## 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 12, 2011

### CYCLACEL PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

	Delaware	0-50626		91-1707622						
	(State or other jurisdiction (Commission		File Number)	(IRS Employer Identification No.)						
	of incorporation)									
	200 Connell Drive, Suite 15	00								
	Berkeley Heights, NJ			07922						
	(Address of principal executive o	offices)		(Zip Code)						
	Registrant's telephone number, including area code: <b>(908) 517-7330</b> (Former name or former address, if changed since last report.)									
	ck the appropriate box below if the Form 8 er any of the following provisions:	B-K filing is intended	o simultaneously sat	isfy the filing obligation of the registrant						
0	Written communications pursuant to Rule	e 425 under the Securi	ties Act (17 CFR 23	0.425)						
0	Soliciting material pursuant to Rule 14a-	12 under the Exchang	e Act (17 CFR 240.1	4a-12)						
0	Pre-commencement communications pur	suant to Rule 14d-2(b	) under the Exchange	Act (17 CFR 240.14d-2(b))						

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 12, 2011, announcing certain financial results for the first quarter ended March 31, 2011.

The Company will conduct a conference call to review its financial results on Thursday, May 12, 2011, at 4:30 p.m., Eastern Time.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit

Number Description

99.1 Press release announcing financial results for the first quarter ended March 31, 2011, dated May 12, 2011.

#### **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: /s/ Paul McBarron
Name: Paul McBarron

Title: Executive Vice President—Finance,

Chief Financial Officer and Chief Operating Officer

Date: May 12, 2011



PRESS RELEASE

#### CYCLACEL PHARMACEUTICALS REPORTS FINANCIAL RESULTS FOR FIRST QUARTER 2011

— Conference Call Scheduled May 12, 2011 at 4:30 p.m. Eastern Time —

**Berkeley Heights, NJ, May 12, 2011** — Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; Cyclacel or 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 reported its financial results and business highlights for the first guarter ended March 31, 2011.

The net loss for the first quarter of 2011 was \$4.6 million as compared to a net loss of \$5.1 million for the same period in 2010. As of March 31, 2011, cash and cash equivalents totaled \$25.4 million. The Company's net loss applicable to common stockholders for the first quarter of 2011 was \$4.8 million or \$0.10 per basic and diluted share, compared to a net loss applicable to common stockholders of \$5.8 million or \$0.18 per basic and diluted share for the first quarter of 2010.

"With the SEAMLESS Phase 3 trial open and enrolling patients with acute myeloid leukemia, or AML, Cyclacel is a step closer to our ultimate goal of getting sapacitabine to patients in need and potentially the market," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "We are looking forward to the upcoming presentation at a major medical conference of pilot study data of sapacitabine in combination with decitabine in patients with AML. In addition, we expect to report later this year additional sapacitabine data in hematological malignancies and non-small lung cancer, or NSCLC, and seliciclib biopsy analysis data in NSCLC."

#### **Business Highlights**

- Opened enrollment of the SEAMLESS pivotal Phase 3 study for sapacitabine oral capsules as a front-line treatment of elderly patients aged 70 years or older with newly diagnosed AML who are not candidates for intensive induction chemotherapy. SEAMLESS is being conducted under a Special Protocol Assessment (SPA) agreement that Cyclacel reached with the U.S. Food and Drug Administration (FDA). The trial builds on promising 1-year survival observed in elderly patients aged 70 years or older with newly diagnosed AML or AML in first relapse enrolled in a Phase 2 study of single agent sapacitabine.
- Announced publication of preclinical data in the Proceedings of the National Academy of Sciences, demonstrating that cyclin E plays a major role in making Human Epidermal growth factor Receptor 2 positive (HER2+) breast cancer resistant to trastuzumab (Herceptin®), a widely used medicine for breast cancer patients who test positive for HER2. The publication provides a rationale for exploring Cyclacel's orally available CDK inhibitors in this population of patients with breast cancer.
- Presented preclinical results for two Cyclacel clinical compounds, sapacitabine and CY116, at the 102<sup>nd</sup> Annual Meeting of the American Association of Cancer Research in Orlando, Florida.

#### First Quarter 2011 Financial Results

#### **Product Revenue**

Revenues for the quarter were \$0.2 million, compared to \$0.3 million for the same period in 2010. Cyclacel's product revenues were comprised of sales of Xclair® Cream for radiation dermatitis and Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia.

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#### **Research and Development Expenses**

Research and development expenses in the first quarter of 2011 were \$3.1 million compared to \$2.2 million for the same period in 2010. The increase in costs of \$0.9 million is primarily due to \$1.6 million of contractual expenses, resulting from the achievement of a milestone triggered by the opening of enrollment in our SEAMLESS trial, pursuant to the Daiichi-Sankyo license under which Cyclacel licenses certain patent rights for sapacitabine. This cost was partially offset by reductions of \$0.4 million in stock-based and other employee related compensation.

