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**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 11, 2014

**CYCLACEL PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation)

0-50626  
(Commission File Number)

91-1707622  
(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

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(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))
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## 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 exhibits 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 11, 2014, announcing certain financial results for the third quarter ended September 30, 2014.

The Company conducted a conference call to review its financial results on November 11, 2014, at 4:30 p.m., Eastern Time. A transcript of the conference call is attached hereto as Exhibit 99.2.

## Forward-Looking Statements

This Form 8-K 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](http://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.

## Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release announcing financial results for the third quarter ended September 30, 2014, dated November 11, 2014.
99.2	November 11, 2014 Conference Call Transcript.

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**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 12, 2014

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Cyclacel Pharmaceuticals, Inc.

## P R E S S   R E L E A S E

## CYCLACEL PHARMACEUTICALS REPORTS THIRD QUARTER 2014 FINANCIAL RESULTS

— Conference Call Scheduled November 11, 2014 at 4:30 p.m. EST —

**Berkeley Heights, NJ, November 11, 2014** - Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; “Cyclacel” or the “Company”), a biopharmaceutical company developing oral therapies that target the various phases of cell cycle control for the treatment of cancer and other serious disorders, today reported its financial results and business highlights for the third quarter ended September 30, 2014.

The Company’s net loss applicable to common shareholders for the third quarter ended September 30, 2014 was \$5.0 million, or \$0.22 per basic and diluted share, compared to net loss applicable to common shareholders of \$5.7 million, or \$0.32 per basic and diluted share for the third quarter ended September 30, 2013. As of September 30, 2014, cash and cash equivalents totaled \$26.7 million.

“We are pleased to report that enrollment in our SEAMLESS, registration-directed, Phase 3 study has reached approximately 90%,” said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. “As we approach completion of enrollment, we are looking forward to three key SEAMLESS milestones that are expected to occur around the end of 2014 or early 2015. These are the Data Safety Monitoring Board’s (DSMB) interim analysis for futility, the DSMB’s review of data from 400 patients enrolled and completion of enrollment. As we approach these milestones, we expect that our capital resources are sufficient to fund operations beyond announcement of SEAMLESS top-line data during the second half of 2015 or first half of 2016. In parallel to SEAMLESS, we are preparing for the start of the MDS randomized trial next year, continuing clinical investigation of our sapacitabine-seliciclib combination regimen in patients with solid tumors and filing an IND for our novel CYC065 Cyclin Dependent Kinase (CDK) inhibitor.”

**Business Highlights*****Sapacitabine in SEAMLESS, pivotal, Phase 3 study for first-line treatment in elderly patients with acute myeloid leukemia (AML):***

- Study enrollment reached approximately 90% of the required patients with the majority from US sites
- Over 100 sites open in the US and Europe
- The study’s DSMB conducted the fourth planned safety review of 317 randomized patients with at least 60 days of follow-up and recommended that the study should continue as planned without modifications

***Sapacitabine in Phase 2b randomized, controlled trial (RCT) for patients with myelodysplastic syndromes (MDS) after treatment failure of front-line hypomethylating agents***

- Disclosed proposed study design for eligible patients aged 60 years or older with intermediate-2 or high-risk MDS who have failed prior hypomethylating agent therapy
- Approximately 250 patients will be enrolled in a Phase 2b RCT with a lead-in stage
- Feasibility assessment is in progress
- Clinical trial anticipated to begin in 2015

## CYC065

- Presented preclinical data demonstrating therapeutic potential of CYC065, Cyclacel's second-generation cyclin dependent kinase (CDK) inhibitor, to treat acute leukemias, and in particular those with rearrangements in the mixed lineage leukemia (MLL) gene
  - § Data showed that, *in vitro*, all tested human AML and acute lymphocytic leukemia (ALL) cell lines with MLL rearrangements (MLLr) were sensitive to CYC065 and that the drug inhibited MLL-driven gene expression
  - § Potent anticancer activity of CYC065 was demonstrated *in vivo* in AML xenograft models resulting in over 90% inhibition of tumor growth
  - § Data were presented at the 2014 Society of Hematologic Oncology (SOHO) meeting

