

PHARMACYCLICS INC

FORM 8-K (Current report filing)

Filed 11/08/10 for the Period Ending 11/08/10

Address	PHARMACYCLICS INC 995 E ARQUES AVE SUNNYVALE, CA 94085-4521
Telephone	408 774 0330
CIK	0000949699
Symbol	PCYC
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	06/30

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 8, 2010**

PHARMACYCLICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	000-26658	94-3148201
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)
995 E. Arques Avenue Sunnyvale, California		94085-4521
(Address of principal executive offices)		(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 November 8, 2010, Pharmacyclics, Inc., a Delaware corporation (the “Registrant”), issued a press release regarding its financial results for its first quarter of fiscal 2011. 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 November 8, 2010, 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 November 8, 2010.

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: November 8, 2010

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 November 8, 2010.



Contact
Ramses Erdtman
Vice President of Finance
 Phone: 408-215-3333

Pharmacyclics Reports Recent Developments and Financial Results for Fiscal First Quarter 2011

SUNNYVALE, CA, November 8, 2010

Pharmacyclics, Inc. (Nasdaq: PCYC) today reported recent developments and financial results for its fiscal first quarter which ended September 30, 2010.

Recent Developments & Highlights

- **Three distinguished individuals nominated to join our Board of Directors :**
 - o Gwen A. Fyfe, M.D. is an oncology biotechnology veteran with more than 20 years of drug development experience. From 1992 to 2009, Dr. Fyfe was an employee of Genentech, Inc. where she held a variety of positions including most recently Vice President, Oncology Development; Vice President, Avastin® Franchise Team; as well as the honorary title of Senior Staff Scientist. Dr. Fyfe played an important role in the development of Genentech's approved oncology agents including Rituxan®, Herceptin®, Avastin® and Tarceva®. Dr. Fyfe sat on the Development Oversight Committee for all of Genentech's products and participated in the Research Review Committee that moved products from research into clinical development. Since leaving Genentech in 2009, Dr. Fyfe has been a consultant for venture capitalists and for a variety of biotechnology companies, including the Company. Dr. Fyfe is a recognized oncology expert in the broader oncology community and has been an invited member of Institute of Medicine panels, National Cancer Institute working groups and grant committees and American Society of Clinical Oncologists oversight committees. She is a graduate of Washington University School of Medicine and a board certified pediatric oncologist.
 - o Robert F. Booth, Ph.D. is currently the Chief Executive Officer of Virobay, Inc., a drug discovery and development company. Dr. Booth was also the Executive Chairman of Virobay, Inc. from 2006 to 2010 and served concurrently as an Operating Partner and Senior Advisor at TPG Biotech, a venture capital company. From 2006 to 2007, Dr. Booth served as the acting Chief Scientific Officer of Galleon Pharmaceuticals, a company which is developing new therapeutics for diseases of the respiratory system. From 2002 to 2006, Dr. Booth was the Chief Scientific Officer at Celera Genomics, where he was responsible for leading all discovery and development activities. The therapeutic areas pursued by Celera included oncology, autoimmunity, respiratory diseases and thrombosis. Dr. Booth was Senior Vice President at Roche Bioscience from 1989 to 2002, and was responsible for research and early development activities in the therapeutic areas of inflammation, autoimmunity, respiratory diseases, transplantation, bone diseases and viral diseases. Dr. Booth was a member of the Global Research Management Team and a member of the Business Development Committee, which oversaw licensing opportunities for Roche. During his time at Roche, Dr. Booth managed R&D organizations in both the US and Europe. The Biology team for which Dr. Booth was responsible in the U.K. discovered and contributed to the development of saquinavir, the first HIV protease inhibitor to be launched. This achievement was recognized by the winning of the Prix Galien for Roche. Dr. Booth is currently a member of the Scientific Advisory Board of ShangPharma, a large, privately held CRO in China. Dr. Booth received his Ph.D. and B.S. from the University of London in the field of biochemistry.

