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

Washington, D.C. 2004

# 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 6, 2008

# **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 1500						
Berkeley Heights, NJ		07922				
(Address of Principal Executive Off	lices)	(Zip Code)				
(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 230.4	25)				
		10)				

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 6, 2008, announcing certain financial results for the quarter ended September 30, 2008.

#### Item 9.01 Financial Statements and Exhibits

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

Exhibit No.Description99.1Press Release dated November 6, 2008

### 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 and Chief Operating Officer

Date: November 6, 2008

# EXHIBIT INDEX

Exhibit No.Description99.1Press Release dated November 6, 2008



#### CYCLACEL PHARMACEUTICALS ANNOUNCES THIRD QUARTER 2008 FINANCIAL RESULTS

- Conference Call Scheduled Thursday, November 6 at 4:30 p.m. Eastern -

**BERKELEY HEIGHTS, NJ** — **November 6, 2008** — Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP) announced today financial and operating results for the third quarter of 2008. The Company's net loss for the quarter, which included \$0.5 million of one-time restructuring charges and non-cash items of \$6.3 million of goodwill and intangibles impairment and \$4.8 million of unrealized foreign exchange losses, was \$17.6 million or \$0.86 per share. For the third quarter of 2008, the Company recorded \$0.3 million of net product sales of Xclair<sup>®</sup> and Numoisyn<sup>™</sup> representing an increase of 53 percent compared to the prior quarter. As of September 30, 2008, the Company had \$33.7 million in cash, cash equivalents and short-term investments.

Cyclacel also announced that FDA has granted an end of Phase 2 meeting in which the development of sapacitabine for the treatment of acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS) will be discussed. The meeting is scheduled to take place in the first quarter of 2009.

"Cyclacel continued to make progress in the third quarter across our business. The completion of enrollment ahead of schedule in the Phase 2 clinical trial of sapacitabine in elderly patients with AML and the rapid initiation of the MDS stratum underline the strong interest by investigators and patients in sapacitabine. We look forward to upcoming milestones including the end of Phase 2 meeting with FDA and the readout of the Phase 2 data once they mature," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "Our sales force has been steadily building awareness of our marketed products and achieved promising quarter-on-quarter growth. During the quarter, we also revised our operating plan to reduce expenditure and concentrate our efforts on developing sapacitabine as rapidly as possible."

"Following the revised operating plan and consequent reduction in our burn rate, we anticipate that current cash and cash equivalents will be sufficient to meet our funding needs until the first quarter of 2010," said Paul McBarron, Executive Vice President, Finance and Chief Operating Officer. "In addition, subject to certain conditions, we have access to the committed equity financing facility with Kingsbridge Capital for up to \$60 million; although we have not as yet drawn down from this facility."

#### Third Quarter Highlights:

- Completed enrollment in the Phase 2 clinical trial of sapacitabine in elderly patients with AML.
- Initiated Phase 2 development of sapacitabine as a second-line treatment for MDS.
- An independent data review committee, or IDRC, recommended that the Phase 2b seliciclib APPRAISE study continue after reviewing data from 173 patients with previously-treated non-small cell lung cancer, or NSCLC, of whom 45 proceeded into the blinded randomized portion of the study. Although new patient enrolment was halted, follow-up of existing patients continues.
- Announced an operating plan revision to concentrate resources on the advancement of sapacitabine, while maintaining the Company's core competency in drug discovery and cell cycle biology.
- Appointed Nicholas Bacopoulos, Ph.D. to the Board of Directors.

#### Key Financials:

Total revenues for the third quarter of 2008 were \$0.3 million representing an increase of 53 percent compared to \$0.2 million recorded in the prior quarter. These were mainly attributable to net product sales of Xclair<sup>®</sup> and Numoisyn<sup>™</sup> by ALIGN, Cyclacel's wholly owned subsidiary acquired in October 2007.

