

PHARMACYCLICS INC

FORM 8-K (Current report filing)

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Address	PHARMACYCLICS INC 995 E ARQUES AVE SUNNYVALE, CA 94085-4521
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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): **February 9, 2012**



PHARMACYCLICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

000-26658

(Commission
File Number)

94-3148201

(IRS Employer
Identification No.)

**995 E. Arques Avenue
Sunnyvale, California**

(Address of principal executive offices)

94085-4521

(Zip Code)

Registrant's telephone number, including area code: **(408) 774-0330**

(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))

Item 2.02. Results of Operations and Financial Condition .

On February 9, 2012, Pharmacyclics, Inc., a Delaware corporation (the “Registrant”), issued a press release regarding its financial results for its second quarter of fiscal 2012. A copy of the press release is attached as Exhibit 99.1.

The foregoing description is qualified in its entirety by reference to the Registrant’s Press Release dated February 9, 2012, a copy of which is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Current Report on Form 8-K, including the exhibit hereto, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities thereof, nor shall it be deemed to be incorporated by reference into future filings by the Company under the Exchange Act or under the Securities Act of 1933, as amended, except to the extent specifically provided in any such filing.

Item 9.01. Financial Statements and Exhibits .

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated February 9, 2012.

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.

Date: February 9, 2012

Pharmacyclics, Inc.

By: /s/ Rainer M. Erdtmann

Rainer M. Erdtmann

Vice President, Finance & Administration and Secretary

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated February 9, 2012.



Pharmacyclics Reports Fiscal 2012 Second Quarter Financial Results

SUNNYVALE, Calif., Feb. 9, 2012 -- Pharmacyclics, Inc. (Nasdaq: [PCYC](#)) today reported financial results and recent developments for its fiscal second quarter ended December 31, 2011.

Financial Results for Second Quarter Ended December 31, 2011

The non-GAAP (Generally Accepted Accounting Principles) net income reported for the fiscal quarter ended December 31, 2011 was \$58.6 million, or \$0.82 diluted earnings per share. This compares with a non-GAAP net loss of \$6.1 million, or \$0.10 loss per share, for the fiscal quarter ended December 31, 2010. See "Use of Non-GAAP Financial Measures" below for a description of our Non-GAAP measures. Reconciliation between certain GAAP and non-GAAP measures is provided at the end of this press release.

The GAAP net income for the fiscal quarter ended December 31, 2011 was \$56.3 million, or \$0.78 diluted earnings per share. This compares with a GAAP net loss of \$7.5 million, or \$0.13 loss per share for the fiscal quarter ended December 31, 2010.

At December 31, 2011, the company had cash, cash equivalents and marketable securities of \$240.3 million, which compares with \$112.3 million at June 30, 2011.

As previously announced on December 8, 2011, the Company entered into a worldwide collaboration with Janssen Biotech, Inc. (Janssen), one of the Janssen Pharmaceutical Companies of Johnson & Johnson, to develop and commercialize PCI-32765, a novel, oral, first-in-class Bruton's Tyrosine Kinase (BTK) inhibitor being developed for the treatment of Non Hodgkin's Lymphoma, Chronic Lymphocytic Leukemia and Multiple Myeloma, all of which are considered hematological malignancies. Pharmacyclics received from Janssen upfront payments totaling \$150 million on signing the contract. In addition, Pharmacyclics will receive up to an additional \$825 million in development and regulatory milestone payments, based upon continued development progress (\$250 million), regulatory progress (\$225 million) and approval of the product (\$350 million), for total potential upfront and milestone payments of \$975 million.

Pharmacyclics and Janssen will collaborate on the development of PCI-32765 for oncology and other indications, excluding inflammation and immune mediated conditions. Each company will lead development for specific indications as stipulated in a global development plan, with development costs shared on a 40/60 basis (Pharmacyclics 40% and Janssen 60%). The agreement includes plans to launch multiple Phase III trials of PCI-32765 over the next several years.

Following regulatory approval, both Pharmacyclics and Janssen will book revenue and co-commercialize PCI-32765. In the US, Pharmacyclics will book sales and take a lead role in US commercial strategy development. Both Pharmacyclics and Janssen will share in commercialization activities. Outside the United States, Janssen will book sales and lead and perform commercialization activities. Profits and losses from the commercialization activities will be split 50/50 on a worldwide basis. Development and commercialization activities under the collaboration will be managed through a shared governance structure.

