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 11, 2023

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 1500
Berkeley Heights, NJ 07922
(Address of principal executive offices and 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 (*see* General Instruction A.2. below):

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

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

☐ **Pre-commencement communications pursuant 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))**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	CYCC	The Nasdaq Capital Market LLC
Preferred Stock, $0.001 par value	CYCCP	The Nasdaq Capital Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 11, 2023, announcing certain financial results for the first quarter ended March 31, 2023.

The Company will conduct a conference call to review its financial results on May 11, 2023, at 4:30 p.m., Eastern Time.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release announcing financial results for the first quarter ended March 31, 2023, dated May 11, 2023.
104	Cover Page Interactive Data File (embedded with the Inline XBRL document).

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 11, 2023

Exhibit 99.1

Cyclacel Pharmaceuticals, Inc.

P R E S S R E L E A S E

CYCLACEL PHARMACEUTICALS REPORTS FIRST QUARTER FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

- Key Catalysts ahead with multiple Value Generating Readouts -
- Expects to Report Phase 1/2 Data Releases with Oral Fadraciclib -
- Advancing single-agent Efficacy with Differentiated Oral Plogosertib -
- Adds to Balance Sheet with non-dilutive $4.7 million from R&D Tax Credit -
- Management to Host Conference Call at 4:30 pm EDT Today -

BERKELEY HEIGHTS, NJ, May 11, 2023 - Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; "Cyclacel" or the "Company"), a biopharmaceutical leader in cell cycle checkpoint control developing innovative medicines based on cancer cell biology, announced today first quarter financial results and provided a business update.

“We are on track to deliver on key readouts this year. For fadraciclib, our oral CDK2/9 inhibitor, we plan to report pharmacokinetic (PK), pharmacodynamic (PD), safety and activity data from the dose escalation stage of our 065-101 study followed by initial clinical activity data from the Phase 2 proof of concept (PoC) stage. We also expect to report PK, PD, safety and activity data from the dose escalation part of our 140-101 Phase 1/2 study of plogosertib, our oral PLK1 inhibitor,” said Spiro Rombotis, President and Chief Executive Officer. “Data collected to date suggest that fadraciclib and plogosertib are differentiated from other molecules in their respective classes. Furthermore, the receipt of $4.7 million in non-dilutive capital from the R&D tax credit along with existing resources supports our ongoing clinical programs.”

“Both clinical programs with fadraciclib and plogosertib are progressing well and are approaching important data readouts,” said Mark Kirschbaum, M.D., Chief Medical Officer. “In 065-101, we are currently recruiting patients at dose level 6A of fadraciclib with the aim of optimizing the recommended Phase 2 dosing schedule before opening the PoC stage. Our Phase 2 clinical sites are ready to enroll patients with the tumor types that appear to be most sensitive to fadraciclib treatment. With plogosertib we are recruiting patients at dose level 4. After observing unexpected efficacy at lower dose levels with three patients on treatment for three to eight cycles, we are investigating the biological rationale for this effect and how we could exploit these findings in subsequent studies. We remain enthusiastic about our clinical stage pipeline and look forward to presenting emerging data from these two programs during the year.“

Key Upcoming Milestones for 2023

- Report final data from dose escalation stage and RP2D determination from the 065-101 study of oral fadraciclib in patients with advanced solid tumors and lymphoma
- First patient dosed with oral fadraciclib in Phase 2 proof-of-concept stage of 065-101 study in patients with advanced solid tumors and lymphoma
- Report Phase 1 data from 140-101 study of oral plogosertib in patients with advanced solid tumors and lymphoma
- Report interim data from initial cohorts in Phase 2 proof-of-concept stage of 065-101 study with oral fadraciclib in patients with advanced solid tumors and lymphoma

Financial Highlights

As of March 31, 2023, pro forma cash and cash equivalents totaled $16.1 million, including the $4.7 million of United Kingdom research & development tax credits received after the end of the quarter. Cash and cash equivalents as of March 31, 2023 was $11.4 million, compared to $18.3 million as of December 31, 2022. Net cash used in operating activities was $6.9 million for the three months ended March 31, 2023 compared to $6.8 million for the same period of 2022. The Company estimates that its available cash will fund currently planned programs into the first quarter of 2024.

