## 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): November 3, 2009

# **CYCLACEL PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Delaware	0-50626	91-1707622				
(State or other Jurisdiction of	(Commission File	Number) (IRS Employer Identification No.)				
Incorporation)						
200 Connell Drive, Suite 1	500					
Berkeley Heights, New Jersey		07922				
(Address of Principal Executive 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.)						

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., dated November 3, 2009, announcing certain financial results for the quarter ended September 30, 2009.

The Company will conduct a conference call to review its financial results on Tuesday, November 3, 2009, at 4:30 p.m., Eastern Time.

#### Item 9.01 Financial Statements and Exhibits

(d) The following exhibit is furnished with this Report:

Exhibit No.Description99.1Press Release dated November 3, 2009

### 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: November 3, 2009

## EXHIBIT INDEX

Exhibit No.Description99.1Press Release dated November 3, 2009



Cyclacel Pharmaceuticals, Inc.

#### CYCLACEL PHARMACEUTICALS ANNOUNCES THIRD QUARTER 2009 FINANCIAL RESULTS

#### - Conference Call Scheduled Tuesday, November 3 at 4:30 p.m. Eastern -

**Berkeley Heights, NJ, November 3, 2009** — Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; "Cyclacel" or the "Company") announced today financial and operating results for the third quarter of 2009. The Company's net loss for the quarter was \$3.1 million or \$0.13 per share. This compared to a net loss of \$17.6 million or \$0.86 loss per share for the same period in 2008. As of September 30, 2009, the Company had \$14.4 million in cash and cash equivalents.

"Our recent achievement of 30% one-year survival in two of the three randomized schedules of the Phase 2 study of sapacitabine as a treatment for elderly patients aged 70 and older with acute myeloid leukemia (AML) provides a strong rationale supporting the continued development of this novel agent," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "We are working with the FDA to design a registration study for sapacitabine in hematological malignancies. We continue to concentrate our efforts on advancing sapacitabine into Phase 3 development for AML and/or myelodysplastic syndromes (MDS) while preserving cash for the next twelve months. We are also looking forward to reporting in 2010 data from our ongoing Phase 2 studies of sapacitabine and seliciclib in lung cancer."

#### Recent Highlights:

- Reported 30% one-year survival from the Phase 2 sapacitabine trial in elderly patients with AML aged 70 and older in two out of three randomized schedules;
- Type A meeting granted by the FDA in the 4th quarter of 2009 to discuss the design of Phase 3 registration studies in AML and/or MDS;
- Phase 3 study designs to be included in an upcoming submission requesting a Special Protocol Assessment or SPA;
- Raised \$3.4 million in gross proceeds in a registered direct offering in July.

#### Key Financials:

Total revenues for the third quarter of 2009 were \$0.2 million representing a decrease of 14% compared to \$0.3 million for the same period in 2008. These revenues were mainly attributable to sales of the Xclair<sup>®</sup> and Numoisyn<sup>®</sup> products.

Total research and development (R&D) expenses in the third quarter of 2009 were \$1.4 million, a 65% decrease as compared to \$4.0 million in the third quarter of 2008. \$1.6 million of the overall decrease was associated with the discontinuation of the Company's preclinical programs from the cost-containment measures implemented in September 2008 and June 2009. The Company recognized cost reductions of approximately \$1.0 million in the third quarter 2009 as compared to the same period in 2008 due to the completion of patient enrollment in the APPRAISE trial in the third quarter of 2008.

Total selling, general and administrative expenses (SG&A) for the third quarter of 2009 were \$2.2 million, a 32% decrease as compared to \$3.2 million in the third quarter of 2008. The reduction in operating expenses in the third quarter of 2009 compared to the same period in 2008 is primarily attributable to the cost-containment measures implemented in September 2008 and June 2009 and the concentration of the Company's resources on the clinical development of sapacitabine.

Other operating expenses in the third quarter of 2008 also included a non-cash charge of \$6.8 million for goodwill and intangibles impairment in respect of the acquisitions of Xcyte Therapies, Inc. and ALIGN following Cyclacel's annual test for impairment and restructuring costs.

