## UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

# FORM 8-K

## **CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 13, 2010

# **CYCLACEL PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Delaware	0-50626	91-1707622			
(State or other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)			
200 Connell Drive, Suite Berkeley Heights, NJ		07922			
(Address of Principal Executive	e Offices)	(Zip Code)			
Registrant's telephone number, including area code: (908) 517-7330					
(Former name or former address if changed since last report.)					
Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:					

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 2.02 Results of Operations and Financial Condition.

The information set forth under this "Item 2.02. Results of Operations and Financial Condition," including the exhibit attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Attached as Exhibit 99.1 is a copy of a press release of Cyclacel Pharmaceuticals, Inc. (the "**Company**"), dated May 13, 2010, announcing certain financial results for the first quarter ended March 31, 2010.

The Company will conduct a conference call to review its financial results on Thursday, May 13, 2010, at 4:30 p.m., Eastern Daylight Time.

# Item 4.02 Non-Reliance on Previously Issued Financial Statements or a Related Audit Report or Completed Interim Review.

(a) On May 13, 2010, Cyclacel Pharmaceuticals, Inc. (the "**Company**") issued a press release, a copy of which is attached hereto as Exhibit 99.2, announcing that the consolidated financial statements as of and for the year ended December 31, 2009 contained in its Annual Report on Form 10-K filed on March 29, 2010 (the "**Original Filing**") will be restated to correct an error in calculating the net loss per share as it relates to the payment of dividends on the Company's 6% Convertible Exchangeable Preferred Stock (the "**Preferred Stock**") in accordance with Accounting Standards Codification, or ASC, 260, "*Earnings Per Share*." Changes are also being made in the consolidated statements of cash flows, but solely to correct disclosures related to dividends on the Preferred Stock. The restatement has no effect on net cash flows.

On May 10, 2010, the Company's management reported the error to the audit committee of its board of directors. After initial discussions with the audit committee, management reviewed these matters in further detail, and after completing its analysis, recommended to the audit committee that the previously reported consolidated financial results as and for the year ended December 31, 2009 be restated to reflect the correction of the net loss per share calculation and other related corrections. The audit committee agreed with this recommendation. Pursuant to the recommendation of the audit committee, the Company's board of directors determined at a meeting on May 13, 2010, that the reported consolidated financial results as and for the year ended December 31, 2009 contained in the Original Filing and the related report of the Company's independent registered public accounting firm contained in the Original Filing should no longer be relied upon.

The Company expects to file an amendment to the Original Filing (the "**Amendment**") with the Securities and Exchange Commission that will reflect the restated financial statements in the next several days. The Company's management and the audit committee of the Company's board of directors have discussed these matters disclosed in this Current Report on Form 8-K with the Company's independent registered public accounting firm.

#### Background and Description of Error

Throughout 2007, 2008 and 2009, the Company had outstanding 2,046,813 shares of its Preferred Stock. The holders of the Preferred Stock are entitled to receive, when, as and if declared, a cash dividend at the annual rate of 6% of the liquidation preference of the Preferred Stock, which dividend is payable quarterly on the first day of February, May, August and November. Until April 6, 2009, the Company declared and paid these dividends. However, as part of the Company's operating plan to reduce expenditure, on April 6, 2009, June 22, 2009, October 19, 2009, January 7, 2010 and March 29, 2010, the Company's board of directors resolved not to declare payment of the cash dividend, which unpaid dividends are accrued.

Although the Company accrued for the unpaid dividends in its consolidated financial statements, it did not include the accrued amount when calculating basic and diluted loss per share of common stock for year ended December 31, 2009. As a result, the net loss per common share has been revised from \$(0.88) per share, as reported in the Original Filing, to \$(0.94), as will be reported in the Amendment. Similar errors occurred in 2007 and 2008 in the net loss per share disclosure.