Research and development (R&D) expenses were $5.7 million for the three months ended March 31, 2023, as compared to $5.0 million for the same period in 2022. R&D expenses relating to fadraciclib were $4.1 million for the three months ended March 31, 2023, as compared to $3.6 million for the same period in 2022 due to increased non-clinical expenditures. R&D expenses related to plogosertib were $1.4 million for the three months ended March 31, 2023, as compared to $1.1 million for the same period in 2022 due to clinical trial costs associated with the progression of the Phase 1/2 study.

General and administrative expenses for the three months ended March 31, 2023 and 2022, remained relatively flat at $1.6 million.

Total other income, net, for the three months ended March 31, 2023, was $0.2 million compared to an income of $1.3 million for the same period of the previous year. The decrease of $1.1 million for the three months ended March 31, 2023, is primarily related to royalty income received in the previous year.

United Kingdom research & development tax credits for the three months ended March 31, 2023 were $1.3 million compared to $1.1 million for the same period of the previous year and are directly correlated to qualifying research and development expenditure.

Net loss for the three months ended March 31, 2023, was $5.8 million, compared to $4.1 million for the same period in 2022.

Conference call information:

US/Canada call: (800) 274-8461 / international call: (203) 518-9783

US/Canada archive: (800) 839-6975 / international archive: (402) 220-6061

Code for live and archived conference call is CYCCQ123. Webcast link

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 clinical-stage, biopharmaceutical company developing innovative cancer medicines based on cell cycle, transcriptional regulation and mitosis biology. The transcriptional regulation program is evaluating fadraciclib, a CDK2/9 inhibitor, and the anti-mitotic program plogosertib, a PLK1 inhibitor, in patients with both solid tumors and hematological malignancies. Cyclacel's strategy is to build a diversified biopharmaceutical business based on a pipeline of novel drug candidates addressing oncology and hematology indications. For additional information, please visit www.cyclacel.com.

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, trials may have difficulty enrolling, Cyclacel may not obtain approval to market its product candidates, the risks associated with reliance on outside financing to meet capital requirements, the potential effects of the COVID-19 pandemic, 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 other filings we file 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.

Contacts

Company: Paul McBarron, (908) 517-7330, pmcbarron@cyclacel.com
Investor Relations: Grace Kim, IR@cyclacel.com

SOURCE: Cyclacel Pharmaceuticals, Inc.

CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS (LOSS)
(In $000s, except share and per share amounts)

	Three Months Ended March 31,	
	2023	**2022**
Revenues	$ -	$ -
Operating expenses:		
Research and development	5,674	4,954
General and administrative	1,645	1,605
Total operating expenses	7,319	6,559
Operating loss	(7,319)	(6,559)
Other income (expense):		
Foreign exchange gains (losses)	(87)	29
Interest income	116	4
Other income, net	166	1,280
Total other income (expense), net	195	1,313
Loss before taxes	(7,124)	(5,246)
Income tax benefit	1,320	1,138
Net loss	(5,804)	(4,108)
Dividend on convertible exchangeable preferred shares	(50)	(50)
Net loss applicable to common shareholders	$ (5,854)	$ (4,158)
Basic and diluted earnings per common share:		
Net loss per share – basic and diluted	$ (0.47)	$ (0.42)
Weighted average common shares outstanding	12,539,189	9,993,135

CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEET
(In $000s, except share, per share, and liquidation preference amounts)

	March 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,435	$ 18,345
Prepaid expenses and other current assets	7,539	6,066
Total current assets	18,974	24,411
Property and equipment, net	31	32
Right-of-use lease asset	139	142
Non-current deposits	2,916	2,916
Total assets	$ 22,060	$ 27,501
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,509	$ 2,561
Accrued and other current liabilities	4,829	4,831
Total current liabilities	7,338	7,392
Lease liability	80	106
Total liabilities	7,418	7,498
Redeemable common stock	4,494	4,494
Stockholders' equity	10,148	15,509
Total liabilities and stockholders' equity	$ 22,060	$ 27,501