Cyclacel Pharmaceuticals, Inc.
Form 10-Q
November 12, 2014

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 September 30, 2014

OR

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

Commission file number 0-50626

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

07922

Berkeley Heights, New Jersey

(Address of principal executive offices) (Zip Code)

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

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

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

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

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

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

As of November 11, 2014 there were 22,976,475 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.

CONDENSED CONSOLIDATED BALANCE SHEETS

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

	December 31, 2013	September 30, 2014 (Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,146	$ 26,707
Prepaid expenses and other current assets	3,388	4,202
Current assets of discontinued operations	639	267
Total current assets	35,173	31,176
Property and equipment (net)	275	454
Long-term assets of discontinued operations	72	—
Total assets	$ 35,520	$ 31,630
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,545	$ 2,201
Accrued and other current liabilities	4,431	4,490
Other liabilities measured at fair value	20	—
Current liabilities of discontinued operations	260	75
Total current liabilities	7,256	6,766
Other liabilities	241	221
Total liabilities	7,497	6,987
Commitments and contingencies	—	—
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2013 and September 30, 2014; 335,273 shares issued and outstanding at December 31, 2013 and September 30, 2014. Aggregate preference in liquidation of $3,989,749 at December 31, 2013 and September 30, 2014.	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2013 and September 30, 2014; 19,369,332 and 22,676,475 shares issued and outstanding at December 31, 2013 and September 30, 2014, respectively.	19	23
Additional paid-in capital	317,543	328,943

Accumulated other comprehensive loss	(109)	(305)
Accumulated deficit	(289,430)	(304,018)
Total stockholders' equity	28,023	24,643
Total liabilities and stockholders' equity	$ 35,520	$ 31,630

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

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CYCLACEL PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2014	2013	2014
Revenues:				
Grant revenue	$309	$735	$785	$1,487
Total revenues	309	735	785	1,487
Operating expenses:				
Research and development	4,575	4,972	8,786	13,861
General and administrative	1,529	1,433	5,999	4,281
Total operating expenses	6,104	6,405	14,785	18,142
Operating loss	(5,795)	(5,670)	(14,000)	(16,655)
Other income (expense):				
Change in valuation of financial instruments associated with stock purchase agreement	—	(4)	—	(115)
Change in valuation of Economic Rights	—	—	570	—
Change in valuation of liabilities measured at fair value	—	—	—	20
Foreign exchange gains (losses)	25	10	44	(23)
Interest income	8	3	12	5
Other income, net	16	—	5,520	26
Total other income (expense)	49	9	6,146	(87)
Loss from continuing operations before taxes	(5,746)	(5,661)	(7,854)	(16,742)
Income tax benefit	730	750	1,218	2,135
Net loss from continuing operations	(5,016)	(4,911)	(6,636)	(14,607)
Discontinued operations:				
Income from discontinued operations	20	6	70	29
Income tax on discontinued operations	(8)	(2)	(28)	(10)
Net income from discontinued operations	12	4	42	19
Net loss	(5,004)	(4,907)	(6,594)	(14,588)
Deemed dividend on convertible exchangeable preferred shares	(661)	—	(9,027)	—
Dividend on convertible exchangeable preferred shares	(63)	(50)	(248)	(150)
Net loss applicable to common shareholders	$(5,728)	$(4,957)	$(15,869)	$(14,738)
Basic and diluted earnings per common share:				
Net loss per share, continuing operations	$(0.32)	$(0.22)	$(1.15)	$(0.68)
Net income per share, discontinued operations	$0.00	$0.00	$0.00	$0.00
Net loss per share applicable to common shareholders	$(0.32)	$(0.22)	$(1.15)	$(0.68)

Weighted average shares of common stock outstanding	17,788,568	22,676,475	13,850,792	21,607,888

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

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CYCLACEL PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In $000s)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2014	2013	2014
Net loss from continuing operations	$ (5,016)	$ (4,911)	$ (6,636)	$ (14,607)
Net income from discontinued operations	12	4	42	19
Net loss	(5,004)	(4,907)	(6,594)	(14,588)
Translation adjustment	(6,985)	6,214	(347)	2,134
Unrealized foreign exchange gain (loss) on intercompany loans	6,818	(6,422)	127	(2,330)
Comprehensive loss	$ (5,171)	$ (5,115)	$ (6,814)	$ (14,784)

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

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CYCLACEL PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
(In $000s)
(Unaudited)

	Nine Months Ended September 30,	
	2013	2014
Operating activities:		
Net loss	$ (6,594)	$ (14,588)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in valuation of liabilities measured at fair value	(1,120)	(20)
Change in valuation of financial instruments associated with stock purchase agreement	—	115
Depreciation	58	115
Gain on sale of patents	(5,500)	—
Stock-based compensation	244	589
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(746)	(842)
Accounts payable and other current liabilities	837	(403)
Net cash used in operating activities	(12,821)	(15,034)
Investing activities:		
Purchase of property, plant and equipment	(99)	(302)
Minimum royalty payments received from termination of ALIGN license agreement	264	288
Proceeds from sale of patents	5,500	—
Net cash provided by (used in) investing activities	5,665	(14)

Financing activities:		
Proceeds from issuance of common stock, net of issuance costs	25,636	10,965
Payment of preferred stock dividend	(255)	(150)
Net cash provided by financing activities	25,381	10,815
Effect of exchange rate changes on cash and cash equivalents	(150)	(206)
Net increase (decrease) in cash and cash equivalents	18,075	(4,439)
Cash and cash equivalents, beginning of period	16,412	31,146
Cash and cash equivalents, end of period	$ 34,487	$ 26,707
Supplemental cash flow information:		
Cash received during the period for:		
Interest	9	5
Taxes	970	1,811
Schedule of non-cash transactions:		
Issuance of Ordinary shares in lieu of cash bonus	181	—

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

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CYCLACEL PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Nature of Operations

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

Cyclacel's clinical development priorities are focused on sapacitabine, an orally available, cell cycle modulating nucleoside analogue.