- o *Mr. Roy C. Hardiman* spent almost two decades with Genentech, Inc. in roles that included Vice President of Alliance Management in 2009, Vice President, Corporate Law from 2000 to 2009 and Director and Far East Representative, Business Development from 1998 to 2000. In these roles, Mr. Hardiman had accountability for all Genentech alliances, for jointly leading the Partnering Merger Transition Team and the Roche/Genentech Joint Business Committee and for leading all Genentech corporate law matters, including accountability for the legal relationship with Roche. Mr. Hardiman also chaired the Commercial Compliance Committee and the Environmental Sustainability and Compliance Committees at Genentech. Prior to joining Genentech, Mr. Hardiman was an attorney with the law firm Morrison & Foerster. Mr. Hardiman also serves on the board of Woodlands, Inc., a private company. Mr. Hardiman has degrees in law from the University of California, Los Angeles biology (biochemistry/molecular biology) and pharmacology from the University of California, Santa Barbara.
- ***Expansion of our Oncology Team*** with the appointment of Eric Hedrick, M.D. as VP, Oncology Clinical Development. From October 2009 to August 2010, Dr. Hedrick was an independent drug development consultant, including consulting with the Company on the development of PCI-32765. From November 2000 to September 2009 Dr. Hedrick was an employee of Genentech, Inc. where he held a variety of positions including Group Medical Director/Development Sub-Team Leader and Senior Clinical Scientist and was responsible for multiple aspects of the drug development and post-marketing programs for rituximab (Rituxan®) and bevacizumab (Avastin®). Prior to his time at Genentech Dr. Hedrick was an Associate Attending Physician at Memorial Sloan-Kettering Cancer Center where he focused on clinical research in non-Hodgkin's lymphoma, myelodysplastic syndromes, multiple myeloma and hematopoietic growth factors. He served as resident and chief resident in Internal Medicine at Boston City Hospital and completed a fellowship in Medical Oncology and Hematology at the Memorial Sloan-Kettering Cancer Center. Dr. Hedrick received his M.D. from the University of Maryland School of Medicine and is Board certified in Medical Oncology and Internal Medicine.
- ***Three Oral Presentations and one poster presentation for Btk Inhibitor, PCI-32765***, accepted at the American Society of Hematology (ASH) National Meeting in Orlando, FL (Dec 4-7th, 2010). Meaningful update to the ASH published abstracts and tumor response results on all evaluable patients will be provided in a conference call following the ASH presentations on December 7th, 2010 at 10:00 EST. The ASH Presentations are scheduled as follows:
 - ORAL SESSION at the 2010 ANNUAL MEETING
 Publication Number: 45
 Submission ID: 29422
 TITLE: Brutons Tyrosine Kinase Inhibitor PCI-32765 Abrogates BCR- and Nucleoside Cell-Derived Activation of CLL Cells In Vitro and In Vivo.
 Presenter: Dr. Ponader
 Session Name: CLL-Biology and Pathophysiology, excluding Therapy
 Session Date: Sunday, December 5, 2010
 Session Time: 4:30 PM - 6:00 PM
 Presentation Time: 5:00 PM
 Room: Orange County Convention Center, Valencia B/C

- ORAL SESSION at the 2010 ANNUAL MEETING
 Publication Number: 57
 Submission ID: 34300
 TITLE: The Bruton Tyrosine Kinase Inhibitor, PCI-32765, Is Well Tolerated and Demonstrates Promising Clinical Activity In Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL):An Update on Ongoing Phase I Studies
 Presenter: Dr. Jan Burger
 Session Name: CLL-Therapy, excluding Transplantation: Novel Agents and New Approaches
 Session Date: Sunday, December 5, 2010
 Session Time: 4:30 PM - 6:00 PM
 Presentation Time: 5:00 PM
 Room: Orange County Convention Center, Valencia D
 ORAL SESSION at the 2010 ANNUAL MEETING
 Publication Number: 964
 Submission ID: 34320
- ORAL SESSION at the 2010 ANNUAL MEETING
 Publication Number: 96
 Submission ID: 34320
 TITLE: The Btk Inhibitor, PCI-32765, Induces Durable Responses with Minimal Toxicity In Patients with Relapsed/Refractory B-Cell Malignancies: Results From a Phase I Study
 Presenter: Dr. Fowler
 Session Name: Lymphoma-Therapy with Biologic Agents, excluding Pre-Clinical Models: Novel approaches for T Cell at Mantle Cell Lymphoma
 Session Date: Tuesday, December 7, 2010
 Session Time: 7:30 AM - 9:00 AM
 Presentation Time: 8:15 AM
 Room: Orange County Convention Center, 312
- POSTER SESSION at the 2010 ANNUAL MEETING
 Publication Number: 1385
 Submission ID: 31805
 TITLE: The Kinase Inhibitor, PCI-32765, Demonstrates Activity In Chronic Lymphocytic Leukemia Cells Independent of Microenvironmental Survival Signals
 Poster presentation at the 2010 Annual Meeting of the American Society of Hematology in Orlando, Florida
 Session Name: CLL - Therapy, excluding Transplantation: Poster I
 Presenter: Sarah E.M. Herman, PhD
 Date: Saturday, December 4, 2010
 Presentation Time: 5:30 PM - 7:30 PM
 Location: Orange County Convention Center, Hall A3/A4 Poster Board no.: I-365
- ***Strong patient accrual in existing Btk Inhibitor trials (PCI-32765)*** with over 100 patients enrolled to date. Rapid expansion into various Phase II studies in select histologies (Mantle Cell Lymphoma, Chronic Lymphocytic Leukemia and Diffuse Large B-Cell Lymphoma)
- ***Btk Inhibitor for Autoimmune Diseases, PCI-45292, poster presentation*** at the American College of Rheumatology (Nov 5-11th, 2010 Atlanta, GA) National Meeting, describing the mechanism of action and providing new preclinical data.