"We have now formally kicked off our partnership with Janssen for the global development of our BTK inhibitor PCI-32765, and we are extremely pleased with the progress to date. The spirit of cooperation and alignment between the two teams is remarkable, and reaffirms what we believed so strongly when we signed the deal last year that the values of the two companies and their commitment to the potential of PCI-32765 are very much aligned," said Bob Duggan, CEO and Chairman of the Board. "Together we intend to launch broad and aggressive Phase III development programs that will utilize the best of both teams with unwavering focus on our shared mission. This is what patients expect and deserve from us."

Recent Developments & Highlights

Bruton's Tyrosine Kinase (BTK) Inhibitor for Oncology

Results from our Phase Ib/II trial of PCI 32765 in patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) (PCYC-1102-CA) were presented in an oral presentation at the American Society of Hematology (ASH) Annual Meeting in San Diego, California in December 2011. The trial included a total of 61 patients with relapsed or refractory CLL/SLL enrolled at two dose levels, 420 mg (n=27) or 840 mg (n=34). Oral PCI-32765 was administered daily until disease progression. Data was available from a landmark analysis of 12 months. With a median follow-up of 12.6 months in the 420mg cohort and 9.3 months in the 840mg cohort, the overall response rate (ORR), including PR and CR, for the 420mg dose level was 67% and for the 840 mg dose 68%, as measured by the 2008 International Workshop on Chronic Lymphocytic Leukemia criteria. The responses have been independent of high-risk clinical or genetic features. The estimated landmark 12 month PFS for the pooled cohorts was 86%. The safety profile of PCI-32765 was particularly notable for minimal off target toxicities. The most common treatment related adverse events reported in the trial were Grade 1 (mild) or 2 (moderate) diarrhea, cough, fatigue, and upper respiratory infections, and only 2 of 61 patients have discontinued study treatment due to adverse events regardless of relationship to PCI-32765. The company anticipates having further information on the development of a Phase III program of PCI-32765 in relapsed or refractory CLL/SLL patients in the second quarter of calendar 2012.



Results from our Phase II trial of PCI 32765 in patients with relapsed or refractory mantle cell lymphoma (PCYC-1104-CA) were also presented in an oral presentation at the ASH Annual Meeting in December 2011. The interim analysis included a total of 68 patients accrued to this Phase II trial. PCI-32765 was administered orally at 560 mg daily until disease progression. 51 patients (31 patients had bortezomib-naïve disease, 20 patients had previously received bortezomib) had post-baseline tumor assessments and were thus evaluable for response. The ORR, according to the 2007 Non-Hodgkin's Lymphoma International Working Group criteria, was 69% (35/51 patients). ORR was similar in bortezomib-naïve and bortezomib-exposed patients (71% and 65%, respectively). At the time of this analysis 31 of 35 (89%) responding patients have ongoing responses with the median follow-up of 3.7 months. Consistent with previous trials of PCI-32765, the most common adverse events reported in this trial were Grade 1 (mild) or 2 (moderate) fatigue, diarrhea and nausea. Only 3 of 68 patients discontinued study treatment due to adverse events regardless of relationship to PCI-32765. The company anticipates having further information on the development of a Phase III program of PCI-32765 as a single agent in previously treated mantle cell patients in the second quarter of calendar 2012.

As of the end of December 2011 we enrolled approximately 400 patients into clinical trials evaluating PCI-32765. The ongoing Phase I/II program currently includes the following studies:

