



Pharmasset Reports Fiscal Second Quarter 2010 Financial Results

PRINCETON, N.J., May 5, 2010 /PRNewswire via COMTEX News Network/ -- Pharmasset, Inc. (Nasdaq: VRUS), a clinical stage pharmaceutical company committed to discovering, developing, and commercializing novel drugs to treat viral infections, today reported financial results and operational highlights for the quarter ended March 31, 2010.

Financial Results

Revenues were \$0.3 million during the quarter ended March 31, 2010 compared to \$1.9 million for the quarter ended March 31, 2009 and include amortization of up-front and subsequent collaborative and license payments received from Roche. Revenues during the quarter ended March 31, 2009 also include \$1.4 million of non-recurring research and development payments from Roche for activities related to holding the IND application for RG7128.

Net cash used in operating activities was \$27.3 million for the six months ended March 31, 2010, as compared to \$30.7 million for the six months ended March 31, 2009. Net cash used in operating activities for the three months ended March 31, 2010 was \$12.8 million. Pharmasset had \$61.0 million in cash and cash equivalents as of March 31, 2010.

Total operating expenses for the quarter ended March 31, 2010 were \$15.7 million as compared to \$16.6 million for the same period in 2009. The decrease in operating expenses for the quarter ended March 31, 2010 was primarily the result of discontinuing our clevidine program in April 2009, partially offset by increases in development costs for PSI-7977, PSI-938 and PSI-661.

Pharmasset reported a net loss of \$16.1 million, or \$0.54 per share, for the quarter ended March 31, 2010, as compared to a net loss of \$15.5 million, or \$0.59 per share, for the quarter ended March 31, 2009.

Recent Operational Highlights:

- On February 17, 2010, Pharmasset announced that its partner Roche completed enrollment of the RG7128 phase 2b study (PROPEL), enrolling approximately 400 treatment naïve patients with hepatitis C virus (HCV) genotypes 1 and 4. The PROPEL study is investigating a 12 week duration of RG7128 with the standard of care (SOC), followed by an additional 12 weeks of SOC. The last patient enrolled in this study is to receive his or her last dose of RG7128 or placebo in early May.
- Roche has also initiated a second phase 2b trial investigating 24 weeks of treatment with RG7128 and SOC. This trial has completed enrollment of approximately 180 treatment naïve patients with hepatitis C virus (HCV) genotypes 1 and 4.
- The PROPEL and 24 week studies have been amended so that patients that failed treatment with placebo and SOC will receive RG7128 1000mg BID for 24 weeks followed by 24 weeks of SOC, starting in 3Q10.
- On April 8, 2010, Pharmasset announced that it had initiated a phase 1 study with PSI-938 for the treatment of HCV.
- On April 15, 2010, Pharmasset presented follow-up data from the 28 day study with RG7128 in genotype 2 and 3 non-responder patients, demonstrating a 65% SVR. Of those patients that received 48 weeks of therapy 90% achieved an SVR. Further *in vitro* data was presented on the combination of PSI-7977 and PSI-938 at the European Association for the Study of the Liver (EASL) meeting in Vienna, Austria
- On May 4, 2010, Pharmasset announced efficacy and preliminary safety results from its 28-day Phase 2a study of PSI-7977 dosed once daily (QD) in combination with SOC in patients with HCV genotype 1 who have not been treated previously. On an intent-to-treat analysis, patients receiving PSI-7977 100mg QD, 200mg QD or 400mg QD in combination with SOC achieved RVR rates of 88%, 94% and 93%, respectively, compared to 21% in the placebo plus SOC arm. Preliminary safety and tolerability across all doses were comparable to placebo administered with SOC.

"Pharmasset had a very productive start to 2010," stated Schaefer Price, President and Chief Executive Officer, "as we recently reported positive Phase 2a results for our PSI-7977 program demonstrating high RVR rates in patients, consistent with RVR rates previously reported for RG7128. Safety results to date from both compounds are encouraging. During the quarter, we also advanced our first of two guanine nucleotide analogs, PSI-938, into the clinic. Based on the data from our compounds, we believe our nucleoside/tide analogs continue to differentiate themselves as a class of direct acting antivirals for the treatment of HCV and we look forward to reporting updates for our programs throughout the rest of 2010."

Calendar Year 2010 Anticipated Milestones:

- Roche expects to initiate a Phase 2b study of RG7128 in combination with SOC in patients with HCV genotypes 2 and 3

in the second half of 2010

- Pharmasset expects to present the PSI-7977 Phase 2a data at a scientific meeting later in 2010
- Pharmasset expects to initiate 12-week Phase 2b study of PSI-7977 in the fourth quarter of 2010
- Pharmasset expects to report top line Phase 1 antiviral data for PSI-938 in the third quarter of 2010
- Pharmasset expects to submit an IND or foreign regulatory equivalent for its second guanine nucleotide, PSI-661 (formerly PSI-879), in the fourth quarter of 2010

About Pharmasset

Pharmasset is a clinical-stage pharmaceutical company committed to discovering, developing, and commercializing novel drugs to treat viral infections. Pharmasset's primary focus is on the development of oral therapeutics for the treatment of hepatitis C virus (HCV) and, secondarily, on the development of Racivir(TM) for the treatment of human immunodeficiency virus (HIV). Our research and development efforts focus on nucleoside/tide analogs, a class of compounds which act as alternative substrates for the viral polymerase, thus inhibiting viral replication. We currently have four clinical-stage product candidates. RG7128, a cytosine nucleoside analog for chronic HCV infection, is in two Phase 2b clinical trials in combination with Pegasys(R) plus Copegus(R) and is also in the INFORM studies, the first series of studies designed to assess the potential of combinations of small molecules without pegylated interferon and ribavirin to treat chronic HCV. These clinical studies are being conducted through a strategic collaboration with Roche. Our other, unpartnered, clinical stage product candidates for the treatment of HCV include PSI-7977, a uracil nucleotide analog that has completed a Phase 2a trial and is preparing to move into phase 2b, and PSI-938, a guanine nucleotide analog that is in a Phase 1 trial. We also have in our pipeline an additional guanine nucleotide analog, PSI-661, which is in advanced preclinical development for the treatment of HCV. Racivir, for the treatment of HIV, has completed a Phase 2 clinical trial.

