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

SUNNYVALE, Calif., May 4, 2011 /PRNewswire/ -- Pharmacyclics, Inc. (Nasdaq: PCYC) today reported recent developments and financial results for its fiscal third quarter that ended March 31, 2011.

Recent Developments & Highlights

- ***Broad Clinical Development Progress for Btk Inhibitor PCI-32765 in B-cell Malignancies***

Based upon encouraging data from a Phase I study, Pharmacyclics has initiated a broad Phase II clinical development program in chronic lymphocytic leukemia, mantle cell lymphoma and diffuse large B-cell lymphoma. This program was designed to enable Phase III decisions in these indications based upon ongoing analysis of the clinical data. To date, over 185 patients have been treated with PCI-32765 in clinical trials with once daily oral dosing. We have observed considerable activity in multiple B-cell malignancies, with a relatively benign safety profile and no evidence of cumulative toxicity. It is anticipated that an additional 200 patients will be treated in clinical trials during the second half of calendar 2011.

Updated efficacy and safety data from the Phase IB/II study of PCI-32765 in CLL/SLL will be presented at the 47th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago on June 6th and at the 11th International Conference on Malignant Lymphoma in Lugano, Switzerland on June 17th. In addition, the Phase IA study of PCI-32765 in B-cell malignancies will also be updated at the 11th International Conference on Malignant Lymphoma in Lugano, Switzerland on June 18th.

- ***Chronic Lymphocytic Leukemia/Small Cell Lymphocytic Lymphoma (CLL/SLL)***

A Phase IB/II study of PCI-32765 in CLL/SLL (PCYC-1102) has achieved its original enrollment target. Ongoing studies in CLL/SLL include two studies initiated in Q1 2011, a Phase II study of PCI-32765 in combination with ofatumumab (PCYC-1109) and a Phase II study of PCI-32765 in a combination with either bendamustine/rituximab (BR) or fludarabine/cyclophosphamide and rituximab (FCR) (PCYC-1108). We expect to complete enrollment in both of these studies, each with 30 or more patients, in the second half of calendar 2011.

- ***Mantle Cell Lymphoma (MCL)***

We began enrollment in a Phase II study of single-agent PCI-32765 in relapsed or refractory MCL (PCYC-1104) in Q1 2011. This study is evaluating the safety and activity of PCI-32765 in separate cohorts with either patients with bortezomib-naïve or bortezomib-exposed relapsed or refractory MCL. We expect to complete enrollment with up to a total of 100 patients in this global study by the end of calendar 2011. We also plan to evaluate the safety of PCI-32765 in combination with bortezomib in a Phase IB trial (PCYC-1110). We expect enrollment to be completed for this study in the first half of calendar 2012.

- ***Diffuse Large B-cell Lymphoma (DLBCL)***

A multicenter, open-label, Phase II study of PCI-32765 in patients with relapsed or refractory DLBCL (PCYC-1106) is currently in start-up phase in 15 US sites. 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 study will enroll up to 60 patients and we expect to complete enrollment in the first quarter of calendar 2012. Other trials evaluating the combination of PCI-32765 with chemotherapy in DLBCL are under development.

- ***Other B-cell malignancies***

Based upon activity we have seen across the spectrum of B-cell malignancies in our Phase I trial, there are additional plans to broaden the program via company sponsored or investigator sponsored trials.

- ***Btk Inhibitor PCI-32765 addresses large unmet needs in Non-Hodgkin's Lymphoma (NHL) Market***

There are over 25 distinct subtypes of B-cell malignancies; the common NHLs include the following: follicular lymphoma, chronic lymphocytic leukemia/small lymphocytic lymphoma, diffuse large B-cell lymphoma and mantle cell lymphoma. The NHL therapy market will experience robust annual growth (7.6% per year) and more than double in size over the years 2009-2019 from approximately $4.1 billion in 2009 to approximately $8.4 billion in 2019, as forecasted by Decision Resources, Inc. in the Non-Hodgkin's Lymphoma Onkos Study, April 2011.

There are significant and distinct areas of unmet medical need across the NHL subtypes. Within the indolent lymphomas, we believe a need exists for active therapies that avoid the toxicities typically seen with conventional chemotherapies. Such active therapies are needed as part of effective combinations early in the course of treatment, and also as effective single-agent treatments later in the course of disease progression. In particular, drugs which are well tolerated and which do not limit subsequent treatment options because of bone marrow or other organ toxicity are demanded. In

the aggressive lymphomas, it is our belief that the need exists for agents that can combine with standard therapies to improve cure rate, and for agents that are effective in patients that fail potentially curative therapy.

