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): August 10, 2022

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 Stock Market LLC
Preferred Stock, $0.001 par value	CYCCP	The Nasdaq Stock 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 August 10, 2022, announcing certain financial results for the second quarter ended June 30, 2022.

The Company will conduct a conference call to review its financial results on August 10, 2022, 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 second quarter ended June 30, 2022, dated August 10, 2022.
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: August 10, 2022

Cyclacel Pharmaceuticals, Inc.

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

CYCLACEL PHARMACEUTICALS REPORTS SECOND QUARTER 2022 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

- Oral fadraciclib demonstrated good tolerability with continuous dosing; anticipate entering Phase 2 POC stage in 2H 2022 –

- Demonstrated evidence of target engagement for CDK2 and CDK9 –

- Company to host R&D day in fall of 2022 to highlight data updates for fadraciclib and CYC140 in solid tumor Phase 1/2 studies

- Cash runway into 2H 2023 -

- Conference call scheduled for August 10, 2022 at 4:30 pm ET -

BERKELEY HEIGHTS, NJ, August 10, 2022 - Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; "Cyclacel" or the "Company"), a biopharmaceutical company developing innovative medicines based on cancer cell biology, today announced second quarter 2022 financial results and provided a business update.

“In the first half of 2022 we have established that oral fadraciclib, our CDK2 and CDK9 inhibitor, is well-tolerated and demonstrated single-agent, anticancer activity across multiple solid tumor and lymphoma patients in our 065-101 study,” said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. “In the second half of 2022 we are optimizing the dosing schedule to maximize target coverage and determine recommended Phase 2 dose (RP2D). We then anticipate advancing into Phase 2 proof of concept stage of 065-101. We believe that daily dosing of oral fadraciclib targeting both CDK2 and CDK9 at efficacious doses without dose limiting toxicities may represent best-in-class properties. We look forward to reporting additional clinical and preclinical data at our upcoming R&D Day for both fadraciclib and CYC140, our differentiated PLK1 inhibitor, also in a Phase 1/2 study.”

“We are excited with the progress of oral fadraciclib in our Phase 1/2 solid tumor and lymphoma study because of the promising safety and early efficacy results we are seeing in a challenging Phase 1 population,” said Mark Kirschbaum, M.D., Chief Medical Officer of Cyclacel. “As fadraciclib has been relatively well tolerated, 065-101 principal investigators agreed to continue dose escalation with the current 4-week schedule. Following Food and Drug Administration (FDA) clearance of a protocol amendment, we are recruiting patients at the sixth dose level of 065-101. We have previously observed partial response and anticancer activity including tumor shrinkage in endometrial, lymphoma and pancreatic cancer patients. In parallel we are determining which tumor types to prioritize for the Phase 2 stage of 065-101 informed by preclinical modeling and data from our clinical collaborators. The 065-102 study of fadraciclib in advanced leukemias continues to enroll at the 100mg twice a day dose level after clearance of a protocol amendment that allowed us to skip two dose levels. We are also encouraged that the 140-101 dose escalation study of CYC140 is now recruiting patients with solid tumors and lymphomas for the second dose level.”

Key Highlights

- **Oral fadraciclib 065-101 Phase 1/2 study in advanced solid tumors:** The study has enrolled seventeen patients with advanced solid tumors and lymphomas treated with oral fadraciclib up to dose level five (100mg dosed twice daily, 4 weeks out of 4) with no-dose limiting toxicities observed thus far. Following recent FDA clearance to escalate, two additional, higher dose levels will be evaluated before determining recommended Phase 2 dose. Dose level six is now recruiting.

Summary of key efficacy, safety and PK findings to date:

- A cutaneous T cell lymphoma (CTCL) patient achieved partial response (PR) in the first oral treatment cycle.
- A patient with a very aggressive form of peripheral T cell lymphoma (PTCL) achieved 38% reduction in target lesions by PET scan in the first oral treatment cycle.
- An endometrial cancer patient achieved stable disease with 15% reduction of target lesions after the first oral treatment cycle. In an earlier study of intravenous fadraciclib as monotherapy, a patient with MCL1 amplified endometrial cancer achieved confirmed complete response (CR) and remains on study after two and a half years of treatment.
- A pancreatic cancer patient achieved stable disease by confirmatory scan for five oral treatment cycles.
- No dose limiting toxicities have been observed at any of the five dose levels evaluated thus far. The FDA has cleared a protocol amendment to escalate to two additional dose levels; dose level six at 150mg and dose level 7 at 200mg twice daily.
- Demonstrated evidence of target engagement for CDK2 and CDK9 in cell assay systems; patient PK data suggested that these targets are potentially inhibited at 100mg twice daily levels.

The 065-101 study is enrolling at four sites. Several additional sites are in start-up preparations to join the Phase 2 proof-of-concept stage of this registration-directed study. The Phase 2 part of 065-101 includes seven histologically defined cohorts thought to be sensitive to the drug's mechanism: breast, colorectal (including KRAS mutant), endometrial/uterine, hepatobiliary, ovarian cancers and lymphomas. The study also includes an eighth basket cohort which will enroll patients regardless of histology with biomarkers relevant to the drug's mechanism, including MCL1, MYC and/or cyclin E amplified.

