



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

SUNNYVALE, Calif., Feb. 4, 2011 /PRNewswire/ -- Pharmacyclics, Inc. (Nasdaq: PCYC) today reported recent developments and financial results for its fiscal second quarter that ended December 31, 2010.

Recent Developments & Highlights

- **Broad Clinical Development Progress for Btk Inhibitor PCI-32765 in B-cell malignancies**
Pharmacyclics has designed a broad Phase II Program in mantle cell lymphoma, chronic lymphocytic leukemia and diffuse large B-cell lymphoma to inform the Phase III program and regulatory path for PCI-32765. Throughout 2011 we will closely monitor these Phase II studies for confirmatory efficacy and safety signals to establish our regulatory approval strategy in a timely manner. Please refer to our website on the key trials listed below.
- **Mantle Cell Lymphoma (MCL)**
Our Phase IA results in the MCL subset presented at the 2010 American Society of Hematology (ASH) Meeting showed promising activity. We therefore designed a Phase II program which includes 1) an evaluation of PCI-32765 as a single agent in 2 groups (cohorts) of patients with relapsed or refractory disease, those who have failed bortezomib and those who have not yet received bortezomib and 2) a safety study of PCI-32765 in combination with bortezomib. The single agent trial protocol has been developed and we expect to enroll a total of approximately 100 patients, beginning in Q1 of calendar year 2011.
- **Chronic Lymphocytic Leukemia/Small Cell Lymphocytic Lymphoma (CLL/SLL)**
The Phase IB/II CLL/SLL program is well underway; to date we have dosed 75 patients and plan to complete enrollment by adding another 7 patients during the remainder of Q1 of calendar 2011. We are also evaluating the safety of PCI-32765 in combination with ofatumumab in a Phase IB/II study of patients with relapsed/refractory CLL/SLL. We began enrollment in this study in January of 2011 and expect to dose up to 40 patients and complete enrollment in the second half of calendar year 2011. We also plan to evaluate the safety of PCI-32765 in combination with several other common therapies in CLL and expect to begin enrollment in Q2 of calendar year 2011.
- **Diffuse Large B-Cell Lymphoma (DLBCL)**
Research has demonstrated that there are 2 distinct molecular subtypes in diffuse large B-cell lymphoma (ABC and GCB). Activated B-cell, or ABC, is the poorer prognostic subtype and is characterized by activation of the B-cell receptor signaling pathway. Our Phase II program will evaluate 2 separate cohorts of patients with relapsed or refractory DLBCL who will receive single agent PCI-32765, those lymphoma patients with ABC and those with germinal center B-cell (GCB), the other molecular subtype. This study will evaluate safety and efficacy in approximately 60 patients. We anticipate that enrollment will begin during the first half of 2011. In parallel, we are also developing a Phase II safety trial combining PCI-32765 with chemotherapy in patients with relapsed or refractory DLBCL.
- **Abstract submitted to the 47th Annual Meeting of the American Society of Clinical Oncology (June 3 — 7, 2011) based on the Phase IB/II study data, evaluating safety and efficacy of administering the Btk Inhibitor, PCI-32765 as a single agent in CLL/SLL patients**
- **Poster presentation at the 2011 GI Cancers Symposium of first in human Phase I results of Factor VIIa Inhibitor, PCI-27483** In the Phase I portion of the study, ascending repeated doses of PCI-27483 (dosages ranging from 0.8 to 1.5 mg/kg) were evaluated in 8 patients with pancreatic cancer receiving concomitant gemcitabine chemotherapy. Among the 5 patients in Phase I considered evaluable, all 5 had stable disease at week 12 and opted to extend treatment with PCI-27483. Three of the 5 patients have a progression free survival $> / = 30$ weeks (7 months). None of the patients receiving PCI-27483 experienced a thromboembolic event. We are currently in the Phase II portion of the study enrolling patients who receive either gemcitabine alone or gemcitabine plus PCI-27483 (dose at 1.2 mg/kg twice daily). We anticipate completion of enrollment in the Phase II portion during calendar year 2011.