- TITLE: PCI-45292, a Novel Btk Inhibitor with Optimized Pharmaceutical Properties, Demonstrates Potent Activities in Mouse Models of Arthritis"
Session Type: ACR Poster Session A
Session Name: Rheumatoid Arthritis - Animal Models: Cytokines, Novel Therapeutics and Mechanisms of Action
Date: Monday, November 8, 2010
Presenter: Betty Chang, Ph.D.
Presentation Time: 9:00 AM - 11:00 AM
Location: Hall B1 & B2
Presentation Number: 286
For further information please see our website under www.pharmacyclics.com.

- ***Factor VIIa Inhibitor, PCI-27483, continues enrollment*** in a Phase II trial. Most recently an abstract was submitted to the American Society of Clinical Oncology GI Symposium in San Francisco CA, January 2011, covering 16 week safety and efficacy assessment from patients with metastatic or locally advanced pancreatic cancer with gemcitabine.
- ***HDAC Inhibitor, PCI-24781 continues enrollment***, in a Phase II lymphoma trial and a Phase I/II sarcoma trial. Most recently a poster has been accepted at the American Society of Hematology (ASH) National Meeting in Orlando, FL (Dec 4-7th, 2010), suggesting that PCI-24781 may have potent anti-inflammatory activities and may be useful to treat inflammatory disorders including RA and sepsis in humans.
 - Session Name: Lymphocytes, Lymphocyte Activation and Immunodeficiency, including HIV and Other Infections: Poster III
Date: Monday, December 6, 2010
Presentation Time: 6:00 PM - 8:00 PM
Location: Orange County Convention Center, Hall A3/A4
Poster Board no.: III-693

Calendar 2011 Selected Corporate Objectives

- Including patients treated to date, we plan to have treated 200 patients with Btk Inhibitor PCI-32765 in the first half of calendar 2011 and 400 patients by year end 2011.
- File IND for Btk autoimmune inhibitor, PCI-45292, by the end of the second quarter calendar 2011.
- Complete Phase II enrollment of Factor VIIa Inhibitor, PCI-27483, in 46 patients in calendar 2011 with metastatic or locally advanced pancreatic cancer receiving gemcitabine.

Financial Results for our First Quarter in Fiscal 2011

The non-GAAP (Generally Accepted Accounting Principles) net loss reported for the fiscal quarter ended September 30, 2010 was \$5.4 million, or \$0.09 per share. This compares with a non-GAAP net loss of \$4.6 million, or \$0.11 per share, for the fiscal quarter ended September 30, 2009. Reconciliation between GAAP and non-GAAP results is provided at the end of this press release.

The GAAP net loss for the fiscal quarter ended September 30, 2010 was \$7.5 million, or \$0.13 per share. This compares with a GAAP net loss of \$4.8 million, or \$0.12 per share for the fiscal quarter ended September 30, 2009.

Total revenue was \$2.0 million for the fiscal quarter ended September 30, 2010. Upon the signing of a drug supply agreement with Les Laboratoires Servier ("Servier") in the quarter ended December 31, 2009, the company began recognizing revenue from its collaboration agreement with Servier, which was entered into in April 2009. No revenue was generated in the fiscal quarter ended September 30, 2009.

As of September 30, 2010, the company had cash, cash equivalents and marketable securities totaling \$67.8 million. This compares with \$74.1 million in cash, cash equivalents and marketable securities as of June 30, 2010. We received the third scheduled payment of \$1.0 million from our Collaboration and License Agreement with Les Laboratoires Servier in November 2010 and we expect to receive the fourth and final payment of \$1 million in the second calendar quarter of 2011.

In November 2010, the company received notice that it has been approved under Section 48D for a tax grant for its qualifying therapeutic discovery project applications. We expect that three of the company's programs (PCI-32765 Btk Inhibitor, PCI-24781 HDAC Inhibitor and PCI-27483 Factor VIIa Inhibitor) will each receive the maximum available pro rata government allocation under this program, which totals approximately \$725,000.