## Third Quarter 2014 Financial Results

### Grant Revenue

Revenue for the three months ended September 30, 2014 was \$0.7 million compared to \$0.3 million for the same period of the previous year. The revenue is related to previously awarded grants from the UK government being recognized over the period to progress CYC065, a CDK inhibitor, to IND and to complete IND-directed preclinical development of CYC140, a novel, orally available, Polo-Like Kinase 1 (PLK 1) inhibitor.

### Research and Development Expenses

Research and development expenses increased to \$5.0 million for the three months ended September 30, 2014 compared to \$4.6 million for the same period in the previous year. The increase was primarily due to increased expenditures related to grant funded research and development, partially offset by the absence of drug manufacturing costs related to the SEAMLESS study that were incurred during the three months ended September 30, 2013.

### General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2014 decreased to \$1.4 million compared to \$1.5 million for the same period in 2013. The decrease was primarily due to lower legal and professional fees during the three months ended September 30, 2014.

## Cyclacel's Key Milestones for 2014/2015

- Sapacitabine in SEAMLESS:
  - DSMB safety review of approximately 400 patients enrolled with approximately 60-day follow-up
  - DSMB review of SEAMLESS data for futility once approximately 212 events have been observed
  - Completion of SEAMLESS enrollment
- Sapacitabine in MDS:
  - Complete feasibility assessment of proposed RCT
- Sapacitabine in solid tumors:
  - Report updated Phase 1 sapacitabine and seliciclib combination data in patients with solid tumors including those carrying gBRCA mutations
- Advance early pipeline

## Conference call and Webcast Information:

Cyclacel will conduct a conference call on November 11, 2014 at 4:30 p.m. Eastern Time to review the third quarter 2014 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) 585-8367 / international archive: (404) 537-3406

Code for live and archived conference call is 23317872

For the live and archived webcast, please visit the Corporate Presentations and Events page on the Cyclacel website at [www.cyclacel.com](http://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 biopharmaceutical company developing oral therapies that target the various phases of cell cycle control for the treatment of cancer and other serious diseases. Sapacitabine, Cyclacel's most advanced product candidate, is the subject of SEAMLESS, a Phase 3 trial being conducted under an SPA with the FDA as front-line treatment for acute myeloid leukemia (AML) in the elderly, and other studies for myelodysplastic syndromes (MDS), chronic lymphocytic leukemia (CLL) and solid tumors including breast, lung, ovarian and pancreatic cancer and in particular those carrying gBRCA mutations. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a development pipeline of novel drug candidates. Please visit [www.cyclacel.com](http://www.cyclacel.com) for additional information.

**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](http://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 for Cyclacel Pharmaceuticals, Inc.**

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**CYCLACEL PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(In \$000s, except share and per share amounts)

(Unaudited)