A typical treatment of NHL includes a diverse combination of chemotherapies in addition to rituximab or other monoclonal antibodies. Such treatments, particularly in combination, can exceed a cost of $100,000 for a 12-month treatment period.

In the major pharmaceutical markets in the US, Europe and Japan, Decision Resources, Inc. estimates the following for 2011: There are 305,440 prevalent cases living with DLBCL, with 50,180 patients estimated to be in the first line setting and 34,320 patients estimated to be in the relapsed/refractory setting. CLL/SLL constitutes about one-third of the B-cell malignancy population. There are 172,630 prevalent cases living with CLL, with 39,390 patients estimated to be in the first line setting and 33,550 patients estimated to be in the relapsed/refractory CLL setting. Follicular lymphoma (FL) constitutes about 20% of the B-cell malignancy population and is considered an indolent, yet incurable, disease. There are 136,450 prevalent cases living with FL, with 21,050 patients estimated to be in the first line setting and 14,270 patients estimated to be in the relapsed/refractory setting. MCL, generally an aggressive form of lymphoma, comprises approximately 5% of the newly diagnosed B-cell malignancies. There are 32,180 prevalent cases living with MCL, with 5,300 patients estimated to be in the first line setting and 4,140 patients estimated to be in the relapsed/refractory setting.

The prevalence of NHL is large and according to the Leukemia & Lymphoma Society, in 2010 there were approximately 475,000 people in the United States alone living with NHL (active disease or in remission).

- ***Oral presentation at the 47th Annual Meeting of the American Society of Clinical Oncology (June 3 — 7, 2011)***

  Date/Time: Monday, June 6, 2011; 9:30 AM — 12:30 PM (CT); Session Title: Leukemia, Myelodysplasia and Transplantation

  Location: Arie Crown Theater

  Abstract #6508: Activity and tolerability of the Bruton's tyrosine kinase (Btk) inhibitor PCI-32765 in patients with chronic lymphocytic leukemia/small cell lymphocytic lymphoma (CLL/SLL): Interim results of a Phase Ib/II study. John C. Byrd et al., The Ohio State University, Columbus, Ohio.

- ***Oral Presentations at the 11th International Conference on Malignant Lymphoma in Lugano, Switzerland, June 15-18, 2011***

  Friday, June 17, 2011; 9:45 AM; Session 10-CLL

  Abstract # 122: The Btk Inhibitor PCI-32765 is Highly Active and Tolerable in Patients with Poor-Risk CLL: Interim Results from a Phase Ib/II Study. S. O'Brien et al. Houston, TX USA

  Saturday, June 18, 2011; 9:30 AM; Session 14-Signalling Pathways in Lymphoma

  Abstract # 153: The Btk inhibitor PCI-32765 is highly active and well tolerated in patients (pts) with relapsed/refractory B-cell malignancies: Final results from a Phase Ia study. R.H. Advani et al., Stanford, CA USA

- ***Servier ongoing 5 trial program and payment of $7 million milestone in April 2011***

  In April 2009, we entered into a collaboration agreement with Les Laboratoires Servier ("Servier") pursuant to which Pharmacyclics granted to Servier an exclusive license for its pan-HDAC inhibitors, including PCI-24781, for territories throughout the world excluding the United States. In April 2011, Pharmacyclics received a $7 million milestone payment from Servier. Over the past two years, Servier has engaged in several exploratory studies. Currently Servier has five Phase I and I/II trials ongoing in Europe in lymphomas and solid tumors. Pharmacyclics is continuing its enrollment with PCI-24781 as a single agent in relapsed/refractory follicular lymphoma patients and anticipates completing enrollment of this trial in the second half of calendar 2011.

- ***Factor VIIa Inhibitor Program ongoing***

  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 I portion of the study, which evaluated safety and established the Phase II dose of PCI-27483, has completed enrollment and interim results were reported at the 2011 GI Cancers Symposium on January 21, 2011. The Phase II portion of the study is enrolling and patients are being randomized into two groups to receive either gemcitabine alone or gemcitabine plus PCI-27483 (1.2 mg/kg twice daily). The company anticipates completing enrollment in the first half of calendar 2012.

Financial Results for Third Quarter Fiscal 2011

The non-GAAP (Generally Accepted Accounting Principles) net loss reported for the fiscal quarter ended March 31, 2011 was $7.4 million, or $0.12 per share. This compares with a non-GAAP net loss of $2.6 million, or $0.05 per share, for the fiscal quarter ended March 31, 2010. 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 March 31, 2011 was $9.2 million, or $0.15 per share. This compares with a GAAP net loss of $3.1 million, or $0.06 per share for the fiscal quarter ended March 31, 2010.

