, notwithstanding the generality or specificity of any provision hereof, the provisions of this Agreement as they pertain to MD Anderson are enforceable only to the extent authorized by the constitution and laws of the State of Texas; accordingly, to the extent any provision hereof conflicts with the constitution or laws of the State of Texas or exceeds the right, power or authority of MD Anderson to agree to such provision, then that provision will not be enforceable against MD Anderson or the State of Texas.

In witness whereof, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives to be effective as of the Effective Date.

The University of Texas M. D. Anderson Cancer Center Cyclacel Limited

Date: _____

Date: _____

Name
Title:

Name
Title:

21 August 2018

*Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

Appendix I

Four studies planned; the listed studies are subject to Principal Investigator/Cyclacel discussion and may vary from the final protocols agreed

1. CYC065 and venetoclax in relapsed/refractory CLL
 2. [***]
 3. [***]
 4. CYC140 first-in-human study in relapsed/refractory AML or MDS
-

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

Appendix II

MILESTONE AND SALES PAYMENTS

*Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

Appendix III

CLINICAL COLLABORATION AGREEMENT - STUDY ORDER

This Study Order ("Study Order"), effective as of the ___ day of XXXX ("Effective Date"), is entered into by and between The University of Texas MD Anderson Cancer Center, with a place of business located at 1515 Holcombe Blvd., Houston, TX 77030, USA ("MD Anderson"), a member institution of The University of Texas System ("System") and Cyclacel Limited, with a place of business located at 1 James Lindsay Place, Dundee, Scotland, DD1 5JJ, United Kingdom, ("Cyclacel"). (MD Anderson and Cyclacel each a "Party" and collectively the "Parties"). This Study Order is a part of, and is subject to, the terms and conditions of the Clinical Collaboration Agreement entered into between MD Anderson and dated August ___ 2018 ("Agreement").

1. The Parties enter into this Study Order in connection with:

The Study entitled _____, to be conducted pursuant

to Protocol No. [**Insert Protocol number**] which may be attached hereto in Exhibit A and is incorporated herein.

2. _____ is the Principal Investigator (as defined in the Agreement) for the Study which will be conducted at MD Anderson.

Cyclacel Drug Candidate for the above referenced Study is _____.

Other Drug for the above referenced Study is _____.

The Study Indication is XXXXXXX

The quantity and delivery dates of Cyclacel Drug Candidate are XXXX

[if applicable] The quantity and delivery dates of Other Drug are XXXX

3. The parties may further exchange the following Proprietary Materials (other than Cyclacel Drug Candidate) with each other in connection with the Study:

_____ being provided by [Insert name of providing party]

_____ being provided by [Insert name of providing party]

4. Term: This Study Order will continue until the Study is completed, which is expected to be (__) months after the Effective Date, or until terminated early as provided in the Agreement.

5. Notices.

Any notice or other formal communication related to this Agreement must be in writing and will be deemed given only if: (a) delivered in person; or (b) sent by internationally recognized overnight delivery service or air courier guaranteeing next day delivery. Until a change of address is communicated, as provided below, all notices and other communications must be sent to the Parties at the following addresses or facsimile numbers:

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

If to MD Anderson:

The University of Texas
MD Anderson Cancer Center
1515 Holcombe Boulevard, Box 1643
Houston, TX 77030
Attn: Vice President, Strategic Industry Ventures

With a copy to:

The University of Texas
MD Anderson Cancer Center
Legal Services—Unit 1674
PO Box 301407
Houston, TX 77230-1407
Attn: Chief Legal Officer

And to:

[insert investigator information]

If to Cyclacel Limited:

Cyclacel Limited
1 James Lindsay Place
Dundee, Scotland, DD1 5JJ
United Kingdom
Attn: Chief Operating Officer

With a copy to:

Cyclacel Pharmaceuticals, Inc.
200 Connell Drive #1500
Berkeley Heights, NJ 07922
Attn: Chief Executive Officer

All notices will be effective and will be deemed delivered: (a) if by personal delivery, delivery service or courier, on the date of delivery; and (b) if by electronic facsimile communication, on the date of transmission of the communication. Either Party may change its notice address by sending notice of the change to the other Party in the manner set forth above.

6. Specific superseding terms: N/A.

[Signatures on Following Page]

*Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

In witness whereof, the Parties hereto have caused this Study Order to be executed by their duly authorized representatives to be effective as of the Effective Date.

The University of Texas M. D. Anderson Cancer

Cyclacel Limited Center

Date: _____

Date: _____

Name
Title:

Name
Title:

READ AND UNDERSTOOD:

I confirm that I have received a copy of the Agreement under which this Study Order is issued, and that I have read and understand the Agreement and this Study Order.

Principal Investigator

Date: _____

Name

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

Exhibit A

[Protocol]

**Certification of Principal Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Spiro Rombotis, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the three months ended September 30, 2018 of Cyclacel Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2018

/s/ Spiro Rombotis

Spiro Rombotis
President & Chief Executive Officer
(Principal Executive Officer)

**Certification of Principal Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Paul McBarron, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the three months ended September 30, 2018 of Cyclacel Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2018

/s/ Paul McBarron

Paul McBarron
Chief Operating Officer, Chief Financial Officer
and Executive Vice President, Finance
(Principal Financial Officer)

**Certification of Principal Executive Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

Pursuant to 18 U.S.C. s 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Cyclacel Pharmaceuticals, Inc. (the "Company") hereby certifies, to such officer's knowledge, that:

- (i) the Quarterly Report on Form 10-Q of the Company for the three months ended September 30, 2018 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 13, 2018

/s/ Spiro Rombotis

Spiro Rombotis
President & Chief Executive Officer

**Certification of Principal Financial Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

Pursuant to 18 U.S.C. s 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Cyclacel Pharmaceuticals, Inc. (the "Company") hereby certifies, to such officer's knowledge, that:

- (i) the Quarterly Report on Form 10-Q of the Company for the three months ended September 30, 2018 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 13, 2018

/s/ Paul McBarron

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