	Three Months Ended September 30,	
	2013	2014
<b>Revenues:</b>		
Grant revenue	\$ 309	\$ 735
<b>Total revenues</b>	<b>309</b>	<b>735</b>
<b>Operating expenses:</b>		
Research and development	4,575	4,972
General and administrative	1,529	1,433
<b>Total operating expenses</b>	<b>6,104</b>	<b>6,405</b>
<b>Operating loss</b>	<b>(5,795)</b>	<b>(5,670)</b>
Other income (expense):		
Change in valuation of financial instruments associated with stock purchase agreement	—	(4)
Change in valuation of Economic Rights	—	—
Change in valuation of liabilities measured at fair value	—	—
Foreign exchange gains	25	10
Interest income	8	3
Other income, net	16	—
Total other income (expense)	49	9
<b>Loss from continuing operations before taxes</b>	<b>(5,746)</b>	<b>(5,661)</b>
Income tax benefit	730	750
<b>Net loss from continuing operations</b>	<b>(5,016)</b>	<b>(4,911)</b>
<b>Discontinued operations:</b>		
Income from discontinued operations	20	6
Income tax on discontinued operations	(8)	(2)
<b>Net income from discontinued operations</b>	<b>12</b>	<b>4</b>
<b>Net loss</b>	<b>(5,004)</b>	<b>(4,907)</b>
Deemed dividend on convertible exchangeable preferred shares	(661)	—
Dividend on convertible exchangeable preferred shares	(63)	(50)
<b>Net loss applicable to common shareholders</b>	<b>\$ (5,728)</b>	<b>\$ (4,957)</b>
<b>Basic and diluted earnings per common share:</b>		
Net loss per share, continuing operations	\$ (0.32)	\$ (0.22)
Net income per share, discontinued operations	\$ 0.00	\$ 0.00
Net loss per share applicable to common shareholders	\$ (0.32)	\$ (0.22)
Weighted average shares of common stock outstanding	17,788,568	22,676,475

**CYCLACEL PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

(In \$000s, except share, per share, and liquidation preference amounts)

	December 31, 2013	September 30, 2014 (Unaudited)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 31,146	\$ 26,707
Prepaid expenses and other current assets	3,388	4,202
Current assets of discontinued operations	639	267
Total current assets	35,173	31,176
Property and equipment (net)	275	454
Long-term assets of discontinued operations	72	—
Total assets	<u>\$ 35,520</u>	<u>\$ 31,630</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,545	\$ 2,201
Accrued and other current liabilities	4,431	4,490
Other liabilities measured at fair value	20	—
Current liabilities of discontinued operations	260	75
Total current liabilities	7,256	6,766
Other liabilities	241	221
Total liabilities	7,497	6,987
Commitments and contingencies	—	—
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 31, 2013 and September 30, 2014; 335,273 shares issued and outstanding at December 31, 2013 and September 30, 2014. Aggregate preference in liquidation of \$3,989,749 at December 31, 2013 and September 30, 2014.	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized at December 31, 2013 and September 30, 2014; 19,369,332 and 22,676,475 shares issued and outstanding at December 31, 2013 and September 30, 2014, respectively.	19	23
Additional paid-in capital	317,543	328,943
Accumulated other comprehensive loss	(109)	(305)
Accumulated deficit	(289,430)	(304,018)
Total stockholders' equity	28,023	24,643
Total liabilities and stockholders' equity	<u>\$ 35,520</u>	<u>\$ 31,630</u>

SOURCE: Cyclacel Pharmaceuticals, Inc.

**CYCLACEL PHARMACEUTICALS, INC.**  
**Third Quarter 2014 Earnings Conference Call**

**November 11, 2014**  
**4:30 p.m. ET**

**TRANSCRIPT**

**CORPORATE PARTICIPANTS**

**Bill Harris** *Cyclacel Pharmaceuticals, Inc. – Corporate Controller*

**Spiro Rombotis** *Cyclacel Pharmaceuticals, Inc. – President and CEO*

**Paul McBarron** *Cyclacel Pharmaceuticals, Inc. – Executive Vice President, Finance and Chief Operating Officer*

**Dr. Judy Chiao** *Cyclacel Pharmaceuticals, Inc. – Vice President of Clinical Development and Regulatory Affairs*

**CONFERENCE CALL PARTICIPANT**

**Mike King** *JMP Securities – Analyst*

**PRESENTATION**

**Operator:** Good afternoon and welcome to Cyclacel Pharmaceuticals third quarter 2014 earnings conference call and Webcast. Today's call is being recorded.

At this time, all participants have been placed in a listen-only mode and the floor will be open for questions following the participation – presentation. If you would like to ask a question at that time, please press star one on your touchtone phone. If at any point your question has been answered, you may remove yourself from the queue by pressing the pound key. In posing your question, we ask that you please pick up your handset to allow optimal sound quality. Lastly, if you should require operator assistance, please press star zero.

