



Savient Pharmaceuticals Reports Third Quarter 2009 Financial Results

EAST BRUNSWICK, N.J., Nov 04, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Savient Pharmaceuticals, Inc. (Nasdaq: SVNT) today reported financial results for the three and nine months ended September 30, 2009, ending the quarter with \$67.5 million in cash and short-term investments, a reduction of \$11.1 million from December 31, 2008. In October 2009, we raised \$60.9 million in cash, net of \$4.8 million of offering costs from an underwritten public offering of 4,945,000 shares of our common stock. The effect of combining the offering with our existing cash brings Savient to approximately \$128.4 million in cash and short-term investments as of September 30, 2009, on a pro forma basis.

"Our strengthened cash position will support future important initiatives in addition to our focused efforts for the resubmission of our Biologics License Application for KRYSTEXXA(TM) to the U.S. Food and Drug Administration for the treatment of chronic gout in patients refractory to conventional treatment, which we expect will be submitted in early 2010," stated Paul Hamelin, President of Savient.

Operational Key Events:

- During July 2009, we completed the dosing phase of our open label extension (OLE) study for KRYSTEXXA. This study is currently in an observation only stage.
- In July 2009, we received a complete response letter (CRL) from the U.S. Food and Drug Administration (FDA) stating that the FDA at that time could not approve our Biologics License Application (BLA) for KRYSTEXXA. The complete response letter cited deficiencies with the chemistry, manufacturing and controls (CMC) section of the BLA and also provided a draft of the proposed labeling and further guidance regarding a Risk Evaluation and Mitigation Strategy (REMS).
- Our requested Type A meeting with the FDA occurred on September 14, 2009 to discuss the CRL and next steps. The meeting with the FDA provided clarification and alignment on a resubmission plan for us to fully address all deficiencies and issues identified in the CRL. Since the resubmission will include REMS materials, this is subject to a Class 2 review cycle, meaning a Prescription Drug User Fee Act date for all components of our filing six months after the date of our resubmission.
- In September 2009, we committed to a corporate restructuring plan where we reduced our workforce by 25 employees. We expect that this cost savings initiative will save \$2.9 million through the year ending December 31, 2010, net of \$1.2 million of severance-related expenses.
- In October 2009, we raised \$65.7 million from an underwritten public offering of 4,945,000 shares of our common stock that yielded \$60.9 million in cash, net of \$4.8 million of offering costs.

The net loss for the third quarter of 2009 was \$13.9 million, or \$0.23 per basic and diluted share, on total revenues of \$0.3 million, compared with a net loss of \$18.2 million, or \$0.34 per basic and diluted share, on total revenues of \$0.5 million for the third quarter of 2008. Partially offsetting our net loss for the three months ended September 30, 2009 was non-cash gain of \$11.8 million due to a valuation adjustment relating to warrants that we issued in connection with our April 2009 registered direct offering. On a non-Generally Accepted Accounting Principles (GAAP) basis and excluding the \$11.8 million non-cash gain due to a valuation adjustment on our warrants, our net loss for the third quarter of 2009 was \$25.7 million, or \$0.42 per

basic and diluted share, compared with a GAAP net loss for the third quarter of 2008 of \$18.2 million, or \$0.34 per basic and diluted share.

The net loss for the first nine months of 2009 was \$90.6 million, or \$1.56 per basic and diluted share, on total revenues of \$2.1 million, compared with a net loss of \$60.0 million, or \$1.12 per basic and diluted share, on total revenues of \$2.1 million for the same period in 2008. The net loss for the nine months ended September 30, 2009 includes a non-cash charge of \$24.1 million due to a valuation adjustment relating to warrants that we issued in connection with our April 2009 registered direct offering. On a non-GAAP basis, excluding the \$24.1 million non-cash charge, our net loss for the first nine months of 2009 was \$66.5 million, or \$1.15 per basic and diluted share, compared with a GAAP net loss of \$60.0 million for the nine months ended September 30, 2008, or \$1.12 per basic and diluted share.