- PCYC-04753: A Phase I of PCI-32765 in patients with recurrent B-cell malignancies. This study was designed to assess the safety and tolerability of PCI-32765. Patient enrollment is completed with 66 patients enrolled in the main portion of the study. Enrollment into the diffuse large B-cell lymphoma (DLBCL) activated B-cell (ABC) investigator-led cohort is still ongoing with the National Cancer Institute.
- PCYC-1102-CA: A multicenter, open-label, single agent Phase Ib/II study of PCI-32765 in subjects with relapsed/ refractory or with treatment-naïve (65 years of age or older) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). This study was designed to assess safety, tolerability, and efficacy of PCI-32765. Patient enrollment is complete, with 117 patients enrolled. An update on the relapsed or refractory patients treated on this trial was provided at the American Society of Hematology Annual Meeting in December of 2011. We intend to report an interim analysis of elderly treatment naïve patients at one of the upcoming scientific conferences mid-year 2012.
- PCYC-1104-CA: A multicenter, Phase II study of PCI-32765 in patients with relapsed or refractory mantle cell lymphoma, including cohorts of subjects either previously treated with bortezomib or naïve to bortezomib treatment. This trial is active in several US and European sites and, as of the end of December 2011, had enrolled 95 patients. An interim report on this trial was provided at the American Society of Hematology Annual Meeting in December of 2011. We anticipate to complete enrollment of this trial in the first half of calendar 2012 and will report on updated study results thereafter.
- PCYC-1106-CA: A multicenter, open-label, Phase II study of PCI 32765 in subjects with relapsed or refractory DLBCL. This study is designed to assess the activity of PCI-32765 in two genetically distinct subtypes of DLBCL, the activated B-cell (ABC) subtype and the germinal center (GC) subtype. This trial is active in several US sites and, as of the end of December 2011, had enrolled 30 patients. We expect to complete enrollment of all 60 patients within the first half of calendar 2012.
- PCYC-1108-CA: A Phase Ib, multicenter, open-label, study of PCI 32765, in combination with bendamustine and rituximab (BR) in subjects with relapsed or refractory CLL or SLL. This trial completed enrollment with 30 patients. We intend to report an interim analysis of these patients at one of the upcoming scientific conferences mid-year 2012.
- PCYC-1109-CA: A Phase Ib/II study of PCI-32765 in combination with ofatumumab in subjects with relapsed or refractory CLL or SLL is ongoing and enrolled 47 patients as of the end of December 2011. This trial has been expanded and will now enroll up to 70 patients and we are expecting to complete enrollment within the first half of 2012. We intend to report data from a subset of these patients at one of the upcoming scientific conferences mid-year 2012.
- PCYC-1111-CA: A Phase II study of PCI-32765 in subjects with relapsed/refractory multiple myeloma (MM) is on track to start enrolling patients in Q1 of calendar 2012. Pre-clinical studies, both internally as well as through external collaborations, have suggested a potentially vital role of BTK in both malignant plasma cells and osteoclasts, which are involved in bone complications of this disease. The MM trial is expected to enroll 35 patients and we anticipate completing the enrollment by early 2013.

Factor VIIa (FVIIa) Inhibitor

A multicenter Phase I/II of PCI-27483 in patients with locally advanced or metastatic pancreatic cancer that are either receiving or are planned to receive gemcitabine therapy is currently ongoing. The Phase II portion of the study is enrolling and patients are being randomized to receive either gemcitabine alone or gemcitabine plus PCI-27483. The objectives are to assess the safety of FVIIa Inhibitor PCI-27483 at pharmacologically active dose levels, to assess potential inhibition of tumor progression and to obtain initial information of the effects on the incidence of thromboembolic events. This trial is active in several US sites and by the end of December 2011 enrolled 28 patients. Due to a paradigm shift in the use of gemcitabine alone for the treatment of pancreatic cancer enrolling patients onto this randomized study has been challenging. An interim analysis of the results of a subset of the patients enrolled is planned for the first half of calendar 2012.

Histone Deacetylase (HDAC) Inhibitor

Abexinostat (aka PCI-24781) is an oral histone deacetylase inhibitor that is being evaluated in multiple clinical trials by Pharmacyclics and our ex-US collaboration partner, Les Laboratoires Servier (Servier) with approximately 250 patients treated by the end of calendar 2011. Pharmacyclics has completed 2 Phase I studies using abexinostat as a single agent in patients with advanced solid tumors, and is currently conducting a Phase I/II trial in sarcoma patients (in combination with doxorubicin, an anti-tumor agent) and a Phase I/II trial testing abexinostat single agent in patients with relapsed or refractory Non-Hodgkin's lymphoma (NHL). In the sarcoma trial, co-sponsored by the Massachusetts General Hospital and Dana-Farber Cancer Institute, the Phase I dose escalation has been completed and the maximum tolerated dose in combination with doxorubicin has been established. The Phase II portion is currently being planned. In the single agent NHL trial, we are enrolling patients in a Phase II follicular lymphoma arm and expect to complete enrollment by the end of Q1 of calendar 2012. Our collaboration partner for ex-US markets, Servier has expanded its clinical development program of abexinostat and currently has six Phase I/II trials ongoing in Europe in lymphomas and solid tumors with abexinostat as single agent and in combination with radiation as well as other therapeutic agents. The Phase II portion of Servier's single agent lymphoma trial was opened in Q4 of calendar 2011 and is currently enrolling patients. Further analysis of these trials and any updates will be released by Servier.