It is now my pleasure to turn the floor over to Bill Harris, Cyclacel's Corporate Controller. Sir, you may begin.

**Bill Harris:** Thank you, Kristen. Good afternoon and welcome to our quarterly conference call. During today's call, members of our senior management team will review Cyclacel's financial performance and business highlights for the third quarter ended September 30th, 2014.

Before turning the call over to senior management, I would like to remind everyone that during this conference call, any forward-looking statements made by management are intended to fall within the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995 and Section 21-E of the Securities Exchange Act of 1934 as amended. As set forth in our press release, forward-looking statements involve risks and uncertainties that may

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affect the company's business and prospects, including those discussed in our filings with the SEC which include, among other things, our Forms 10-Q and 10-K. These filings are available from the SEC or our website. All of our projections and other forward-looking statements represent our judgment as of today and Cyclacel does not take any responsibility to update such information.

With us today are Spiro Rombotis, President and Chief Executive Officer; Paul McBarron, Executive Vice President Finance and Chief Operating Officer; and Dr. Judy Chiao, Vice President of Clinical Development and Regulatory Affairs. At this time, I would like to turn the call over to Spiro Rombotis, our President and CEO.

**Spiro Rombotis:**

Thank you, Bill. And good afternoon, everyone. Our primary focus on today's call will be our SEAMLESS pivotal phase three study of sapacitabine as a frontline treatment in elderly patients with acute myeloid leukemia or AML who have refused or are not suitable for intensive chemotherapy.

We are pleased to report that enrollment in SEAMLESS has now reached approximately 90 percent of the required number of patients. You may recall that earlier this year, we expanded the study from the U.S. into Europe and we now have over 100 sites open. With the continuing support of U.S. and European investigators and their patients, we expect to complete enrollment of SEAMLESS around the end of 2014 or early 2015 as planned. Although we have had very strong uptake in Europe, we expect that about two-thirds of the total number of patients will have been recruited from U.S. sites. In other words, if the sample size is N equals 485, we expect that over 300 patients will be from U.S. sites.

The long journey of enrolling the randomized part of SEAMLESS which started in late 2011 is approaching the finish line with a projected enrollment time of 3.2 years. The speed of accrual in SEAMLESS compares favorably to a similar study called DACO-016 which compared decitabine versus low-dose chemotherapy with a sample size of also N equals 485. DACO-016 took 3.5 years to enroll in a total of 65 sites. Of note, only 35 patients were enrolled in U.S. sites. These facts may suggest that SEAMLESS is an attractive study

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design for U.S. and now European elderly patients with AML seeking low intensity treatment alternatives.

Last month, we announced that the Data Safety Monitoring Board, or DSMB, of SEAMLESS reviewed data from 317 patients with approximately 60 days of follow-up in its fourth planned review. The DSMB determined that there were no safety or efficacy concerns and recommended that the study should continue as planned. We expect that the next DSMB review will be the interim analysis for futility and the review of approximately 400 patients enrolled to take place around the end of this year or early 2015.

In SEAMLESS, the interim analysis for futility was prospectively defined to occur when approximately 212 events or deaths occurred in the study. Our communication of the DSMB's recommendations may therefore occur at approximately the same timeframe as the estimated completion of enrollment. An interim analysis for futility of a pivotal phase three trial is an important milestone for any sponsor company and one of interest to investors.

The purpose of the interim analysis is to determine if the primary endpoint is futile, which means unlikely to be met if the study continued to full enrollment, or not futile. Typically, an interim analysis would occur closer to the midpoint of a clinical trial. In a futile outcome, usually the study will be stopped if there is no statistical chance that the experimental arm would be superior to the control arm. The case of SEAMLESS is perhaps atypical given the timing coincidence of the interim analysis of futility and completion of enrollment.

