



Pharmacyclics Reports Financial Results and Recent Developments for Fiscal Year and Fourth Quarter 2011 - Conference Call Set for Today at 4:30 PM EDT

SUNNYVALE, Calif., Sept. 12, 2011 /PRNewswire/ -- Pharmacyclics, Inc. (Nasdaq: PCYC) today reported financial results and recent developments for its fiscal year and fourth quarter ended June 30, 2011.

Financial Results for Year and Fourth Quarter Ended June 30, 2011

The non-GAAP (Generally Accepted Accounting Principles) net loss reported for the fiscal year ended June 30, 2011 was \$28.0 million, or \$0.47 per share. This compares with a non-GAAP net loss of \$13.6 million, or \$0.28 per share, for the year ended June 30, 2010. For the quarter ended June 30, 2011 the non-GAAP net loss was \$9.1 million, or \$0.15 per share, which compares with a non-GAAP net loss of \$4.9 million, or \$0.10 per share for the 2010 quarter. 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 loss for the fiscal year ended June 30, 2011 was \$35.2 million, or \$0.59 per share. This compares with a GAAP net loss of \$15.0 million, or \$0.31 per share for the year ended June 30, 2010. For the quarter ended June 30, 2011, the GAAP net loss was \$11.0 million or \$0.18 per share, which compares with a GAAP net loss of \$6.8 million, or \$0.13 per share for the 2010 quarter.

At June 30, 2011, the company had cash, cash equivalents and marketable securities of \$112.3 million, which compares with \$74.1 million at June 30, 2010. During the quarter ended June 30, 2011 we raised a net of \$56.0 million from the sale of approximately 6.4 million common shares and also received a \$7.0 million advance development milestone payment from Les Laboratoires Servier under our collaboration agreement.

"Fiscal 2011 was a year to remember for Pharmacyclics. Our efforts to create a coming era of patient friendly, medicinal solutions received a major boost. While all three of our in-clinic molecules performed admirably, Btk Inhibitor PCI-32765 was in all forms of measurement truly outstanding. We plan to initiate our first Phase III trial for 32765 in this fiscal year ending June 30, 2012. We currently also plan to initiate a second Phase III during calendar year 2012. In terms of human and financial capital we are in good shape. Opportunity attracts great people and so it is the case with us. Our expanding team continues to be very focused on building a viable pharmaceutical company that makes a truly significant difference for the better." said Bob Duggan, CEO and Chairman of the Board. "We at Pharmacyclics take great pride in our accomplishments over the past few years and we maintain a keen sense of obligation and enthusiasm as we create our future."

Recent Developments & Highlights

Bruton's Tyrosine Kinase (Btk) Inhibitor for Oncology

- Results from our Phase IB/II trial of PCI 32765 in chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) were presented at an oral presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois in June 2011. As reported at the meeting, treatment with PCI-32765 was generally well-tolerated. The most common adverse events were Grade 1 (mild) or Grade 2 (moderate) diarrhea, fatigue, and nausea. Durable anti-tumor activity was also observed; 3 of 83 patients who were evaluable at the time of presentation had experienced disease progression. An abstract with an updated analysis of this trial has been submitted for the 2011 American Society of Hematology (ASH) Annual Meeting to be held in San Diego in December, 2011.
- In August 2011, we entered into a five-year Cooperative Research and Development Agreement with the National Cancer Institute (NCI) to collaborate on the development of PCI-32765. Under the Agreement, the NCI's Division of Cancer Treatment and Diagnosis plans to sponsor Phase I and Phase II trials of PCI-32765 in various hematologic malignancies.
- The Phase II clinical program, designed to enable potential registrational paths in CLL, mantle cell lymphoma (MCL), and diffuse large B-cell lymphoma (DLBCL), is ongoing. We anticipate that these Phase II trials will allow for Phase III enabling decisions in these indications based upon ongoing analysis of the data in the next 6-12 months.

- As of the end of August, 2011 we enrolled 320 patients into clinical trials evaluating PCI-32765. The ongoing Phase II program currently includes the following studies:
 - PCYC-1104: A multicenter, Phase II study of PCI-32765 in 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 by the end of August, 2011 enrolled 60 patients. We have submitted a preliminary analysis of this study for consideration for the 2011 ASH meeting in December, 2011.
 - PCYC-1106: 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 by the end of August, 2011 enrolled 13 patients. We expect to complete enrollment of all 60 patients by calendar Q1 2012. A separate pilot study of PCI-32765 in patients with ABC subtype DLBCL is currently being conducted at the NIH Clinical Center. An abstract detailing an interim analysis of this pilot trial has been submitted for consideration for the 2011 ASH meeting in December, 2011.
 - PCYC-1108: A Phase IB, multicenter, open-label, study of PCI 32765, in combination with intensive immune chemotherapy (FCR = fludarabine, cyclophosphamide and rituximab; or BR = bendamustine and rituximab) in subjects with CLL or SLL lymphoma. This trial is active in several US sites and completed enrollment with 30 of 30 patients to the BR cohort. We anticipate providing an update of safety results from this study concurrent with releases that are planned for calendar Q4 2011.
 - PCYC-1109: 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 33 patients as of the end of August, 2011. We anticipate providing an update on safety results from this study concurrent with releases that are planned for calendar Q4 2011.
- Ongoing pre-clinical studies, both internally as well as through external collaborations, have suggested a potentially vital role for Btk in both malignant plasma cells and osteoclasts, which are involved in the bone complications of this disease. Therefore, we believe that Btk represents a viable therapeutic target in Multiple Myeloma and we are on track to initiate a Phase II trial of PCI-32765 in this disease in Q1 of calendar 2012.