Conference Call and Webcast Details

Based on timelines of occurring events and availability of our key executives due to travel arrangements, a conference call to update our investors is anticipated to occur in the first week of March.

For further questions please contact Ramses Erdtmann, VP Finance at: 408-215-3325

Use of Non-GAAP Financial Measures

This press release contains non-GAAP financial measures, including operating and other expenses adjusted to exclude certain non-cash and non-recurring expenses. These measures are not in accordance with, or an alternative to generally accepted accounting principles, or GAAP, and may be different from non-GAAP financial measures used by other companies. The items included in GAAP presentations but excluded for purposes of determining non-GAAP financial measures for the periods presented in this press release are employee related non-cash expenses and the net amount of the therapeutic discovery project tax grant. We believe the presentation of non-GAAP financial measures provides useful information to management and investors regarding various financial and business trends relating to our financial condition and results of operations. When GAAP financial measures are viewed in conjunction with non-GAAP financial measures, investors are provided with a more meaningful understanding of our ongoing operating performance. In addition, these non-GAAP financial measures are among those indicators we use as a basis for evaluating operational performance, allocating resources and planning and forecasting future periods. Non-GAAP financial measures are not intended to be considered in isolation or as a substitute for GAAP financial measures. To the extent this release contains historical non-GAAP financial measures, we have also provided corresponding GAAP financial measures for comparative purposes. Reconciliation between certain GAAP and non-GAAP measures is provided below.

About Pharmacyclics

Pharmacyclics® is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative small-molecule drugs for the treatment of cancer and immune mediated diseases. Our mission and goal is to build a viable biopharmaceutical company that designs, develops and commercializes novel therapies intended to improve quality of life, increase duration of life and resolve serious unmet medical healthcare needs; and to identify promising product candidates based on scientific development expertise, develop our products in a rapid, cost-efficient manner and pursue commercialization and/or development partners when and where appropriate.

Presently, Pharmacyclics has three product candidates in clinical development and several preclinical molecules in lead optimization. We are committed to high standards of ethics, scientific rigor, and operational efficiency as we move each of these programs to viable commercialization.

The Company is headquartered in Sunnyvale, California and is listed on NASDAQ under the symbol PCYC. To learn more about how Pharmacyclics advances science to improve human healthcare visit us at <http://www.pharmacyclics.com>.

NOTE: This announcement may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding our expectations and beliefs regarding our future results or performance. Because these statements apply to future events, they are subject to risks and uncertainties. When used in this announcement, the words "anticipate", "believe", "estimate", "expect", "expectation", "should", "would", "project", "plan", "predict", "intend" and similar expressions are intended to identify such forward-looking statements. Our actual results could differ materially from those projected in the forward-looking statements. Additionally, you should not consider past results to be an indication of our future performance. For a discussion of the risk factors and other factors that may affect our results, please see the Risk Factors section of our filings with the Securities and Exchange Commission, including our annual report on Form 10-K and quarterly reports on Form 10-Q. We do not intend to update any of the forward-looking statements after the date of this announcement to conform these statements to actual results, to changes in management's expectations or otherwise, except as may be required by law.

Pharmacyclics, Inc.

Condensed Consolidated Balance Sheets

(unaudited; in thousands)

	December 31, 2011	June 30, 2011
ASSETS		
Cash, cash equivalents and marketable securities*	\$ 240,330	\$ 112,329
Other current assets	4,552	2,367
Total current assets	244,882	114,696
Property and equipment, net	2,528	1,312
Other assets	344	344
Total assets	<u>\$ 247,754</u>	<u>\$ 116,352</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Deferred revenue – current portion	\$ 8,041	\$ 7,000
Other current liabilities	14,404	7,268
Total current liabilities	22,445	14,268
Deferred revenue – non-current portion	71,174	-
Deferred rent	547	410
Total liabilities	94,166	14,678
Stockholders' equity	153,588	101,674
Total liabilities and stockholders' equity	<u>\$ 247,754</u>	<u>\$ 116,352</u>
* Marketable securities	<u>\$ 10,116</u>	<u>\$ 24,572</u>

Pharmacyclics, Inc.