As we expect to soon complete SEAMLESS enrollment, we would like to take this opportunity to thank patients and investigators who have participated in the study for helping Cyclacel achieve this forthcoming milestone.

In parallel with our efforts on the enrollment front, we are planning a fast-track submission and a rolling NDA submission strategy that allows us to submit certain sections of the NDA when they are completed. For example, biopharmaceutical or chemistry, manufacturing and controls or CMC sections

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would be submitted ahead of the clinical section which would be submitted last when final data from the pivotal study would become available.

Turning to sapacitabine in myelodysplastic syndromes, or MDS, you recall that in May, we held an investor event in Chicago concurrently with the ASCO conference to review our activities and plans for advancing sapacitabine in MDS into a phase 2B randomized controlled trial or RCT. Since that meeting, we have obtained initial feedback from experts in the field and commissioned a feasibility assessment with multiple CROs bidding for the project. The project has since been awarded and work is underway. Subject to the outcome of feasibility, we expect to initiate the RCT in 2015.

Of note, one of the opportunities of opening a large number of European sites for SEAMLESS is that many of these may be interested in our MDS RCT, as well. As before, we are also reaching out to U.S. investigators, including SEAMLESS participants, to determine their interest in our MDS study. In parallel with our sapacitabine program in liquid tumors, we have been reviewing the opportunities that may arise in solid tumors for sapacitabine as well as our earlier stage cyclin-dependent kinase, or CDK, inhibitor program.

In the last year or so, the pharmaceutical industry has been expressing increased interest in CDK inhibitors. Recently the first NDA in the class was submitted to the FDA for the CDK inhibitor palbociclib in combination with letrozole for the treatment of postmenopausal women with ER positive, HER2 negative advanced breast cancer who have not received previous systemic treatments.

Our lead CDK inhibitor, seliciclib, targeting CDK2 and CDK9, is currently being evaluated in Phase 1 study in combination with sapacitabine in patients with homologous recombination, or HR, deficient cancers, including those with breast and ovarian cancers who carry germline or gBRCA mutations.

We have previously reported at the American Association of Cancer Research 2013 meeting, promising clinical data with this all oral combination regimen of two Cyclacel drugs. Durable clinical responses were observed in patients with breast, ovarian and pancreatic cancers and in particular those who carry

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gBRCA mutations. We continue to evaluate this regimen in an enriched patient population that is all patients treated must first test positive for gBRCA mutations as we seek to expand and confirm earlier clinical findings.

Our second generation CDK inhibitor, CYC065, is a highly selective inhibitor of CDK enzymes with a similar isoform target profile to seliciclib that is also targeting CDK2 and CDK9. Unlike seliciclib, we intend to administer CYC065 by both intravenous and oral administration routes. Investigational new drug or IND enabling studies with CYC065 have now been completed and the program is ready to advance into first in human studies. CYC065 has been shown to have increased anti-proliferative potency and improved pharmaceutical properties compared to seliciclib. CYC065 has shown efficacy in pre-clinical cancer models of both solid tumor, including breast cancer and acute leukemias, including AML.

In breast cancer, we're particularly excited with regard to CYC065's potential to reverse resistance to trastuzumab, one of the most successful breast cancer drugs in history. Independent investigators have published evidence of CYC065's activity in HER2 positive trastuzumab-resistant breast cancer cells extracted from patients. Together with our advisors, we are currently evaluating clinical development plans in a number of different patient populations in whom targeting CDK2 and CDK9 may confer clinical benefit.

Before turning the call over to Paul, let me summarize our key upcoming milestones.

- Announce the results of the SEAMLESS interim analysis for futility and safety analysis of approximately 400 randomized patients around the end of this year or early 2015
  - Completion of enrollment in SEAMLESS around the end of this year or early 2015
  - Complete feasibility assessment of the MDS RCT
  - Begin patient enrollment of the MDS RCT in 2015
  - Announce topline outcomes of the SEAMLESS trial during second half 2015 or first half 2016
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- Report updated phase one sapacitabine and seliciclib combination data in patients with solid tumors
- Advance our earlier pipeline assets

We will now review our financials. Paul?

