Cyclacel Pharmaceuticals, Inc.
Form 10-Q
May 14, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2018

OR

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

Commission file number 000-50626

CYCLACEL PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**91-1707622**

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

200 Connell Drive, Suite 1500 Berkeley Heights, New Jersey	**07922**
(Address of principal executive offices)	(Zip Code)

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

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

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

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

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

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

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

Emerging growth company ¨

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

As of May 11, 2018 there were 11,997,447 shares of the registrant's common stock outstanding.

CYCLACEL PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

CYCLACEL PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

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

(Unaudited)

	December 31, 2017	March 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,910	$21,725
Prepaid expenses and other current assets	2,064	3,007
Total current assets	25,974	24,732
Property and equipment, net	29	45
Total assets	$ 26,003	$24,777
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,558	$1,949
Accrued and other current liabilities	2,555	2,309
Total current liabilities	4,113	4,258
Other liabilities	124	124
Total liabilities	4,237	4,382
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2017 and March 31, 2018; 6% Convertible Exchangeable preferred stock; 335,273 shares issued and outstanding at December 31, 2017 and March 31, 2018. Aggregate preference in liquidation of $4,006,512 as of December 31, 2017 and March 31, 2018.	-	-
Series A convertible preferred stock; 264 shares issued and outstanding at December 31, 2017 and March 31, 2018.	-	-
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2017 and March 31, 2018; 11,997,447 shares issued and outstanding at December 31, 2017 and March 31, 2018.	12	12
Additional paid-in capital	365,057	365,086

Accumulated other comprehensive (loss)	(794)	(846)
Accumulated deficit	(342,509)	(343,857)
Total stockholders' equity	21,766	20,395
Total liabilities and stockholders' equity	$ 26,003	$24,777

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 March 31,	
	2017	2018
Revenues:		
Total revenues	$—	$—
Operating expenses:		
Research and development	1,312	798
General and administrative	1,381	1,364
Total operating expenses	2,693	2,162
Operating loss	(2,693)	(2,162)
Other income (expense):		
Foreign exchange (losses)	(59)	(4)
Interest income	12	69
Other income, net	879	566
Total other income, net	832	631
Loss before taxes	(1,861)	(1,531)
Income tax benefit	306	182
Net loss	(1,555)	(1,349)
Dividend on convertible exchangeable preferred shares	(50)	(50)
Net loss applicable to common stockholders	$(1,605)	$(1,399)
Basic and diluted earnings per common share:		
Net loss per share – basic and diluted	$(0.38)	$(0.12)
Weighted average common shares outstanding	4,271,324	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 March 31,	
	2017	2018
Net loss	$ (1,555)	$ (1,349)
Translation adjustment	(1,940)	(6,328)
Unrealized foreign exchange gain on intercompany loans	1,935	6,276
Comprehensive loss	$ (1,560)	$ (1,401)

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

CYCLACEL PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In $000s)

(Unaudited)

	Three Months Ended March 31,	
	2017	2018
Operating activities:		
Net loss	$ (1,555)	$ (1,349)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	9	7
Stock-based compensation	69	81
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,137)	(876)
Accounts payable and other current liabilities	(1,196)	(2)
Net cash used in operating activities	(3,810)	(2,139)
Investing activities:		
Purchase of property, plant and equipment	(2)	(22)
Net cash used in investing activities	(2)	(22)
Financing activities:		
Proceeds from issuance of common stock, net of issuance costs	86	—
Payment of preferred stock dividend	(50)	(50)
Net cash provided by / (used in) financing activities	36	(50)
Effect of exchange rate changes on cash and cash equivalents	(15)	26
Net decrease in cash and cash equivalents	(3,791)	(2,185)
Cash and cash equivalents, beginning of period	16,520	23,910
Cash and cash equivalents, end of period	$ 12,729	$ 21,725
Supplemental cash flow information:		
Cash received during the period for:		
Interest	12	69
Taxes	8	—
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 March 31, 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 March 31, 2018, the consolidated statements of operations, comprehensive loss and cash flows for the three months ended March 31, 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 March 31, 2018, and the results of operations, comprehensive loss and cash flows for the three months ended March 31, 2018, have been made. The interim results for the three months ended March 31, 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 $21.7 million as of March 31, 2018 will be sufficient to fund its operating expenses and capital expenditure requirements through to the first 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 first 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 the transcriptional regulation program, evaluating CYC065 in patients with advanced cancers or the DNA damage response program, evaluating a sequential regimen of sapacitabine and seliciclib in patients with BRCA positive, advanced solid cancers. Additional funding may not be available to the Company on favorable terms, or at all. If the Company is unable to obtain additional funds, it will need to reduce operating expenses, enter into a collaboration or other similar arrangement with respect to development and/or commercialization rights to its CDK inhibitors or sapacitabine, if available, or be forced to delay or reduce the scope of its CDK inhibitors and sapacitabine development programs, including any potential regulatory filings related to the SEAMLESS study, and/or limit or cease its operations. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies.

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 ended March 31, 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 is described below. The comparative financial information for the three months ended March 31, 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 the 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 the 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 contra against 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; (1) identify the contract with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when, or as, the Company satisfies a performance obligation. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts.

The 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.

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 other income. 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 must be adopted on a modified retrospective transition approach for leases existing, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The Company is currently evaluating the impact of the guidance on the consolidated financial statements.

3. Revenue

Revenue recognized in the three months ended March 31, 2018 was $nil and contract liability as of December 31, 2017 and March 31, 2018 was $150,000 and is included in Accrued and other current liabilities on the accompanying balance sheets.

The aggregate transaction price that is allocated to performance obligations that are unsatisfied (or partially unsatisfied) as of March 31, 2018 was $nil.

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 months ended March 31, 2017 and 2018, as the result would be anti-dilutive:

	March 31, 2017	March 31, 2018
Stock options	387,519	708,400
Convertible preferred stock	1,698	1,698
Series A preferred stock	-	132,000
Common stock warrants	-	7,490,500
Total shares excluded from calculation	389,217	8,332,598

5. Prepaid Expenses and Other Current Assets

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

	December 31, 2017	March 31, 2018
Research and development tax credit receivable	$ 1,054	$ 1,278
Prepayments and VAT receivable	772	1,045
Other current assets	238	684
	$ 2,064	$ 3,007

Included in current assets as at March 31, 2018 is approximately $0.6 million of receivables. This relates to royalty payments receivable due 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 $0.6 million of other income arising from sales of chimeric antigen receptor T cell manufacturing technology (CAR-T) related to this transaction during the three months ended March 31, 2018.

6. Accrued and Other Liabilities

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

	December 31, 2017	March 31, 2018
Accrued research and development	$ 1,645	$ 1,601
Accrued legal and professional fees	248	416
Other current liabilities	662	292
	$ 2,555	$ 2,309

Other current liabilities at March 31, 2018 includes $150,000 of contract liabilities 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 months ended March 31, 2017 and 2018 as shown in the following table (in $000s):