The following tables set forth the effects of the restatement relating to net loss per share on affected line items within the Company's previously reported Consolidated Statements of Operations for the years 2007, 2008 and 2009. The restatement has no effect on net cash flows, the reported net loss or the consolidated balance sheet in each of the years.

Effect on Consolidated Statements of Operations:

	Years ended December 31,		
	2007	2008	2009
	(\$000s except for per share amounts)		
Net loss reported	(24,053)	(40,386)	(19,570)
Restatement Changes:			
Less: preferred dividends	(307)	(1,227)	(1,228)
Net loss applicable to common shareholders	(24,360)	(41,613)	(20,798)
Weighted-average common shares outstanding during the period	19,873,911	20,433,129	22,196,840
Restatement changes	(\$0.02)	(\$0.06)	(\$0.06)
Loss per share — basic and diluted	(\$1.23)	(\$2.04)	(\$0.94)

#### Cash flows disclosures

There were errors related to the presentation and disclosure of the Company's Preferred Stock dividends in the statement of cash flows in 2007 through and including 2009. These errors had no effect on net cash flows or any impact on the consolidated balance sheet or consolidated statement of operations. In 2009, the Preferred Stock dividend of \$307,000 paid on February 1, 2009 was disclosed incorrectly in the statement of cash flows within Net cash used in operating activities and should have been disclosed within Financing activities. Other disclosure errors were related to the terms of the make-whole dividend payment feature of the Company's Preferred Stock. This make-whole dividend payment feature was considered to be an embedded derivative and was recorded on the balance sheet at fair value as a current liability. As a consequence of this feature, which expired in November 2007, amounts paid with respect to the period of the make-whole provision should be disclosed in Net cash used in operating activities rather than financing activities. Additionally, in the Supplemental cash flow information; Schedule of non-cash items, we accrued dividends on Preferred Stock for 2007 through and including 2009. These errors had no effect on the net cash flows or any impact on the consolidated balance sheet or consolidated statement of operations.

## Timing of Restatement

The Company is working diligently to complete the restatement of its financial statements. The Company expects to file the Amendment in the next several days.

## Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release announcing financial results for the quarter ended March 31, 2010, dated May 13, 2010.
99.2	Press release announcing the restatement of and non-reliance on 2009 annual financial statements, dated May 13, 2010.

### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

## CYCLACEL PHARMACEUTICALS, INC.

By: <u>/s/ Paul McBarron</u> Name: Paul McBarron Title: Executive Vice President—Finance, Chief Financial Officer and Chief Operating Officer

Date: May 13, 2010

Exhibit 99.1



Cyclacel Pharmaceuticals, Inc.

#### PRESS RELEASE

#### CYCLACEL PHARMACEUTICALS REPORTS FINANCIAL RESULTS FOR FIRST QUARTER 2010

#### - Conference Call Scheduled May 13, 2010 at 4:30 p.m. Eastern Time -

**BERKELEY HEIGHTS, NJ** — **May 13, 2010** — Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP), a biopharmaceutical company developing oral therapies that target the various phases of cell cycle control for the treatment of cancer and other serious disorders, today reported its financial results and business highlights for the first quarter ended March 31, 2010. The net loss for the first quarter was \$5.1 million, or \$0.18 per basic and diluted share. This compared to a net loss of \$5.1 million, or \$0.26 per basic and diluted share, for the same period in 2009. As of March 31, 2010, cash and cash equivalents totaled \$24.2 million.

"We made important progress during the quarter in advancing the development of sapacitabine, our lead product candidate," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "We submitted to FDA a Special Protocol Assessment (SPA) request for a randomized Phase 3 study of sapacitabine in elderly patients with acute myeloid leukemia (AML). The FDA has reviewed our proposed Phase 3 protocol and statistical analysis plan. Following consultations with the FDA, we expect to receive action on the SPA in the near future. Looking to the rest of the year in our sapacitabine program, we are preparing to initiate the Phase 3 study in AML, planning to report Phase 2 data in MDS and progressing our Phase 2 study in lung cancer. We are also continuing to evaluate the broad therapeutic utility of our cyclin-dependent kinase (CDK) inhibitor drug candidates in treating cancers that are resistant to available therapies."