Total research and development (R&D) expenses in the third quarter of 2008 were \$4.0 million as compared to \$4.4 million in the third quarter of 2007. The decrease in spending in the third quarter of 2008, compared to the same period in 2007, was primarily due to decreased spending on early stage programs.

Total selling, general and administrative expenses (SG&A) for the third quarter of 2008 were \$3.2 million as compared to \$2.5 million in the third quarter of 2007. The increase in spending in the third quarter of 2008, compared to the same period in 2007, was primarily attributable to ALIGN for which there were no costs in the comparative period.

Other income (expense) in the third quarter of 2008 showed an expense of \$4.1 million as compared to income of \$2.3 million in the third quarter of 2007. The increase in expense was primarily due to unrealized foreign exchange loss of \$4.8 million in the third quarter of 2008 compared to a \$0.5 million foreign exchange gain in the same period in 2007 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.

Other operating expenses in the third quarter of 2008 also included a non-cash charge of \$6.3 million for goodwill and intangibles impairment in respect of the acquisitions of Xcyte Therapies, Inc. and ALIGN following Cyclacel's annual test for impairment. For the three months ended September 30, 2007 there was no impairment charge for either goodwill or intangibles. The third quarter of 2008 also included one-time restructuring costs of \$0.5 million related to the implementation of the revised operating plan.

The net loss in the third quarter of 2008 was \$17.6 million or \$0.86 per share as compared to \$4.2 million in the third quarter of 2007 or \$0.21 per share.

Cyclacel also reported results of its operations for the nine months ended September 30, 2008. For the nine months ended September 30, 2008, the Company reported revenues of \$0.6 million. These revenues were largely attributable to sales of Xclair<sup>®</sup> and Numoisyn<sup>™</sup> sold by Cyclacel's wholly owned subsidiary, ALIGN, which was acquired in October 2007.

For the nine months ended September 30, 2008, R&D expenses were \$15.7 million as compared to \$12.7 million in the comparable period in 2007. The increase in spending in the first nine months of 2008, compared to the same period in 2007, was primarily due to increased spending on the clinical development of sapacitabine.

For the nine months ended September 30, 2008, SG&A expenses were \$11.3 million as compared to \$8.0 million in the comparable period in 2007. The increase in spending in the first nine months of 2008, compared to the same period in 2007, was primarily attributable to ALIGN for which there were no costs in the comparative period as well as increased professional and personnel costs.

Other income (expense) for the nine months ended September 30, 2008 showed an expense of \$0.4 million as compared to income of \$6.5 million in the comparable period in 2007. The increase in expense was primarily due to unrealized foreign exchange loss of \$4.6 million in the nine months ended September 30, 2008 compared to a \$1.1 million foreign exchange gain in the same period in 2007 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.

Other operating expenses for the nine months ended September 30 2008 also included a non-cash charge of \$6.3 million for goodwill and intangibles impairment in respect of the acquisitions of Xcyte Therapies, Inc. and ALIGN following Cyclacel's annual test for impairment. For the nine months ended September 30, 2007 there was no impairment charge required for either goodwill or intangibles. The third quarter of 2008 also included restructuring costs of \$0.5 million related to the implementation of the revised operating plan.

For the nine months ended September 30, 2008, the Company reported a net loss of \$32.4 million, or \$1.59 per share, compared to a net loss for the same period in 2007 of \$12.7 million, or \$0.65 per share.



Conference call and Webcast Information:

Cyclacel management will conduct a conference call on November 6, 2008 at 4:30 p.m. Eastern Time to review its results. 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 71872501

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 biopharmaceutical company dedicated to the discovery, development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. Three orally-available Cyclacel drugs 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 cutaneous T-cell lymphoma. Seliciclib (CYC202 or R-roscovitine), a CDK (cyclin dependent kinase) inhibitor, is in Phase 2 for the treatment of lung cancer and nasopharyngeal cancer. CYC116, an Aurora kinase and VEGFR2 inhibitor, is in Phase 1 in patients with solid tumors. Several additional programs are at an earlier stage. Cyclacel's ALIGN Pharmaceuticals subsidiary markets directly in the U.S. Xclair® Cream for radiation dermatitis, Numoisyn™ Logid and Numoisyn™ Lozenges for xerostomia. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology, oncology and other therapeutic areas 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. Note: The Cyclacel logo and Cyclacel<sup>®</sup> are trademarks of Cyclacel Pharmaceuticals, Inc.; Numoisyn<sup>™</sup> and Xclair<sup>®</sup> are trademarks of Sinclair Pharma plc.