Financial Results of Operations for the Three Months Ended September 30, 2009

Total revenues for the third quarter of 2009 were \$0.3 million compared with \$0.5 million for the third quarter of 2008, a decrease of \$0.2 million mainly due to lower gross sales of Oxandrin(R) as a result of decreased overall demand for the product from increased generic competition. Additionally, we adjusted our Oxandrin product return reserve in both the current and prior year quarters to reflect higher actual return experience. We expect that sales of Oxandrin will continue to decline slightly or remain flat in future periods. The decrease in Oxandrin sales was partially offset by a \$0.1 million increase in sales of our authorized generic oxandrolone, due to increased market share being achieved by Watson Pharmaceuticals, Inc. (Watson), our authorized generic distributor.

Research and development expenses for the third quarter of 2009 were \$17.7 million, compared with \$10.9 million for the third quarter of 2008, an increase of \$6.8 million, or 62%. The increase is primarily due to \$4.5 million in contingency charges recorded in the third quarter of 2009 relating to amending the fee schedule and total obligation under our services agreement with our proposed secondary source supplier of pegloticase active pharmaceutical ingredient (API). We also incurred \$1.0 million in higher expenses resulting from increased outside laboratory testing services supporting our OLE study for KRYSTEXXA.

Selling, general and administrative expenses for the third quarter of 2009 were \$8.5 million, compared with \$7.6 million for the third quarter of 2008, an increase of \$0.9 million, or 13%, primarily due to severance expense related to our plan of termination that reduced our workforce by 25 employees in the third quarter of 2009.

Investment income, net for the third quarter of 2009 was \$0.5 million, compared with \$0.3 million for the three months ended September 30, 2008, an increase of \$0.2 million, or 48%, primarily due to realized gains on the sale of short-term investments.

Other income, net for the third quarter of 2009 was \$11.8 million, compared with Other expense, net of \$0.1 million for the third quarter of 2008, an increase to income of \$11.9 million as a result of the non-cash gain on the mark-to-market valuation adjustment to our warrant liability during the three months ended September 30, 2009.

Financial Results of Operations for the Nine Months Ended September 30, 2009

Total revenues for the first nine months of 2009 were \$2.1 million, consistent with the same period of 2008.

Research and development expenses for the first nine months of 2009 were \$42.1 million, compared with \$37.8 million for the same period of 2008, an increase of \$4.3 million, or 11%. The increase was primarily due to higher expenses of \$3.5 million associated with the production of pegloticase API commercial batches at BTG, severance expense of \$2.5 million recorded during the current year and contingency charges of \$4.5 million recorded in the third quarter of 2009 relating to amending the fee schedule and total obligation under a services agreement for the manufacture of conformance batches at our proposed secondary source supplier of pegloticase API. The above increases in expense were partially offset by approximately \$3.2 million of lower technology transfer costs from our proposed secondary source supplier of pegloticase API as the majority of the work was performed in the prior year and has now been substantially completed. Additionally, we incurred lower expenses for reservation fees as the prior year period reflects a \$2.2 million payment to BTG to reserve manufacturing space in their facility.

Selling, general and administrative expenses for the first nine months of 2009 were \$25.4 million, compared with \$27.3 million for the same period of 2008, a decrease of \$1.9 million, or 7%. The decrease was primarily due to lower legal fees of \$3.2 million as the prior year results reflect expenses for Oxandrin-related patent infringement litigation and \$2.1 million of lower compensation and benefits, including share-based compensation, due primarily to decreased headcount and share-based awards. Partially offsetting the lower costs are \$1.2 million in higher severance expenses, increased pre-launch market research and recruiting expenses of \$1.1 million and \$1.0 million, respectively, both incurred in preparation for a potential commercial launch of KRYSTEXXA.

Investment income, net for the first nine months of 2009 was \$0.3 million, compared with \$1.7 million for the same period of 2008, a decrease of \$1.4 million, or 84%. The lower investment income was primarily due to decreased dividend and interest

income from lower cash, cash equivalent and investment balances and as a result of lower yields earned on those investments.