Mr. Duggan stated: "Chief among the responsibilities and obligations of Team Pharmacyclics is delivering measureable progress toward accomplishing our Mission Statement - Creating a viable biopharmaceutical company which consistently and predictably makes a significant difference for the better for patients in the field of human healthcare. This Statement embodies what we endeavor to accomplish on a daily basis.

Quarter by quarter we are expanding our team, accessing necessary resources and generating patient outcomes that give us pride in our accomplishments and faith in our future."

Mr Duggan further added "On behalf of all shareholders, I want to express my gratitude to Mr. Jason Adelman, Dr. Cynthia Bamdad and Dr. Glenn Rice for their service to Pharmacyclics as members of our board of directors. Without the encouragement and unwavering support each of these individuals provided us during a critical period in our existence, we would not have achieved the promising outlook now in place."

Conference Call and Webcast Details

The Company will hold a conference call today at 5:00 p.m. EDT. To participate in the conference call, please dial 1-877-407-8133 for domestic callers and 1-201-689-8040 for international callers. To access the live audio broadcast or the subsequent archived recording, log on to <http://ir.pharmacyclics.com/events.cfm>. The archived version of the webcast will be available for 30 days on the Investor Relations section of the company's Web site at www.pharmacyclics.com.

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, and includes operating and other expenses adjusted to exclude certain non-cash and non-recurring expenses. These measures are not in accordance with, or an alternative for 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 that we present are: non-cash interest expense associated with the loan from an affiliate of Robert W. Duggan and employee related non-cash expenses. 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.

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 exceptional scientific development expertise, develop our products in a rapid, cost-efficient manner and pursue commercialization and/or development partners when and where appropriate. We exist to make a difference for the better and these are important times to do just that.

Presently, Pharmacyclics has four product candidates in clinical development, a clinical development candidate in late stage preclinical evaluation and several preclinical molecules in lead optimization. We are committed to high standards of ethics, scientific rigor, and operational efficiency; 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, changes in management's expectations or otherwise, except as may be required by law.

Pharmacyclics, Inc.
(a development stage enterprise)
Condensed Balance Sheets
(unaudited) (in thousands, except per share data)

	September 30, 2010	June 30, 2010
ASSETS		
Cash, cash equivalents and marketable securities*	\$ 67,771	\$ 74,149
Other current assets	1,903	1,896
Total current assets	69,674	76,045
Property and equipment, net	504	450
Other assets	315	316
Total assets	\$ 70,493	\$ 76,820

LIABILITIES AND STOCKHOLDERS' EQUITY

Deferred revenue	\$ 4,166	\$ 6,099
Other current liabilities	4,017	3,910
Total current liabilities	8,183	10,009
Deferred rent	43	50
Total liabilities	8,226	10,059
Stockholders' equity	62,267	66,761
Total liabilities and stockholders' equity	\$ 70,493	\$ 76,820
 * Marketable securities	 \$ 53,749	 \$ 22,950

PHARMACYCLICS, INC.
(a development stage enterprise)
Condensed Statements of Operations
(unaudited; in thousands, except per share data)

	Three Months Ended September 30,	
	2010	2009
Revenues:		
License and milestone revenues	\$ 1,964	\$
Total revenues	1,964	
Operating expenses:		
Research and development	7,702	3,288
General and administrative	1,834	1,533
Total operating expenses	9,536	4,821
Loss from operations	(7,572)	(4,821)
Interest and other income (expense), net	49	(24)
Net loss	\$ (7,523)	\$ (4,845)
Basic and diluted net loss per share	\$ (0.13)	\$ (0.12)
Shares used to compute basic and diluted net loss per share	59,278	40,993

Reconciliation of selected GAAP measures to non-GAAP measures ⁽¹⁾
(unaudited) (in thousands)

	Three Months Ended September 30,	
	2010	2009
GAAP net loss	\$ (7,523)	\$ (4,845)
Adjustments:		
Research & Development share-based compensation ⁽²⁾	1,694	158
General & Administrative share-based compensation ⁽²⁾	478	90
Interest Adjustment for related party loan ⁽³⁾	-	43
	2,172	291
Non-GAAP net loss	\$ (5,351)	\$ (4,554)
Non-GAAP net loss per share	\$ (0.09)	\$ (0.11)

(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) Due to the below market interest rate of the related party loan, total GAAP interest expense includes non-cash interest expense of \$43 for the three months ended September 30, 2009.