#### **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, 2007, as supplemented by the interim quarterly reports, filed with the SEC.

Contacts for Cyclacel:

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# CYCLACEL PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	For the months Septem 2007	s ended	For th months Septem 2007	ended	Period from August 13, 1996 (inception) to September 30, 2008
			(\$000s)		
Revenues: Collaboration and research and development					
revenue	—	—	10	—	3,000
Product revenue	—	257	—	590	590
Grant revenue	33	12	107	36	3,632
	33	269	117	626	7,222
<b>•</b>					
Operating expenses:		100		015	015
Cost of goods sold	4 440	120	10 740	315	315
Research and development Selling, general and	4,449	4,030	12,742	15,718	157,262
administrative	2,523	3,218	8,022	11,337	59,291
Goodwill and intangibles	2,525	5,210	0,022	11,557	59,291
impairment	_	6,344	_	6,344	6,344
Restructuring costs	_	489	81	489	2,268
Total operating expenses	6,972	14,201	20,845	34,203	225,480
Operating loss	(6,939)	(13,932)	(20,728)	(33,577)	(218,258)
Other income (expense): Costs associated with aborted 2004 IPO	_	_	_	_	(3,550)
Change in valuation of derivative	(19)	_	(89)	_	(308)
Change in valuation of warrants	951	432	2,815	3,321	6,526
Foreign exchange					
gains/(losses)	459	(4,776)	1,139	(4,638)	(4,180)
Interest income	955	287	2,769	1,184	13,345
Interest expense	(54)	(69)	(154)	(244)	(4,383)
Total other income (expense)	2,292	(4,126)	6,480	(377)	7,450
Loss before taxes	(4,647)	(18,058)	(14,248)	(33,954)	(210,808)
Income tax benefit	433	411	1,549	1,511	16,036
Net loss	(4,214)	(17,647)	(12,699)	(32,443)	(194,772)
Dividends on Preferred Ordinary shares					(38,123)
Net loss applicable to ordinary shareholders	(4,214)	(17,647)	(12,699)	(32,443)	(232,895)
Net loss per share — basic and diluted	\$ (0.21)	\$ (0.86)	\$ (0.65)	\$ (1.59)	
Weighted average shares	20,433,129	20,433,129	19,685,457	20,433,129	

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# CYCLACEL PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

	As of December 31 <u>2007</u> \$000	As of September 30, <u>2008</u> \$000
ASSETS	<i>Q</i> UUU	<i><b>Q</b></i> <b>UUU</b>
Current assets:		
Cash and cash equivalents	30,987	26,723
Short-term investments	27,766	6,998
Inventory	213	571
Prepaid expenses and other current assets	4,811	3,017
Total current assets	63,777	37,309
Property, plant and equipment (net)	3,016	2,288
Deposits and other assets	196	196
Intangible assets (net)	4,305	—
Goodwill	4,618	1,832
Total assets	75,912	41,625
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	4,958	1,301
Accrued liabilities	4,015	5,710
Other current liabilities	1,279	1,291
Warrant liability	3,545	224
Current portion of other accrued restructuring charges	905	1,349
Current portion of equipment financing	10	
Total current liabilities	14,712	9,875
Other accrued restructuring charges, net of current	2,090	1,361
Other long term payables	1,141	616
Total liabilities	17,943	11,852
Stockholders' equity:	57,969	29,773
Total liabilities and stockholders' equity	75,912	41,625

SOURCE: Cyclacel Pharmaceuticals, Inc.

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