Financial Results for Second Quarter Fiscal 2011

The non-GAAP (Generally Accepted Accounting Principles) net loss reported for the fiscal quarter ended December 31, 2010 was \$6.1 million, or \$0.10 per share. This compares with a non-GAAP net loss of \$1.4 million, or \$0.03 per share, for the fiscal quarter ended December 31, 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 December 31, 2010 was \$7.5 million, or \$0.13 per share. This compares with a GAAP net loss of \$0.2 million, or \$0.00 per share for the fiscal quarter ended December 31, 2009.

Total revenue was \$2.8 million for the fiscal quarter ended December 31, 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. Total revenue for the fiscal quarter ended

December 31, 2009 was \$4.7 million, of which \$1.2 million represents the pro rata portion of revenue attributable to the period from April 2009 (i.e., the signing of the collaboration agreement) to June 30, 2009.

As of December 31, 2010, the company had cash, cash equivalents and marketable securities totaling \$61.6 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 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 research payment of \$1.0 million in the second calendar quarter of 2011.

Mr. Duggan stated, "Our Btk Inhibitor, our Factor VII Inhibitor and our HDAC Inhibitor are now in Phase II. We are pleased with our progress and remain focused on building shareholder value by continuing on the regulatory pathways we have set."

Conference Call and Webcast Details

The Company will hold a conference call today at 1:00 p.m. EST. 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 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 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)

	December 31, 2010	June 30, 2010
ASSETS		
Cash, cash equivalents and marketable securities*	\$ 61,610	\$ 74,149
Other current assets	1,751	1,896
Total current assets	63,361	76,045
Property and equipment, net	536	459
Other assets	315	316
Total assets	<u>\$ 64,212</u>	<u>\$ 76,820</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Deferred revenue	\$ 2,368	\$ 6,099
Other current liabilities	4,483	3,910
Total current liabilities	6,851	10,009
Deferred rent	36	50
Total liabilities	6,887	10,059
Stockholders' equity	57,325	66,761
Total liabilities and stockholders' equity	<u>\$ 64,212</u>	<u>\$ 76,820</u>
* Marketable securities	<u>\$ 43,771</u>	<u>\$ 22,950</u>

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

	Three Months Ended December 31,		Six Months Ended December 31,	
	2010	2009	2010	2009
Revenues:				
License and milestone revenues	\$ 2,824	\$ 4,702	\$ 4,788	\$ 4,702
Total revenues	2,824	4,702	4,788	4,702
Operating expenses:				
Research and development	8,256	3,723	15,958	7,011
General and administrative	2,093	1,765	3,927	3,298
Total operating expenses	10,349	5,488	19,885	10,309
Loss from operations	(7,525)	(786)	(15,097)	(5,607)
Interest and other income (expense), net	26	18	75	(6)
Loss before provision for income tax	(7,499)	(768)	(15,022)	(5,613)
Benefit from income tax	-	550	-	550
Net loss	<u>\$ (7,499)</u>	<u>\$ (218)</u>	<u>\$ (15,022)</u>	<u>\$ (5,063)</u>
Basic and diluted net loss per share	\$ (0.13)	\$ (0.00)	\$ (0.25)	\$ (0.11)

Shares used to compute basic and diluted net loss per share	59,715	50,076	59,497	45,535
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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,	
	2010	2009
GAAP net loss	\$ (7,499)	\$ (218)
Adjustments:		
Research & development share-based compensation(2)	1,267	216
General & administrative share-based compensation(2)	671	356
Income tax adjustment(3)	-	(550)
Therapeutic discovery project tax grant, net(4)	(586)	-
	1,352	22
License and collaboration revenues(5)	-	(1,211)
	-	(1,211)
Non-GAAP net loss	\$ (6,147)	\$ (1,407)
Non-GAAP net loss per share	\$ (0.10)	\$ (0.03)

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

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

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

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

	Six Months Ended December 31,	
	2010	2009
GAAP net loss	\$ (15,022)	\$ (5,063)
Adjustments:		
Research & development share-based compensation(2)	2,961	374
General & administrative share-based compensation(2)	1,149	446
Interest adjustment for related party loan(3)	-	21
Income tax adjustment(4)	-	(550)
Therapeutic discovery project tax grant, net(5)	(586)	-
	3,524	291
License and collaboration revenues(6)	-	(1,211)
	-	(1,211)
Non-GAAP net loss	\$ (11,498)	\$ (5,983)
Non-GAAP net loss per share	\$ (0.19)	\$ (0.13)

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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 six months ended December 31, 2009.

(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.

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