**Paul McBarron:**

Thank you, Spiro. As you saw from today's press release regarding our consolidated financial statements for the quarters ended September 30th, 2014 and September 30th, 2013, our cash position was \$26.7 million as of September 30th, 2014 compared to \$31.1 million at the end of 2013.

The movement of \$4.4 million was primarily due to approximately \$10.8 million of net proceeds from the sale of common stock, partially offset by \$15.0 million of net cash used in operating activities. There is no outstanding debt.

Revenue for the three months ended September 30th, 2014 was \$0.7 million compared to \$0.3 million for the same period of the previous year. The revenue is related to previously awarded grants from the U.K. government being recognized over the period to progress CYC065, our CDK inhibitor, to IND and to complete IND-directed pre-clinical development of CYC140, a novel, orally available, Polo-Like Kinase 1 or PLK1 inhibitor.

Research and development expenses increased to \$5.0 million for the three months ended September 30th, 2014 compared to \$4.6 million for the same period in the previous year. The increase was primarily due to costs related to grant-funded research and development, partially offset by the absence of drug manufacturing costs related to the seamless study that were incurred during the three months ended September 30th, 2013. Research and development tax credits for the three months ended September 30th, 2014 and 2013 were approximately \$0.7 million. The R&D tax credits relate to cash we elect to receive annual from the U.K. tax authorities' eligible R&D expenditure which also includes our clinical studies.

General and administrative expenses for the three months ended September 30th, 2014 decreased to \$1.4 million compared to \$1.5 million for the same

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period in 2013 with the decrease primarily due to lower legal and professional fees.

In summary, we continue to have sufficient capital resources to fund our operations beyond the projected topline data readout of SEAMLESS. Spiro?

**Spiro Rombotis:** Thank you, Paul. We are now ready to take your questions.

**Operator:** The floor is now open for questions. At this time, if you have a question or comment, please press star one on your touchtone phone. If at any point your question is answered, you may remove yourself from the queue by pressing the pound key. Again, we do ask that while you pose your question that you pick up your handset to provide optimal sound quality. Please hold for the first question.

Your first question comes from the line of Mike King with JMP Securities.

**Mike King:** Good morning – good afternoon, guys. Thanks for taking the questions. Congrats on the progress this year.

A couple of things that I wanted to ask about and hopefully I won't run too long. First of all, let me – I just wanted to ask about the MDS study. Just curious about the definition of feasibility. Based on your formal remarks, Spiro, it sounded to me like that's more of a matter of contracting as opposed to any other technical aspect of the study. But perhaps you can clarify that a little bit.

**Spiro Rombotis:** Thanks, Mike. This is a question for Judy to answer.

**Judy Chiao:** Hi, Mike.

**Mike King:** Hi, Judy.

**Judy Chiao:** I think that the feasibility is the formal assessment to looking at the interest of the investigator to participate in the randomized phase two study as designed, which includes whether they think that the control arm is appropriate and whether they have the suitable patient populations. So, I think it is a pretty formal process and we have awarded the project to a CRO. So, I think that we

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really would take a look at the results to decide whether it's feasible to do that or not.

**Mike King:** I see. Can you say anything about what you're thinking about as far as what the control treatment would be?

**Judy Chiao:** It's going to be low-dose Ara-C.

**Mike King:** OK. Is there any data in the literature to support the use of low-dose Ara-C in an HMA failure population that gives us any expectation that there will be activity there?

**Judy Chiao:** Well, that's a very good question. You know that low-dose Ara-C has been used the most extensively. They have not been used exclusively, should I say, in such a population. But it's one of the choices in the recently completed phase three study by Onconova. I believe it's one of the physicians' choice.