Other income (expense) showed income of \$0.2 million in the third quarter of 2009 as compared to expense of \$4.1 million in the third quarter of 2008. The decrease in expense was primarily due to an unrealized foreign exchange loss of \$4.8 million in the third quarter of 2008 compared to a \$0.1 million foreign exchange gain in the same period in 2009 arising from intercompany loans with our wholly-owned subsidiaries due to the translation effects of the US dollar against the British pound together with a change in the valuation of warrants and a reduction in interest income earned.

The net loss in the third quarter of 2009 was \$3.1 million or \$0.13 per share as compared to \$17.6 million in the third quarter of 2008 or \$0.86 per share.

Cyclacel also reported results of its operations for the nine months ended September 30, 2009. Total revenues for the nine months ended September 30, 2009 were \$0.7 million representing an increase of 16% compared to \$0.6 million for the same period in 2008. These revenues were mainly attributable to sales of the Xclair<sup>®</sup> and Numoisyn<sup>®</sup> products.

For the nine months ended September 30, 2009, R&D expenses were \$7.2 million, a 54% decrease as compared to \$15.7 million in the comparable period in 2008.

For the nine months ended September 30, 2009, SG&A expenses were \$6.7 million, a 41% decrease as compared to \$11.3 million in the comparable period in 2008.

The reduction in operating expenses in 2009 compared to 2008 is primarily attributable to the cost-containment measures implemented in September 2008 and June 2009 and the concentration of the Company's resources on the clinical development of sapacitabine.

Other operating expenses for the nine months ended September 30 2008 also included a non-cash charge of \$6.8 million for goodwill and intangibles impairment in respect of the acquisitions of Xcyte and ALIGN and restructuring costs. For the nine months ended September 30, 2009, the Company recorded restructuring costs of \$0.4 million.

Other income (expense) for the nine months ended September 30, 2009 showed an expense of \$2.0 million as compared to \$0.4 million for the same period in 2008. The 2009 loss included a non-operating expense of \$1.7 million related to payments due under an agreement with Scottish Enterprise as a consequence of the headcount reductions implemented by the Company. During 2008, the Company recorded a charge of \$3.3 million associated with the warrant derivative as compared to income of \$0.2 million in 2009 as a result of the Company's common stock price at each quarter end. The decrease in expense was primarily due to unrealized foreign exchange loss of \$4.6 million in the nine months ended September 30, 2008 compared to \$0.1 million foreign exchange loss in the same period in 2009 arising mostly from intercompany loans with our wholly-owned subsidiaries due to the translation effects of the US dollar against the British pound.

For the nine months ended September 30, 2009, the Company reported a net loss of \$15.2 million or \$0.71 per share, compared to a net loss for the same period in 2008 of \$32.4 million or \$1.59 per share.

Conference call and Webcast Information:

Cyclacel management will conduct a conference call on November 3, 2009 at 4:30 p.m. Eastern Time to review the quarterly 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 37927625

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



#### About Cyclacel Pharmaceuticals, Inc.

Cyclacel is a diversified biopharmaceutical company dedicated to the discovery, development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. Sapacitabine, 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 and in Phase 1 in combination with seliciclib. Seliciclib, a CDK (cyclin dependent kinase) inhibitor, is in Phase 2 for the treatment of lung and nasopharyngeal cancer. CYC116, an Aurora kinase and VEGFR2 inhibitor, is in Phase 1 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.

#### **Risk factors**

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. These factors and others are more fully discussed under "Risk Factors" in the Annual Report on Form 10-K for the year ended December 31, 2008, as supplemented by the interim quarterly reports, filed with the SEC.