Other expense, net for the first nine months of 2009 was \$24.4 million, compared with \$0.5 million for the same period of 2008, an increase of \$23.9 million primarily as a result of the non-cash net loss on the mark-to-market valuation adjustment to our warrant liability.

Use of Non-GAAP Measures

To supplement our consolidated financial statements presented in accordance with GAAP, we use the following measures defined as non-GAAP financial measures by the SEC: non-GAAP net loss and non-GAAP loss per basic and diluted share. The presentation of this financial information is not intended to be considered in isolation or as a substitute for the financial information prepared and presented in accordance with GAAP. In addition, the non-GAAP financial measures included in this press release may be different from, and therefore not comparable to, similar measures used by other companies. Although certain non-GAAP financial measures used in this release exclude the accounting treatment of valuation adjustments associated with our outstanding warrants to purchase shares of our common stock, these non-GAAP measures should not be relied upon independently.

Our management believes that these non-GAAP financial measures provide meaningful supplemental information regarding our performance by excluding certain expenses and expenditures that may not be indicative of our core business operating results. We believe that both management and investors benefit from referring to these non-GAAP financial measures in assessing our performance and when planning, forecasting and analyzing future periods. These non-GAAP financial measures also facilitate management's internal comparisons to our historical performance and our competitors' operating results. We believe that these non-GAAP measures are useful to investors in allowing for greater transparency with respect to supplemental information used by management in its financial and operational decision making.

CONFERENCE CALL INFORMATION

Savient's management team will host a live conference call and Webcast on Thursday, November 5 at 10:00 a.m. Eastern Time/7:00 a.m. Pacific Time to review the third quarter financial results. To participate by telephone, please dial 888-397-5354 from the U.S. or 719-457-2615 for international callers. The conference identification number is 6621643. The live and archived Webcast can be accessed on the investor relations section of the Savient Web site at www.savient.com. Please log on to Savient's Web site 15 minutes prior to the start of the call to ensure adequate time for any downloads that may be necessary.

A telephone replay will be available from 1:00 p.m. Eastern Time on November 5, 2009 through 11:59 p.m. Eastern Time on November 19, 2009 by dialing (888) 203-1112 (domestic) or (719) 457-0820 (international) and entering conference ID number 6621643.

ABOUT SAVIENT PHARMACEUTICALS, INC.

Savient Pharmaceuticals, Inc. is a specialty biopharmaceutical company focused on developing KRYSTEXXA(TM) (pegloticase) for the treatment of chronic gout in patients refractory to conventional therapy. Savient has exclusively licensed worldwide rights to the technology related to KRYSTEXXA, formerly referred to as Puricase(R), from Duke University and Mountain View Pharmaceuticals, Inc. Savient also manufactures and supplies Oxandrin(R) (oxandrolone tablets, USP) CIII in the U.S. Puricase is a registered trademark of Mountain View Pharmaceuticals, Inc.

FORWARD-LOOKING LANGUAGE

All statements other than statements of historical facts included in this press release are forward-looking statements that are subject to certain risks, trends and uncertainties that could cause actual results and achievements to differ materially from those expressed in such statements. These risks, trends and uncertainties are in some instances beyond our control. Words such as "anticipate," "believe," "estimate," "expect," "intend," "plan," "will" and other similar expressions identify forward-looking statements, although not all forward-looking statements contain these identifying words. In particular, any statements regarding potential FDA marketing approval for KRYSTEXXA(TM) (pegloticase), whether any further clinical trials will be required, the actions that may be required of Savient by the FDA in connection with the BLA, the reversion to and revalidation of the Phase 3 manufacturing process, the timing of a resubmission to the FDA in response to the complete response letter and the efficacy and safety of KRYSTEXXA are forward-looking statements. These forward-looking statements involve substantial risks and uncertainties and are based on our assessment and interpretation of the currently available data and information, our Phase 3 clinical data, our current understanding of the complete response letter and on current expectations, assumptions, estimates and projections about our business and the biopharmaceutical and specialty pharmaceutical industries in which we operate. Important factors that may affect our ability to achieve the matters addressed in these forward-looking statements include, but are not limited to, the possibility that the FDA may raise further issues regarding the BLA for KRYSTEXXA or require that we conduct additional clinical trials, our ability to commercialize and market acceptance of KRYSTEXXA; difficulties in obtaining financing; potential development of alternative or more effective products by competitors; reliance on third parties to