#### First Quarter 2010 and Recent Highlights

- SPA submission for a randomized Phase 3 study of sapacitabine in elderly patients with AML
- Publication of peer-reviewed journal articles demonstrating non-clinical activity with Cyclacel's seliciclib and its analogue CYC065 in resistant cancers, including lung cancer with Ras mutations, such as K-RAS and N-RAS, and breast cancer resistant to letrozole or trastuzumab
- Presented six abstracts at the American Association for Cancer Research annual meeting, including data on sapacitabine, seliciclib, CYC065, a second-generation CDK inhibitor, and Polo-like kinase 1 (Plk1) inhibitors, highlighting Cyclacel's innovative and diverse oncology pipeline
- Raised \$18.5 million in registered offerings and warrant exercises
- Regained compliance with the minimum \$50 million market value of listed securities requirement for continued listing on The NASDAQ Global Market

"Recently published data demonstrated that seliciclib and CYC065 have activity in resistant lung cancer cell lines with Ras mutations. Building on these findings, we plan to test tissue samples from patients treated with seliciclib for Ras mutations. We were recently encouraged to learn that a cancer patient in one of our seliciclib studies who experienced prolonged stable disease of over a year while on seliciclib treatment was subsequently confirmed to have the K-RAS mutation," added Mr. Rombotis. "Cyclacel and its collaborating scientists and physicians are intrigued by these early results and continue to explore the activity of CDK inhibitors in the setting of resistant cancers."

#### **Future Milestones**

- FDA action regarding the SPA for the Phase 3 study of sapacitabine in elderly patients with AML
- Initiation of Phase 3 study of sapacitabine in elderly patients with AML
- Report myelodysplastic syndromes (MDS) interim Phase 2 data with sapacitabine at the American Society of Clinical Oncology (ASCO) annual meeting
- Report non-small cell lung cancer (NSCLC) interim Phase 2 data with sapacitabine and
- Report top line results from APPRAISE NSCLC Phase 2b trial with seliciclib

#### First Quarter 2010 Financial Results

Revenues for the quarter were \$0.3 million, compared to \$0.2 million for the same period in 2009. Cyclacel's product revenues were comprised of sales of Xclair<sup>®</sup> Cream for radiation dermatitis and Numoisyn<sup>®</sup> Liquid and Numoisyn<sup>®</sup> Lozenges for xerostomia.

The operating loss for the quarter was \$4.5 million compared to \$5.2 million for the same period in 2009. Cyclacel reported a net loss of \$5.1 million, or \$0.18 per share for the first quarter of 2010, compared to a net loss of \$5.1 million, or \$0.26 per share for the same period in 2009.

Research and development expenses in the first quarter of 2010 were \$2.2 million compared to \$3.1 million for the same period in 2009. The \$0.9 million decrease was primarily the result of focusing activities on our lead drug candidate, sapacitabine. Total selling, general and administrative expenses for the first quarter of 2010 were \$2.4 million, compared to \$2.2 million for the same period in 2009 with the \$0.2 million increase primarily related to increased spending on professional costs.

As of March 31, 2010, Cyclacel's cash and cash equivalents were \$24.2 million compared to \$11.5 million as of December 31, 2009. The Company raised \$18.5 million through registered offerings and warrant exercises in this first quarter which resulted in higher cash and cash equivalents balances. The Company expects its existing capital resources should be adequate to fund operations and commitments into 2012.