So, it is, I – we think ethically acceptable. And low-dose Ara-C is one of the most active agents in leukemia. Its activity in this patient population of hypomethylating agent failures has not been fully, extensively studied on a large scale. But it certainly has been used in other studies.

**Mike King:** OK. And from an FDA standpoint, you don't think they would be convinced that a single arm trial would be acceptable given that there is no agreed upon standard of care?

**Judy Chiao:** Mike, I think a single arm study is always difficult because it depends on what the end point that you want to look at is...

**Mike King:** Yes.

**Judy Chiao:** That if it's a survival end point, that it would be a no-go with regulatory agencies. And in view that the Hypomethylating agents themselves in the frontline have CR and PR in the single digits, I think to expect it to have a highly refractory population to going for a response rate is probably not a very good strategy.

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**Spiro Rombotis:** I'd like to remind the audience in our randomized study in MDS, the active arm would be an alternating schedule of sapacitabine with low-dose Ara-C. And as you already heard from Judy, the control arm with be low-dose Ara-C. So, we'll have a very clear separation of the effect that may be observed in this design.

**Mike King:** OK. All right, fair enough. Thank you. Let me just turn quickly to SEAMLESS – a couple questions there. I know we've talked about both of these before, Spiro, but I'd love to get an update on each. And that first one is the you know sort of the enrollment – the shape of the enrollment curve with Europe coming on this year. You pointed out that the enrollment time has been you know is analogous to that of the DACO-016 study. But I wonder if you know if the – it would seem like in DACO-016, your enrollment might have been steadier but slower whereas you might be sort of bi phasic . I'm just wondering if you know are you going to need to do any kind of statistical adjustment on the population when you unblind to account for you know the different enrollment periods.

**Spiro Rombotis:** Mike, you're exactly correct. Unlike DACO-016, we had the added hurdle to jump over of the lack of approval of decitabine in Europe for AML for quite some time – almost two years into the study. Then as many of you may remember, the EMA approved decitabine on a trend in the DACO-016 negative trial and the drug reached the market. And following registration and pricing approvals, we opened the study for European investigators.

So, you're correct – we had this very rapid increase in the slope of the enrollment curve earlier this year as we opened European sites. And as you already heard, we have more than tripled the number of sites. At this point, we don't expect based on analysis of the pooled data that we need to make any adjustments to this study as prospectively defined because we are very much around what was predicted some three years plus ago in terms of the rate of events and enrollment time to complete the study. So, at this point, no adjustments expected.

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**Mike King:** OK. And also, can you tell from the pooled analysis whether the patients in Europe are analogous to the patients in the U.S. in terms of baseline characteristics, demographics, blast count, et cetera?

**Judy Chiao:** Well, that – Mike, we have just met for one DSMB. We haven't met with the next DSMB yet. The last DSMB, we don't believe there were substantial differences between the U.S. and European patients just on the limited numbers that were pooled data – looked at it. We are not allowed to look at per-arm, of course, but we look at...

**Mike King:** Sure.

**Judy Chiao:** But we look at the data.

**Spiro Rombotis:** One point of differentiation from the demographic and patient characteristics in DACO-016, Mike, is that we're enrolling 90 percent plus of our study in U.S. and Western European sites. There are very few probably below 10 percent in the end of the day patients from Eastern Europe and none from Asia and Australia, which were important components of the geographical diversity in DACO-016. So, in that regard, there is less heterogeneity in the patient characteristics. But as Judy said, until we see the final demographic analysis for the next DSMB, will be hard to speculate.

**Mike King:** OK. And then my second question on the SEAMLESS trial, again, we talked about this, but I forget if you're able to see the number of cycles and whether you know whether the you know given again the blinded data, whether the patients are getting the expected number of cycles so that you know indicative of good tolerability and potential longer therapy.

**Judy Chiao:** Mike, we can't say that because you know that the European sites came onboard this year. So, it – some of our patients are still on. So, it's not a fair thing to do to compare to U.S. patients who we have been enrolling for the previous two years. So, if that's what you meant?