Condensed Consolidated Statements of Operations

(unaudited; in thousands, except per share data)

	Three Months Ended December 31,		Six Months Ended December 31,	
	2011	2010	2011	2010
Revenues:				
License and milestone revenues	\$ 77,605	\$ 1,386	\$ 77,605	\$ 2,773
Collaboration services revenues	298	1,438	335	2,015
Total revenues	<u>77,903</u>	<u>2,824</u>	<u>77,940</u>	<u>4,788</u>
Operating expenses*:				
Research and development	12,076	8,256	23,324	15,958
General and administrative	3,944	2,093	7,294	3,927
Total operating expenses	<u>16,020</u>	<u>10,349</u>	<u>30,618</u>	<u>19,885</u>
Income (loss) from operations	61,883	(7,525)	47,322	(15,097)
Interest and other income (expense), net	21	26	44	75
Income (loss) before income taxes	61,904	(7,499)	47,366	(15,022)
Income tax provision	5,651	-	5,651	-
Net income (loss)	<u>\$ 56,253</u>	<u>\$ (7,499)</u>	<u>\$ 41,715</u>	<u>\$ (15,022)</u>
Net income (loss) per share:				
Basic	<u>\$ 0.82</u>	<u>\$ (0.13)</u>	<u>\$ 0.61</u>	<u>\$ (0.25)</u>
Diluted	<u>\$ 0.78</u>	<u>\$ (0.13)</u>	<u>\$ 0.58</u>	<u>\$ (0.25)</u>
Weighted average shares used to compute net income (loss) per share:				
Basic	<u>68,658</u>	<u>59,715</u>	<u>68,491</u>	<u>59,497</u>
Diluted	<u>71,725</u>	<u>59,715</u>	<u>71,312</u>	<u>59,497</u>

* Includes share-based compensation as follows:

Research and development	\$ 1,701	\$ 1,267	\$ 3,239	\$ 2,961
General and administrative	675	671	1,301	1,149
Total	<u>\$ 2,376</u>	<u>\$ 1,938</u>	<u>\$ 4,540</u>	<u>\$ 4,110</u>

Reconciliation of Selected GAAP Measures to Non-GAAP Measures (1)

(unaudited; in thousands, except per share data)

	Three Months Ended December 31,	
	2011	2010
GAAP net income (loss)	<u>\$ 56,253</u>	<u>\$ (7,499)</u>
Adjustments:		
Research & development share-based compensation(2)	1,701	1,267
General & administrative share-based compensation(2)	675	671
Therapeutic discovery project tax grant, net(3)	-	(586)
	<u>2,376</u>	<u>1,352</u>
Non-GAAP net income (loss)	<u>\$ 58,629</u>	<u>\$ (6,147)</u>
Non-GAAP diluted net income (loss) per share	<u>\$ 0.82</u>	<u>\$ (0.10)</u>

- (1) This presentation includes non-GAAP measures. Our non-GAAP measures are not meant to be considered in isolation or as a substitute for comparable GAAP measures and should be read only in conjunction with our financial statements prepared in accordance with GAAP.
- (2) All share-based compensation was excluded for the non-GAAP analysis.
- (3) Represents the therapeutic discovery project tax grant, net of related expenses.
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Reconciliation of Selected GAAP Measures to Non-GAAP Measures (1)

(unaudited; in thousands, except per share data)

	Three Months Ended December 31,	
	2011	2011
GAAP net income (loss)	\$ 41,715	\$ (15,022)
Adjustments:		
Research & development share-based compensation(2)	3,239	2,961
General & administrative share-based compensation(2)	1,301	1,149
Therapeutic discovery project tax grant, net(3)	-	(586)
	<u>4,540</u>	<u>3,524</u>
Non-GAAP net income (loss)	<u>\$ 46,255</u>	<u>\$ (11,498)</u>
Non-GAAP diluted net income (loss) per share	<u>\$ 0.65</u>	<u>\$ (0.19)</u>

- (1) This presentation includes non-GAAP measures. Our non-GAAP measures are not meant to be considered in isolation or as a substitute for comparable GAAP measures and should be read only in conjunction with our financial statements prepared in accordance with GAAP.
- (2) All share-based compensation was excluded for the non-GAAP analysis.
- (3) Represents the therapeutic discovery project tax grant, net of related expenses.