#### Conference call and Webcast Information:

Cyclacel management will review first quarter 2010 financial and business highlights on a conference call scheduled for today at 4:30 p.m. Eastern. Conference call and webcast details are as follows:

US/Canada call: (877) 493-9121/ international call: (973) 582-2750 US/Canada archive: (800) 642-1687 / international archive: (706) 645-9291 Code for live and archived conference call is 73236113

Webcast: For the live and archived webcast, please visit the Corporate Presentations page on the Cyclacel website at www.cyclacel.com. The webcast will be archived for 90 days and the audio replay for 7 days.

#### About Cyclacel Pharmaceuticals, Inc.

Cyclacel is a biopharmaceutical company developing oral therapies that target the various phases of cell cycle control for the treatment of cancer and other serious disorders. Three product candidates are in clinical development: Sapacitabine (CYC682), a cell cycle modulating nucleoside analog, is in Phase 2 studies for the treatment of acute myeloid leukemia in the elderly, myelodysplastic syndromes and lung cancer. Seliciclib (CYC202 or R-roscovitine), a CDK (cyclin dependent kinase) inhibitor, is in Phase 2 studies for the treatment of lung cancer and nasopharyngeal cancer and in a Phase 1 trial in combination with sapacitabine. CYC116, an Aurora kinase and VEGFR2 inhibitor, is in a Phase 1 trial in patients with solid tumors. Cyclacel's



ALIGN Pharmaceuticals subsidiary markets directly in the U.S. Xclair<sup>®</sup> Cream for radiation dermatitis, Numoisyn<sup>®</sup> Liquid and Numoisyn<sup>®</sup> Lozenges for xerostomia. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a portfolio of commercial products and a development pipeline of novel drug candidates. Please visit <u>www.cyclacel.com</u> for additional information.

#### **Forward-looking Statements**

This news release contains certain forward-looking statements that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding, among other things, the efficacy, safety, and intended utilization of Cyclacel's product candidates, the conduct and results of future clinical trials, plans regarding regulatory filings, future research and clinical trials and plans regarding partnering activities. Factors that may cause actual results to differ materially include the risk that product candidates that appeared promising in early research and clinical trials do not demonstrate safety and/or efficacy in larger-scale or later clinical trials, the risk that Cyclacel will not obtain approval to market its products, the risks associated with reliance on outside financing to meet capital requirements, and the risks associated with reliance on collaborative partners for further clinical trials, development and commercialization of product candidates. You are urged to consider statements that include the words "may," "will," "would," "could," "should," "believes," "estimates," "projects," "potential," "expects," "plans," "anticipates," "intends," "continues," "forecast," "designed," "goal," or the negative of those words or other comparable words to be uncertain and forward-looking. For a further list and description of the risks and uncertainties the Company faces, please refer to our most recent Annual Report on Form 10-K and other periodic and current filings that have been filed with the Securities and Exchange Commission and are available at www.sec.gov. Such forward-looking statements are current only as of the date they are made, and we assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

#### Contact for Cyclacel Pharmaceuticals, Inc.

Investors/Media: Corey Sohmer, (908) 517-7330 <u>csohmer@cyclacel.com</u>

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## CYCLACEL PHARMACEUTICALS, INC. (A Development Stage Company) CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (In \$000s, except share and per share amounts) (Unaudited)