Sapacitabine is being evaluated in the SEAMLESS Phase 3 study being conducted under a Special Protocol Assessment ("SPA") agreement with the US Food and Drug Administration ("FDA") for the front-line treatment of acute myeloid leukemia ("AML") in the elderly and in Phase 2 studies for AML, myelodysplastic syndromes ("MDS"), non-small cell lung cancer ("NSCLC") and chronic lymphocytic leukemia. Sapacitabine is also being evaluated in a Phase 1 study in combination with seliciclib, the Company's second clinical candidate, in patients with solid tumors, in particular those carrying gBRCA mutations. The FDA and the European Medicines Agency ("EMA") have designated sapacitabine as an orphan drug for the treatment of both AML and MDS.

In Cyclacel's second development program, the Company is evaluating cyclin dependent kinase, or CDK, inhibitors. CDKs are involved in cancer cell growth, metastatic spread and DNA damage repair. Seliciclib, the Company's most advanced CDK inhibitor, is an oral, highly selective inhibitor of CDK enzymes. To date, seliciclib has been evaluated in several Phase 1 and 2 studies in various cancers, including NSCLC and nasopharyngeal cancer ("NPC"), and has shown signs of anti-cancer activity. Seliciclib will also be evaluated in an investigator-initiated clinical study to treat rheumatoid arthritis ("RA") supported by an approximately $1.5 million grant from the United Kingdom's Medical Research Council.

Cyclacel's second generation CDK inhibitor, CYC065, is an oral, highly selective inhibitor of CDK enzymes. CYC065 has been shown to have increased anti-proliferative potency and improved pharmaceutical properties compared to seliciclib. Investigational new drug ("IND") enabling studies with CYC065 have been completed with support from a $1.9 million grant from the Biomedical Catalyst of the United Kingdom government.

In addition to these development programs, in Cyclacel's polo-like kinase ("PLK") inhibitor program, the Company has discovered CYC140 and other potent and selective small molecule inhibitors of PLK1, a kinase active during cell division, targeting the mitotic phase of the cell cycle. PLK was discovered by Professor David Glover, the Company's Chief Scientist. The Company has received a grant award of approximately $3.7 million from the Biomedical Catalyst of the United Kingdom government to complete IND-directed preclinical development of CYC140.

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

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

Capital Resources

The Company's existing capital resources are expected to be sufficient to take the Company beyond the completion of the SEAMLESS Phase 3 trial but not sufficient to complete development of other indications or product candidates or to commercialize any of the Company's product candidates.

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Basis of Presentation

The condensed consolidated balance sheet as of September 30, 2014, the condensed consolidated statements of operations, comprehensive loss, and cash flows for the three and nine months ended September 30, 2013 and 2014 and all related disclosures contained in the accompanying notes are unaudited. The condensed consolidated balance sheet as of December 31, 2013 is derived from the audited consolidated financial statements included in the 2013 Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC"). The condensed 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 condensed consolidated balance sheet as of September 30, 2014, and the results of operations, comprehensive loss and cash flows for the three and nine months ended September 30, 2014, have been made. The interim results for the three and nine months ended September 30, 2014 are not necessarily indicative of the results to be expected for the year ending December 31, 2014 or for any other year. The condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the accompanying notes for the year ended December 31, 2013, included in the Company's Annual Report on Form 10-K filed with the SEC.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

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

Reclassification

Certain amounts in prior period financial statements have been reclassified to conform to current period financial statement presentation. On the consolidated balance sheet as of December 31, 2013, certain amounts have been

reclassified from “Accrued and other current liabilities” to “Other liabilities.”

Risks and Uncertainties

Drug candidates developed by the Company typically will require approvals or clearances from the FDA or other international regulatory agencies prior to commercial sales. There can be no assurance that the Company’s drug candidates will receive any of the required approvals or clearances. If the Company was denied approval or clearance or such approval was delayed, or is unable to obtain the necessary financing to complete development and approval, there will be a material adverse impact on the Company’s financial condition and results of operations.

Cash and Cash Equivalents

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

Fair Value of Financial Instruments

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

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Revenue Recognition

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

Clinical Trial Accounting

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

Research and Development Expenditures

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

Foreign Currency and Currency Translation

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

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

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

Income Taxes

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

The Company applies the accounting guidance codified in ASC 740 "Income taxes" ("ASC 740") related to accounting for uncertainty in income taxes. ASC 740 specifies the accounting for uncertainty in income taxes recognized in a company's financial statements by prescribing a minimum probability threshold a tax position is required to meet before being recognized in the financial statements.

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