**Mike King:** Well you know I'm not sure. I just didn't know if there was you know any ability – maybe even before you opened Europe – to see if patients were getting you know at least two cycles of sapa and Dacogen.

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**Judy Chiao:** Basically all I can say is that based on the DSMB review, whenever we look at a pooled data, the mortality is not any different than what we would've expected on the 30 day and 60 day.

**Mike King:** OK. And then...

**Spiro Rombotis:** In other words, there is no pattern of discontinuation or stopped treatment, I think, Mike, that we can discern. But remember this would have been pooled data. So, until one has the benefit of unblinding, it's going to be hard to deduce what's going on. But there's been nothing unexpected in how the trial has unfolded; it's pretty much what was originally designed that's actually taken place. So, we don't see an early gradient of withdrawals or some other kind of reason to believe that it is not going as expected.

**Mike King:** No, I'm thinking the opposite. I'm thinking that you know patients are getting more cycles than one would expect given the average. And the average number of cycles in DACO-016 was four, if I remember correctly.

**Spiro Rombotis:** That's right. There was four.

**Mike King:** Yes.

**Spiro Rombotis:** Yes.

**Mike King:** OK. And then finally, switch gears on 065 – just wondering what you know additional work, if any, needs to be done before the IND can be dropped. And maybe you could talk a little bit about why targeting CDKs 2 and 9 are of interest as opposed to palbo or LEE011 which are hitting 4/6. Thank you.

**Spiro Rombotis:** All right, Mike. The first question is that there is nothing left to be done as far as the formal part of filing the IND. As we mentioned in the earlier remarks, we are now discussing with our advisors and certain top key opinion leaders appropriate populations to expose the drug to in phase one. Clearly in a program like this where we are following on the footsteps of our extensive clinical experience with seliciclib, we have some opportunity to do this very

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efficiently – to test if there's a signal in certain specific populations that we have talked about in the earlier section of the call.

The next question you asked was about the isoform profile. And I'm not David Blake, our head of research, but Dr. Blake if he was here would tell you that Cyclacel was informed in this topic from the work of our founding scientists, Professor David Lane, who has for a long time favored the CDK2/9 profile because it is highly differentiated mechanistic and cell cycle biological effects on cancer cells. I think very briefly at the risk of oversimplifying complex biology, 4/6 inhibitors tend to operate on the G1 stage of the cell cycle, delaying the transit of cancer cells at that point and oftentimes associated with senescence. CDK2/9 inhibitors tend to be involved in later cell cycle checkpoint control, the G2M checkpoint, on a dose-dependent basis and do induce apoptotic death of cancer cells, not senescence.

So, for these historical reasons as well as our preclinical – and clinical data, we have steered our pipeline evolution evidently in the CDK2/9 group of drugs and that's why we're not overlapping with the two that you mentioned. This doesn't suggest that at some future date, a combination of CDK4/6 inhibitor could not be contemplated with the CDK2/9 inhibitor. Why? Because if the 4/6 specific compounds eventually encounter resistance, it is plausible that CDK2/9 profile drugs could reverse this resistance exactly as 065 is showing with another drug which is trastuzumab. So, no overlapping isoforms; possibly different mechanistic and biologic effects. But possibly down the road, certainly appropriate rationale for combinations in clinical trials.

**Mike King:** Thanks very much.

**Spiro Rombotis:** Thank you.

**Operator:** We have no further questions. I will now turn the floor back over to Spiro Rombotis for any additional or closing remarks.

**Spiro Rombotis:** Thank you, operator. Thank you, everyone, for listening to our quarterly conference call. We look forward to updating you on upcoming events and

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meeting some of you at our upcoming investor conferences. Operator, at this time please end the call.

**Operator:** Thank you. This does conclude today's teleconference. Please disconnect your line and close your Webcast browser at this time and have a wonderful day.

**END**

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