**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 10, 2021**

# 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 November 10, 2021, announcing certain financial results for the third quarter ended September 30, 2021.

The Company will conduct a conference call to review its financial results on November 10, 2021, 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 third quarter ended September 30, 2021, dated November 10, 2021. |
| 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: November 10, 2021

**Exhibit 99.1**

Cyclacel Pharmaceuticals, Inc.

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

**CYCLACEL PHARMACEUTICALS REPORTS THIRD QUARTER 2021 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE**

***- Second Phase 1/2 Study of Fadraciclib Now Enrolling Patients in Leukemia -***

***- Cash Runway to Early 2023 -***

***- Conference Call Scheduled November 10, 2021 at 4:30 p.m. ET -***

**Berkeley Heights, NJ, November 10, 2021 -** Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; "Cyclacel" or the "Company"), a biopharmaceutical company developing innovative medicines based on cancer cell biology, today reported its financial results for the third quarter 2021. The quarter's business highlights include an update on the Company's progress with fadraciclib and CYC140, Cyclacel's novel CDK2/9 and PLK1 inhibitors, respectively.

"The Cyclacel team continued to execute on our plan during the quarter with the opening of two Phase 1/2 studies for oral fadraciclib and filing an IND for a Phase 1/2 study of our oral PLK1 inhibitor, CYC140," said Spiro Rombotis, President and Chief Executive Officer. "We have now enrolled a total of six patients across two dosing levels in our fadraciclib study in solid tumors and have started the first dose level in the fadraciclib study in leukemia. We are pleased with the strong investigator interest in our studies as we build a global network of participating institutions for our clinical studies and preclinical collaborations.

We are also looking forward to the near future with the planned initiation of two registration-enabling Phase 1/2 studies of CYC140 in patients with solid tumors and leukemias and reporting initial data for fadraciclib in solid tumors. We remain diligently focused on bringing innovative treatment options to cancer patients with unmet medical needs and realizing the promise of our pipeline."

**Key Corporate Highlights**

*Oral fadraciclib program*

- Six patients with advanced solid tumors treated in the first two dosing levels of 065-101, Phase 1/2, registration-directed study
- Two additional internationally-recognized cancer treatment centers added to 065-101 selected for their expertise with tumor types of interest; for a total of four sites
- First patient dosed in the 065-102, Phase 1/2, registration-directed study in patients with leukemia
- Multiple preclinical studies in progress which will inform fadraciclib's clinical development

*Oral CYC140 program*

- Filed with FDA an IND for a streamlined, registration-directed, Phase 1/2 study of orally-available CYC140 in solid tumors
- Initial data in preclinical models show that KRAS mutant cancers are sensitive to oral CYC140 inhibition
- Preclinical collaborative studies ongoing to support selection of histologies to be included in the Phase 1/2 study

**Key Near-Term Business Objectives**

- FDA clearance of IND filing and initiation of oral CYC140 Phase 1/2 advanced solid tumor study
- Initial data from first part of 065-101 study with oral fadraciclib in advanced solid tumors
- First patient to be dosed with oral CYC140 in Phase 1/2 leukemia study
- Initial data from first part of 065-102 study with oral fadraciclib in leukemia

**Financial Highlights**

As of September 30, 2021, cash and cash equivalents totaled $40.2 million, compared to $43.6 million as of June 30, 2021. The decrease of $3.4 million was primarily due to $6.3 million net cash used in operating activities, offset by $2.9 million cash provided by financing activities. The Company estimates that available cash resources will fund currently-planned programs through early 2023.

Research and development (R&D) expenses were $4.2 million for the three months ended September 30, 2021 as compared to $1.1 million for the same period in 2020. R&D expenses relating to fadraciclib increased by approximately $2.5 million for the three months ended September 30, 2021 due to clinical supply manufacturing and opening of clinical trial sites for the evaluation of fadraciclib in Phase 1/2 studies. Additionally, R&D expenses related to CYC140 increased $0.5 million for the quarter as preclinical evaluation and clinical trial supply manufacturing of CYC140 progressed.

General and administrative expenses for the three months ended September 30, 2021 were $1.8 million, compared to $1.5 million for the same period of the previous year due to increased legal, professional and recruitment costs relating to expansion of the clinical team.

United Kingdom research & development tax credits were $1.0 million for the three months ended September 30, 2021, as compared to $0.3 million for the same period in 2020 due to the increase in R&D expenditure.

Net loss for the three months ended September 30, 2021 was $5.0 million, compared to $2.3 million for the same period in 2020.

**Conference call information:**

**Conference ID: CYCCQ321**

US call: (877) 876-9173/ international call: +1 (785) 424-1667

Replay: US: (800) 938-2795 / international archive: +1 (402) 220-9029

Code for live and replay conference call is CYCCQ321 Webcast link.

For the live and archived webcast, please visit the Corporate Presentations page on the Cyclacel website at www.cyclacel.com.

**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, 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: LifeSci Advisors, LLC, Irina Koffler, (646) 970-4681, ikoffler@lifesciadvisors.com

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

| | Three Months Ended September 30, | |
|---|---|---|
| | **2020** | **2021** |
| **Revenues:** | | |
| **Total revenues** | - | - |
| **Operating expenses:** | | |
| Research and development | 1,075 | 4,217 |
| General and administrative | 1,497 | 1,781 |
| **Total operating expenses** | 2,572 | 5,998 |
| **Operating loss** | (2,572) | (5,998) |
| Other income (expense): | | |
| Foreign exchange gains (losses) | (25) | 9 |
| Interest income | 4 | 4 |
| Other income, net | 56 | - |
| Total other income (expense), net | 35 | 13 |
| **Loss before taxes** | (2,537) | (5,985) |
| Income tax benefit | 281 | 998 |
| **Net loss** | (2,256) | (4,987) |
| Dividend on convertible exchangeable preferred shares | (50) | (50) |
| Beneficial conversion feature of Series B preferred stock | - | - |
| **Net loss applicable to common shareholders** | $ (2,306) | $ (5,037) |
| **Basic and diluted earnings per common share:** | | |
| Net loss per share – basic and diluted | $ (0.47) | $ (0.54) |
| Weighted average common shares outstanding | 4,863,984 | 9,368,056 |

SOURCE: Cyclacel Pharmaceuticals, Inc.

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

| | December 31, 2020 | September 30, 2021 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 33,406 | $ 40,219 |
| Prepaid expenses and other current assets | 2,063 | 3,156 |
| Total current assets | 35,469 | 43,375 |
| | | |
| Property and equipment, net | 106 | 71 |
| Right-of-use lease asset | 1,227 | 44 |
| Non-current deposits | - | 1,509 |
| Total assets | $ 36,802 | $ 44,999 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 514 | $ 1,515 |
| Accrued and other current liabilities | 1,972 | 2,076 |
| Total current liabilities | 2,486 | 3,591 |
| Lease liability | 1,057 | 44 |
| Total liabilities | 3,543 | 3,635 |
| | | |
| Stockholders' equity | 33,259 | 41,364 |
| Total liabilities and stockholders' equity | $ 36,802 | $ 44,999 |

SOURCE: Cyclacel Pharmaceuticals, Inc.