- **Oral fadraciclib 065-102 Phase 1/2 study in leukemias or myelodysplastic syndromes:** Based on good tolerability in the 065-101 study, FDA clearance of a protocol amendment in the 065-102 study has accelerated dose progression by omitting dose levels two and three and now enrolling at dose level four.

In April, the Company announced a publication in the journal, *Leukemia*, confirming fadraciclib suppresses MCL1 and synergizes with venetoclax in chronic lymphocytic leukemia. Results from the study confirmed that fadraciclib inhibited CDK9-mediated transcription, reduced levels of the short-lived, anti-apoptotic protein MCL1, and induced apoptosis in primary CLL cells. The data highlighted the importance of continuous treatment to prevent recovery of MCL1 protein levels. Furthermore, fadraciclib was shown to combine synergistically with the BCL2 antagonist, venetoclax, and demonstrated even greater synergy when targeted against 17p deleted CLL cells which were not sensitive to either agent alone.

- **Oral CYC140 140-101 Phase 1/2 study in solid tumors and lymphomas:** The registration-directed, Phase 1 dose escalation stage of this study is enrolling patients at dose level two.

Summary of key efficacy, safety and PK findings to date:

- No dose limiting toxicities observed to date.
- An ovarian cancer patient in 140-101 achieved stable disease with tumor shrinkage after the first treatment cycle and is continuing treatment on cycle three.

The study uses a streamlined design and will initially determine RP2D for single-agent oral CYC140. Following RP2D, the trial will immediately enter into proof-of-concept, cohort stage, using a Simon 2-stage design. In this stage CYC140 will be administered to patients in up to seven mechanistically relevant cohorts including patients with bladder, breast, colorectal (including KRAS mutant), hepatocellular and biliary tract, and lung cancers (both small cell and non-small cell), as well as lymphomas plus an eighth basket cohort which will enroll patients with biomarkers relevant to the drug's mechanism.

Financial Highlights

As of June 30, 2022, cash and cash equivalents totaled $29.1 million, compared to $36.6 million as of December 31, 2021. Net cash used in operating activities was $8.7 million for the six months ended June 30, 2022 compared to $7.8 million for the same period of 2021. The Company estimates that its available cash will fund currently planned programs into the second half of 2023.

Research and development (R&D) expenses were $4.2 million for the three months ended June 30, 2022, as compared to $4.1 million for the same period in 2021. R&D expenses relating to fadraciclib were $2.6 million for the three months ended June 30, 2022, as compared to $2.8 million for the same period in 2021 due to increased clinical trial costs of $0.5 million associated with ongoing clinical trials evaluating fadraciclib in Phase 1/2 studies offset by a reduction of $0.7 million in non-clinical expenditures. R&D expenses related to CYC140 were $1.5 million for the three months ended June 30, 2022, as compared to $1.1 million for the same period in 2021 due to clinical trial costs associated with the start of the CYC140 Phase 1/2 study.

General and administrative expenses for the three months ended June 30, 2022, were $1.6 million, compared to $2.0 million for the same period of the previous year due to a decrease in facilities, professional and recruitment costs

Total other income, net, for the three months ended June 30, 2022, was $0.2 million, compared to $9,000 for the same period of the previous year. The increase of $0.2 million for the three months ended June 30, 2022, is primarily related to foreign exchange gains.

United Kingdom research & development tax credits were $1.0 million for each of the three months ended June 30, 2022 and June 30, 2021 and are directly correlated to qualifying research and development expenditure. Tax credit receipts of $3.3 million in respect of the financial year ended December 31, 2021, were received in April 2022.

Net loss for the three months ended June 30, 2022, was $4.6 million, compared to $5.1 million for the same period in 2021.

Conference call information:

US/Canada call: (800) 225-9448 / international call: (203) 518-9708

US/Canada archive: (888) 269-5330 / international archive: (402) 220-7326

Code for live and archived conference call is CYCCQ222. 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 CYC140, 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

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SOURCE: Cyclacel Pharmaceuticals, Inc.

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

	Three Months Ended June 30,	
	2022	**2021**
Revenues:		
Total revenues	-	-
Operating expenses:		
Research and development	4,205	4,101
General and administrative	1,580	1,999
Total operating expenses	5,785	6,100
Operating loss	(5,785)	(6,100)
Other income (expense):		
Foreign exchange gains (losses)	209	(13)
Interest income	17	4
Other income, net	-	18
Total other income (expense), net	226	9
Loss before taxes	(5,559)	(6,091)
Income tax benefit	984	964
Net loss	(4,575)	(5,127)
Dividend on convertible exchangeable preferred shares	(50)	(50)
Net loss applicable to common shareholders	$ (4,625)	$ (5,177)
Basic and diluted earnings per common share:		
Net loss per share – basic and diluted	$ (0.46)	$ (0.56)
Weighted average common shares outstanding	10,136,089	9,234,110

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

	June 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 29,077	$ 36,559
Prepaid expenses and other current assets	3,000	4,383
Total current assets	32,077	40,942
Property and equipment, net Property and equipment, net	48	64
Right-of-use lease asset	161	30
Property and equipment, net Non-current deposits	3,060	1,551
Total assets	$ 35,346	$ 42,587
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,205	$ 2,117
Accrued and other current liabilities	2,821	3,177
Total current liabilities	5,026	5,294
Lease liability	113	30
Total liabilities	5,139	5,324
Stockholders' equity	30,207	37,263
Total liabilities and stockholders' equity	$ 35,346	$ 42,587