#### Selling, General and Administrative Expenses

Total selling, general and administrative expenses for the first quarter of 2011 were \$1.8 million, compared to \$2.4 million for the same period in 2010 with the \$0.6 million decrease primarily related to professional and consultancy costs.

#### Cash and Cash Equivalents

As of March 31, 2011, Cyclacel's cash and cash equivalents were \$25.4 million compared to \$29.5 million as of December 31, 2010. The Company expects that its cash resources are sufficient to meet anticipated short-term working capital needs and fund on-going sapacitabine clinical trials for at least the next twelve months.

#### Cyclacel's Goals for 2011

- Present pilot study data of sapacitabine in combination with decitabine in patients with AML;
- Present additional sapacitabine data in hematological malignancies both as a single agent and in combination with other anticancer agents;
- Report Data Safety Monitoring Board (DSMB) review of safety data from the SEAMLESS Phase 3 AML study;
- Report top line Phase 2 sapacitabine data in NSCLC; and
- Report patient biomarker analysis from the APPRAISE Phase 2b randomized discontinuation study of seliciclib in patients with NSCLC.

#### **Conference call and Webcast Information:**

Cyclacel will conduct a conference call on May 12, 2011 at 4:30 p.m. Eastern Time to review the first quarter results. Conference call and webcast details are as follows:

Conference call information:

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 66220600

For the live and archived webcast, please visit the Corporate Presentations page on the Cyclacel website at <a href="https://www.cyclacel.com">www.cyclacel.com</a>. 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 diseases. Sapacitabine (CYC682), a cell cycle modulating nucleoside analog, is in Phase 3 development for the treatment of acute myeloid leukemia in the elderly under a Special Protocol Assessment agreement with the U.S. Food and Drug Administration, and in Phase 2 studies for 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. Cyclacel's ALIGN Pharmaceuticals subsidiary markets directly in the U.S. Xclair® Cream for radiation dermatitis, Numoisyn® Liquid and Numoisyn® 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 <a href="https://www.cyclacel.com">www.cyclacel.com</a> 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 forwardlooking 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, trials may have difficulty enrolling, Cyclacel may 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.

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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,  2010 2011			Period from August 13, 1996 (inception) to March 31, 2011		
Revenues:						
Collaboration and research and development revenue	\$	_	\$	_	\$	3,100
Product revenue		254		192		2,514
Grant revenue		17				3,648
		271		192		9,262
Operating expenses:						
Cost of goods sold		142		106		1,498
Research and development		2,178		3,080		179,673
Selling, general and administrative		2,402		1,806		83,772
Goodwill and intangible impairment		_		_		7,934
Restructuring costs						2,634
Total operating expenses		4,722		4,992		275,511
Operating loss		(4,451)		(4,800)		(266,249)
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		(789)		78		6,104
Foreign exchange (losses)/gains		11		(68)		(4,323)
Interest income		9		11		13,691
Interest expense		(24)				(4,677)
Total other income (expense)		(793)		21		5,285
Loss before taxes		(5,244)		(4,779)		(260,964)
Income tax benefit		133		191		18,070
Net loss		(5,111)		(4,588)		(242,894)
Dividends on preferred ordinary shares		_		_		(38,123)
Deemed dividend on convertible exchangeable preferred shares		(419)		_		(3,515)
Dividend on convertible exchangeable preferred shares		(289)		(182)		(3,111)
Net loss applicable to common shareholders	\$	(5,819)	\$	(4,770)	\$	(287,643)
Net loss per share — Basic and diluted	\$	(0.18)	\$	(0.10)		
Weighted average common shares outstanding	31,7	21,822	46	,572,180		

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

	December 31, 2010		March 31, 2011 (Unaudited)	
ASSETS			_	
Current assets:				
Cash and cash equivalents	\$	29,495	\$	25,350
Inventory		174		115
Prepaid expenses and other current assets		1,382		1,401
Total current assets		31,051		26,866
Property, plant and equipment (net)		408		331
Deposits and other assets		_		
Total assets	\$	31,459	\$	27,197
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities:		_		
Accounts payable	\$	1.723	\$	947
Accrued liabilities and other current liabilities	Ψ	4.132	Ψ.	5,264
Warrant liability		680		602
Total current liabilities		6,535		6.813
Total liabilities		6,535		6,813
Stockholders' equity:				
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 31, 2010 and March 31, 2011; 1,213,142 shares issued and outstanding at December 31, 2010 and March 31, 2011. Aggregate preference in liquidation of \$13,344,562 (including undeclared cumulative dividends) at December 31, 2010 and March 31,				
2011		1		1
Common stock, \$0.001 par value; 100,000,000 shares authorized at December 31, 2010 and March 31, 2011; 46,564,914 and 46,577,860 shares issued and				
outstanding at December 31, 2010 and March 31, 2011		47		47
Additional paid-in capital		266,666		266,737
Accumulated other comprehensive loss		31		8
Deficit accumulated during the development stage		(241,821)		(246,409)
Total stockholders' equity		24,924		20,384
Total liabilities and stockholders' equity	\$	31,459	\$	27,197