Pegasys(R) and Copegus(R) are registered trademarks of Roche.

Contact

Richard E. T. Smith, Ph.D.
VP, Investor Relations and Corporate Communications
Office: +1 (609) 613-4181

Forward-Looking Statements

Pharmasset "Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995: Statements in this press release regarding our business that are not historical facts are "forward-looking statements" that involve risks, uncertainties and other important factors, including, without limitation, the risk that adverse events could cause the cessation or delay of any of the ongoing or planned clinical trials and/or our development of our product candidates, the risk that the results of previously conducted studies involving our product candidates will not be repeated or observed in ongoing or future studies involving our product candidates, the risk that our collaboration with Roche will not continue or will not be successful, and the risk that any one or more of our product candidates will not be successfully developed and commercialized. For a discussion of these and other risks, uncertainties and important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended September 30, 2009 and our Quarterly Report on Form 10-Q for the period ended March 31, 2010 filed with the Securities and Exchange Commission and discussions of potential risks, uncertainties and other important factors in our subsequent filings with the Securities and Exchange Commission.

PHARMASSET, INC.
CONDENSED STATEMENTS OF OPERATIONS
(UNAUDITED)
(in thousands, except share and per share amounts)

Three Months Ended
March 31,

2010

2009

	----	----
Revenues	\$251	\$1,903
	----	-----
COSTS AND EXPENSES:		
Research and development	12,028	13,694
General and administrative	3,647	2,894
	-----	-----
Total costs and expenses	15,675	16,588
	-----	-----
Operating loss	(15,424)	(14,685)
Investment income	1	58
Interest expense	(638)	(845)
	----	----
Loss before income taxes	(16,061)	(15,472)
Provision for income taxes	-	-
	---	---
Net loss	\$ (16,061)	\$ (15,472)
	=====	=====
Net loss per share:		
basic and diluted	\$ (0.54)	\$ (0.59)
	=====	=====
Weighted average shares outstanding:		
basic and diluted	29,522,630	26,262,090
	=====	=====

Six Months Ended
March 31,

	-----	-----
	2010	2009
	----	----
Revenues	\$520	\$2,367
	----	-----
COSTS AND EXPENSES:		
Research and development	21,225	27,717
General and administrative	7,887	6,963
	-----	-----
Total costs and expenses	29,112	34,680
	-----	-----
Operating loss	(28,592)	(32,313)
Investment income	5	167

Interest expense	(1,344)	(1,602)
	-----	-----
Loss before income taxes	(29,931)	(33,748)
Provision for income taxes	-	-
	---	---
Net loss	\$(29,931)	\$(33,748)
	=====	=====
Net loss per share:		
basic and diluted	\$(1.04)	\$(1.36)
	=====	=====
Weighted average shares outstanding:		
basic and diluted	28,898,334	24,799,895
	=====	=====

PHARMASSET, INC.
CONDENSED BALANCE SHEETS

(In thousands, except par value, share and per share amounts)

	As of March 31, 2010 ----- (unaudited)	As of September 30, 2009 -----
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$61,036	\$58,408
Amounts due from collaboration partner	15	369
Prepaid expenses and other assets	762	1,656

Total current assets	61,813	60,433
	-----	-----
EQUIPMENT AND LEASEHOLD IMPROVEMENTS:		
Equipment	3,638	3,613
Leasehold improvements	1,837	1,837
	-----	-----
	5,475	5,450
Less accumulated depreciation and amortization	(3,920)	(3,419)
	-----	-----
Total equipment and leasehold improvements, net	1,555	2,031
Restricted cash	100	100
Other assets	152	172
Total	\$63,620	\$62,736
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	\$8,563	\$7,513

Accounts payable	4,210	2,533
Accrued expenses	4,140	7,675
Deferred rent	18	80
Deferred revenue	985	985
	---	---
Total current liabilities	17,916	18,786
Deferred revenue	2,463	2,956
Long-term debt, net of discount of \$290 and \$472 as of March 31, 2010 and September 30, 2009, respectively	7,491	12,096

Total liabilities	27,870	33,838
	-----	-----
Commitments and contingencies		
STOCKHOLDERS' EQUITY:		
Common stock, \$0.001 par value, 100,000,000 shares authorized, 30,244,610 and 28,268,004 shares issued and outstanding at March 31, 2010 and September 30, 2009, respectively	30	28
Warrants to purchase 127,248 shares of common stock for \$12.05 per share as of March 31, 2010 and September 30, 2009, respectively	1,230	1,230
Additional paid-in capital	231,806	195,025
Accumulated deficit	(197,316)	(167,385)
Total stockholders' equity	35,750	28,898
	-----	-----
Total	\$63,620	\$62,736
	=====	=====

SOURCE Pharmasset, Inc.

Copyright (C) 2010 PR Newswire. All rights reserved