Total revenue was $2.0 million for the fiscal quarter ended March 31, 2011. 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. Total revenue for the fiscal quarter ended March 31, 2010 was $2.1 million.

As of March 31, 2011, the company had cash, cash equivalents and marketable securities totaling $54.4 million. This compares with $74.1 million in cash, cash equivalents and marketable securities as of June 30, 2010, our prior fiscal year end. We received the fourth and final scheduled payment of $1.0 million from our Collaboration and License Agreement with Les Laboratoires Servier in April 2011 and as previously announced, we received a $7.0 million development milestone payment from Servier in April 2011.

Conference Call and Webcast Details

The Company will hold a conference call today at 4:30 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, pro-rata revenue related to prior services performed under the Servier Collaboration, employee related non-cash expenses, the withholding tax related to the Servier transaction, 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.

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 medial 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 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 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.
(a development stage enterprise)
Condensed Consolidated Balance Sheets
(unaudited; in thousands)

	March 31, 2011	June 30, 2010
ASSETS		
Cash, cash equivalents and marketable securities*	$ 54,406	$ 74,149
Other current assets	1,434	1,896
Total current assets	55,840	76,045
Property and equipment, net	896	459
Other assets	344	316
Total assets	$ 57,080	$ 76,820
LIABILITIES AND STOCKHOLDERS' EQUITY		
Deferred revenue	$ 339	$ 6,099
Other current liabilities	6,272	3,910
Total current liabilities	6,611	10,009
Deferred rent	264	50
Total liabilities	6,875	10,059
Stockholders' equity	50,205	66,761
Total liabilities and stockholders' equity	$ 57,080	$ 76,820
* Marketable securities	$ 49,701	$ 22,950

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

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2011	2010	2011	2010
Revenues:				
License and milestone revenues	$ 2,059	$ 2,112	$ 6,847	$ 6,814
Total revenues	2,059	2,112	6,847	6,814
Operating expenses:				
Research and development	8,649	3,679	24,607	10,690
General and administrative	2,692	1,577	6,619	4,875
Total operating expenses	11,341	5,256	31,226	15,565
Loss from operations	(9,282)	(3,144)	(24,379)	(8,751)
Interest and other income (expense), net	65	21	140	15
Loss before provision for income tax	(9,217)	(3,123)	(24,239)	(8,736)
Benefit from income tax	-	-	-	550
Net loss	$ (9,217)	$ (3,123)	$ (24,239)	$ (8,186)
Basic and diluted net loss per share	$ (0.15)	$ (0.06)	$ (0.41)	$ (0.17)
Shares used to compute basic and diluted net loss per share	59,931	50,536	59,641	47,202

Reconciliation of Selected GAAP Measures to Non-GAAP Measures (1)
(unaudited; in thousands, except per share data)

	Three Months Ended March 31,	
	2011	**2010**
GAAP net loss	$ (9,217)	$ (3,123)
Adjustments:		
Research & development share-based compensation(2)	1,213	224
General & administrative share-based compensation(2)	649	254
	1,862	478
Non-GAAP net loss	$ (7,355)	$ (2,645)
Non-GAAP net loss per share	$ (0.12)	$ (0.05)

(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.

Reconciliation of Selected GAAP Measures to Non-GAAP Measures (1)
(unaudited; in thousands, except per share data)

	Nine Months Ended March 31,	
	2011	**2010**
GAAP net loss	$ (24,239)	$ (8,186)
Adjustments:		
Research & development share-based compensation(2)	4,174	598
General & administrative share-based compensation(2)	1,798	700
Interest adjustment for related party loan(3)	-	21
Income tax adjustment(4)	-	(550)
Therapeutic discovery project tax grant, net(5)	(586)	-
	5,386	769
License and collaboration revenues(6)	-	(1,211)
	-	(1,211)
Non-GAAP net loss	$ (18,853)	$ (8,628)
Non-GAAP net loss per share	$ (0.32)	$ (0.18)

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(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 $21 for the nine months ended March 31, 2010.

(4) Represents a reclaiming of paid French Withholding Tax of $550 thousand for the $11 million upfront payment from Servier.

(5) Represents the therapeutic discovery project tax grant, net of related expenses.

(6) Represents the pro-rata portion of services performed under the Servier Collaboration arrangement prior to fiscal year 2010.

SOURCE Pharmacyclics, Inc.

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