#### Contacts for Cyclacel Pharmaceuticals, Inc.

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## CYCLACEL PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF OPERATIONS

## (Unaudited)

	For the three months ended September 30,		For the nine months ended September 30,		Period from August 13, 1996 (inception) to September 30,
	2008	2009	<u>2008</u> (\$000s)	2009	2009
Revenues:			(\$0003)		
Collaboration and research and development					
revenue		_		_	3,000
Product revenue	257	223	590	688	1,526
Grant revenue	12	7	36	36	3,671
	269	230	626	724	8,197
Operating expenses:					
Cost of goods sold	120	163	315	472	901
Research and development	4,030	1,394	15,718	7,174	167,587
General and administrative	3,218	2,188	11,337	6,703	70,011
Goodwill and intangibles					
impairment	6,344	_	6,344	_	7,934
Restructuring costs	489		489	366	2,634
Total operating expenses	14,201	3,745	34,203	14,715	249,067
Operating loss	(13,932)	(3,515)	(33,577)	(13,991)	(240,870)
Other income (expense):					
Costs associated with					
aborted 2004 IPO	—	—	—	_	(3,550)
Payment under guarantee	_	—	-	(1,652)	(1,652)
Change in valuation of					(000)
derivative	—	—	—	—	(308)
Change in valuation of	400	101	0.001	(105)	0 540
warrants	432	101	3,321	(195)	6,512
Foreign exchange	$(A, \overline{Z}, \overline{Z}, \overline{Z})$	110	(4,000)	(100)	(4 170)
gains/(losses) Interest income	(4,776) 287	119 7	(4,638)	(129) 94	(4,172)
	(69)	(41)	1,184 (244)	(156)	13,635 (4,613)
Interest expense					
Total other income (expense)	(4,126)	186	(377)	(2,038)	5,852
Loss before taxes	(18,058)	(3,329)	(33,954)	(16,029)	(235,018)
Income tax benefit	411	205	1,511	796	17,070
Net loss	(17,647)	(3,124)	(32,443)	(15,233)	(217,948)
Dividends on Preferred Ordinary shares	_	_	_	_	(38,123)
Net loss applicable to					
common shareholders	(17,647)	(3,124)	(32,443)	(15,233)	(256,071)
Net loss per share — basic and diluted	<u>\$ (0.86</u> )	<u>\$ (0.13</u> )	<u>\$ (1.59</u> )	<u>\$ (0.71</u> )	
Weighted average shares	20,433,129	23,172,259	20,433,129	21,356,206	
weighten average shales	20,433,129	23,112,239	20,433,129	21,330,200	



## CYCLACEL PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	As of	As of
	December 31	September 30
	2008	2009
ASSETS		
Current assets:		
Cash and cash equivalents	24,220	14,433
Short-term investments	1,502	_
Inventory	508	140
Prepaid expenses and other current assets	2,784	1,652
Total current assets	29,014	16,225
Property, plant and equipment (net)	1,748	1,121
Deposits and other assets	195	196
Total assets	30,957	17,542
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	754	1,463
Accrued liabilities	5,186	5,228
Other current liabilities	1,615	1,336
Warrants liability	43	238
Current portion of other accrued restructuring charges	1,029	1,063
Total current liabilities	8,627	9,328
Other accrued restructuring charges, net of current	1,062	267
Other long term payables	626	_
Total liabilities	10,315	9,595
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at		
December 31, 2008 and September 30, 2009, respectively; 2,046,813		
shares issued and outstanding at December 31, 2008 and September 30,		
2009, respectively Aggregate preference in liquidation of \$20,673,000 at		
December 31, 2008 and September 30, 2009	2	2
Common stock, \$0.001 par value; 100,000,000 shares authorized at		
December 31, 2008 and September 30, 2009; 20,433,129, and		
24,433,129 shares issued and outstanding at December 31, 2008 and		
September 30, 2009, respectively	20	24
Additional paid in capital	223,377	225,864
Accumulated other comprehensive loss	(42)	5
Deficit accumulated during the development stage	(202,715)	(217,948)
Total stockholders' equity	20,642	7,947
Total liabilities and stockholders' equity	30,957	17,542

SOURCE: Cyclacel Pharmaceuticals, Inc.

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