	Three Months Ended March 31,		Period from August 13, 1996 (inception) to March 31,
	2009	2010	2010
Revenues:			
Collaboration and research and development revenue	_	_	3,000
Product revenue	216	254	2,002
Grant revenue	12	17	3,652
	228	271	8,654
Operating expenses:			
Cost of goods sold	116	142	1,116
Research and development	3,097	2,178	172,357
Selling, general and administrative	2,230	2,402	74,248
Goodwill and intangible impairment		—	7,934
Restructuring costs			2,634
Total operating expenses	5,443	4,722	258,289
Operating loss	(5,215)	(4,451)	(249,635)
Other income (expense):			
Costs associated with aborted 2004 IPO	—	—	(3,550)
Payment under guarantee		—	(1,652)
Change in valuation of derivative	—		(308)
Change in valuation of warrants	(8)	(789)	5,575
Foreign exchange losses	(137)	11	(4,176)
Interest income	46	9	13,652
Interest expense	(107)	(24)	(4,657)
Total other income (expense)	(206)	(793)	4,884
Loss before taxes	(5,421)	(5,244)	(244,751)
Income tax benefit	358	133	17,355
Net loss	(5,063)	(5,111)	(227,396)
Dividends on preferred ordinary shares	—	_	(38,123)
Deemed dividend on convertible exchangeable preferred shares	_	(419)	(419)
Dividends on convertible exchangeable preferred shares	(307)	(289)	(2,846)
Net loss applicable to common shareholders	(5,370)	(5,819)	(268,784)
Net loss per share — Basic and diluted	\$ (0.26)	\$ (0.18)	,
Weighted average common shares outstanding	20,433,129	31,721,822	

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## CYCLACEL PHARMACEUTICALS, INC. (A Development Stage Company) CONDENSED CONSOLIDATED BALANCE SHEETS (In \$000s, except share amounts)

	December 31, 2009	March 31, 2010 (Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	11,493	24,200
Inventory	145	107
Prepaid expenses and other current assets	1,731	1,558
Total current assets	13,369	25,865
Property, plant and equipment (net)	901	715
Deposits and other assets	196	196
Total assets	14,466	26,776
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	1,709	1,782
Accrued liabilities and other current liabilities	6,709	5,818
Warrant liability	342	1,131
Other accrued restructuring charges	1,062	780
Total current liabilities	9,822	9,511
Stockholders' equity	4,644	17,265
Total liabilities and stockholders' equity	14,466	26,776

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Exhibit 99.2



Cyclacel Pharmaceuticals, Inc.

#### PRESS RELEASE

#### CYCLACEL PHARMACEUTICALS TO RESTATE 2009 ANNUAL FINANCIAL STATEMENTS TO CORRECT NET LOSS PER SHARE AND CONSOLIDATED STATEMENTS OF CASH FLOWS DISCLOSURE AND FILING FORM 8-K FOR NON-RELIANCE ON PREVIOUSLY ISSUED FINANCIALS STATEMENTS

**BERKELEY HEIGHTS, NJ** — **May 13, 2010** — Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; the "Company"), a biopharmaceutical company developing oral therapies that target the various phases of cell cycle control for the treatment of cancer and other serious disorders, today announced that the Company's consolidated financial statements as of and for the year ended December 31, 2009 (the "Financial Statements") contained in its Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 29, 2010 (the "Annual Report") will be restated to correct an error in calculating the net loss per share as it relates to the payment of dividends on the Company's 6% Convertible Exchangeable Preferred Stock (the "Preferred Stock") and disclosures in the consolidated statements of cash flows related to the dividends on the Preferred Stock.

The restatement has no effect on net cash flows, the reported net loss or the consolidated balance sheet. The Company has also determined that the Financial Statements should not be relied upon and is filing a Current Report on Form 8-K under item 4.02 — Non-reliance on previously issued financial statements, that will provide further detail on the restatement.

Although the Company accrued for the unpaid dividends in its Financial Statements, it did not include the accrued amount when calculating basic and diluted loss per common share for the year ended December 31, 2009. As a result, the net loss per common share will be revised from \$0.88 per share, as originally reported in its Annual Report, to \$0.94 per share, as will be reported in an amendment to its Annual Report, which the Company expects to file in the next several days. Similar errors occurred in 2007 and 2008 in the net loss per share disclosure. For 2008 the net loss per common share will be revised from \$1.98 per share, as originally reported, to \$2.04 per share. For 2007 the net loss per common share will be revised from \$1.21 per share, as originally reported, to \$1.23 per share. Changes are also being made in the consolidated statements of cash flows related to dividends on the Preferred Stock. The restatement has no effect on net cash flows.

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