Factor VIIa 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 is 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. Currently we have enrolled 23 patients in the Phase II portion of this trial and we expect to complete enrollment of our planned 40 patients by Q1 of calendar 2012.

Histone Deacetylase (HDAC) Inhibitor

PCI-24781 is an orally-bioavailable histone deacetylase inhibitor that is in multiple clinical trials. We are conducting a Phase I trial in patients with advanced solid tumors, a Phase I/II trial in sarcoma patients (in combination with doxorubicin, an anti tumor agent) and a Phase I/II trial testing PCI-24781 in patients with relapsed or refractory Non-Hodgkin's lymphoma. Currently we are enrolling the final follicular lymphoma patients in the Phase II portion of this trial and expect to complete enrollment by Q4 of calendar 2011. Our collaboration partner for ex-US development, Servier, has five Phase I and I/II trials ongoing in Europe in lymphomas and solid tumors.

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

Non-Hodgkin's Lymphoma (NHL) Market

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.

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 (prevalence is defined as people living with a history of the disease at a particular point in time), with 50,180 patients estimated to be in the first line setting (these are newly diagnosed cases) 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.

There are many distinct subtypes of B-cell malignancies; the common ones 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.

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

| | June 30, 2011 | June 30, 2010 |
|---|-------------------|------------------|
| ASSETS | | |
| Cash, cash equivalents and marketable securities* | \$ 112,329 | \$ 74,149 |
| Other current assets | 2,367 | 1,896 |
| Total current assets | 114,696 | 76,045 |
| Property and equipment, net | 1,312 | 459 |
| Other assets | 344 | 316 |
| Total assets | <u>\$ 116,352</u> | <u>\$ 76,820</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Deferred revenue | \$ 7,000 | \$ 6,099 |
| Other current liabilities | 7,268 | 3,910 |
| Total current liabilities | 14,268 | 10,009 |
| Deferred rent | 410 | 50 |
| Total liabilities | 14,678 | 10,059 |
| Stockholders' equity | 101,674 | 66,761 |
| Total liabilities and stockholders' equity | <u>\$ 116,352</u> | <u>\$ 76,820</u> |
| * Marketable securities | <u>\$ 24,572</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 June 30, | | Year Ended June 30, | |
|---|--------------------------------|-------------------|------------------------|--------------------|
| | 2011 | 2010 | 2011 | 2010 |
| Revenues: | | | | |
| License and milestone revenues | \$ 1,386 | \$ 2,493 | \$ 8,233 | \$ 9,307 |
| Total revenues | 1,386 | 2,493 | 8,233 | 9,307 |
| Operating expenses*: | | | | |
| Research and development | 9,875 | 6,668 | 34,482 | 17,358 |
| General and administrative | 2,506 | 2,686 | 9,125 | 7,561 |
| Total operating expenses | 12,381 | 9,354 | 43,607 | 24,919 |
| Loss from operations | (10,995) | (6,861) | (35,374) | (15,612) |
| Interest and other income (expense), net | 31 | 23 | 171 | 38 |
| Loss before benefit from income tax | (10,964) | (6,838) | (35,203) | (15,574) |
| Benefit from income tax | - | - | - | 550 |
| Net loss | <u>\$ (10,964)</u> | <u>\$ (6,838)</u> | <u>\$ (35,203)</u> | <u>\$ (15,024)</u> |
| Basic and diluted net loss per share | <u>\$ (0.18)</u> | <u>\$ (0.13)</u> | <u>\$ (0.59)</u> | <u>\$ (0.31)</u> |
| Shares used to compute basic and diluted net loss per share | 60,968 | 51,771 | 59,973 | 48,344 |

* Includes share-based compensation as follows:

| | | | | |
|----------------------------|----------|----------|----------|----------|
| Research and development | \$ 1,133 | \$ 1,400 | \$ 5,307 | \$ 1,998 |
| General and administrative | 713 | 492 | 2,511 | 1,192 |
| Total | \$ 1,846 | \$ 1,892 | \$ 7,818 | \$ 3,190 |

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

(unaudited; in thousands, except per share data)

| | Three Months Ended June 30, | |
|--|--------------------------------|-------------------|
| | 2011 | 2010 |
| GAAP net loss | \$ (10,964) | \$ (6,838) |
| Adjustments: | | |
| Research & development share-based compensation(2) | 1,133 | 1,400 |
| General & administrative share-based compensation(2) | 713 | 492 |
| | <u>1,846</u> | <u>1,892</u> |
| Non-GAAP net loss | \$ <u>(9,118)</u> | \$ <u>(4,946)</u> |
| Non-GAAP net loss per share | \$ <u>(0.15)</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.

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

(unaudited; in thousands, except per share data)

| | Year Ended June 30, | |
|--|---------------------|--------------------|
| | 2011 | 2010 |
| GAAP net loss | \$ (35,203) | \$ (15,024) |
| Adjustments: | | |
| Research & development share-based compensation(2) | 5,307 | 1,998 |
| General & administrative share-based compensation(2) | 2,511 | 1,192 |
| Interest adjustment for related party loan(3) | - | 21 |
| Income tax adjustment(4) | - | (550) |
| Therapeutic discovery project tax grant, net(5) | (586) | - |
| | <u>7,232</u> | <u>2,661</u> |
| License and collaboration revenues(6) | - | (1,211) |
| Non-GAAP net loss | \$ <u>(27,971)</u> | \$ <u>(13,574)</u> |
| Non-GAAP net loss per share | \$ <u>(0.47)</u> | \$ <u>(0.28)</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) 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 year months ended June 30, 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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