manufacture, market and distribute many of our products; economic, political and other risks associated with foreign operations; risks of maintaining protection for our intellectual property; risks of an adverse determination in intellectual property litigation; and risks associated with stringent government regulation of the biopharmaceutical industry and other important factors set forth more fully in our reports filed with the Securities and Exchange Commission, to which investors are referred for further information. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements, which speak only as of the date of publication of this press release to shareholders. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. We do not have a policy of updating or revising forward-looking statements and, except as required by law, assume no obligation to update any forward-looking statements.

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(Tables to Follow)

SAVIENT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands, except share data)

	September 30, 2009 ----	December 31, 2008 ----
ASSETS		
Current Assets:		
Cash and cash equivalents	\$67,474	\$76,315
Short-term investments	3	2,282
Accounts receivable, net	592	822
Inventories, net	940	1,892
Recoverable income taxes	-	5,526
Prepaid expenses and other current assets	1,516	2,782
	-----	-----
Total current assets	70,525	89,619
	-----	-----
Deferred income taxes, net	5,200	4,200
Property and equipment, net	1,111	1,393
Other assets (including restricted cash)	1,297	3,010
	-----	-----
Total assets	\$78,133	\$98,222
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$5,651	\$5,888
Deferred revenues	327	451
Warrant liability	36,617	-
Other current liabilities	23,707	18,650
	-----	-----
Total current liabilities	66,302	24,989
Other liabilities	11,059	9,809
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock-\$.01 par value 4,000,000 shares authorized; no shares issued	-	-

Common stock-\$.01 par value 150,000,000 shares authorized; 61,658,000 issued and outstanding at September 30, 2009 and 54,654,000 shares issued and outstanding at December 31, 2008	617	547
Additional paid-in-capital	242,400	214,467
Accumulated deficit	(242,248)	(151,614)
Accumulated other comprehensive income	3	24
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Total stockholders' equity	772	63,424
	---	-----
Total liabilities and stockholders' equity	\$78,133	\$98,222
	=====	=====

SAVIENT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
	---	----	-----	-----
Revenues:				
Product sales, net	\$328	\$499	\$2,092	\$1,958
Other revenues	-	43	4	125
	--	--	--	---
	328	542	2,096	2,083
	---	---	-----	-----
Cost and expenses:				
Cost of goods sold	374	303	1,237	855
Research and development	17,670	10,875	42,071	37,762
Selling, general and administrative	8,538	7,563	25,403	27,277
	-----	-----	-----	-----
	26,582	18,741	68,711	65,894
	-----	-----	-----	-----
Operating loss from continuing operations	(26,254)	(18,199)	(66,615)	(63,811)
Investment income, net	502	340	273	1,704
Other income (expense), net	11,812	(148)	(24,356)	(460)
	-----	----	-----	----
Loss from continuing operations before income taxes	(13,940)	(18,007)	(90,698)	(62,567)
Income tax benefit	(64)	(863)	(64)	(3,673)
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Loss from continuing operations	(13,876)	(17,144)	(90,634)	(58,894)

Loss from discontinued operations, net of taxes	-	(1,070)	-	(1,070)
	--	-----	--	-----
Net loss	\$(13,876)	\$(18,214)	\$(90,634)	\$(59,964)
	=====	=====	=====	=====
Loss per common share, from continuing operations:				
Basic	\$(0.23)	\$(0.32)	\$(1.56)	\$(1.10)
	=====	=====	=====	=====
Diluted	\$(0.23)	\$(0.32)	\$(1.56)	\$(1.10)
	=====	=====	=====	=====
Loss per common share, from discontinued operations:				
Basic	\$ -	\$(0.02)	\$ -	\$(0.02)
	===	=====	===	=====
Diluted	\$ -	\$(0.02)	\$ -	\$(0.02)
	===	=====	===	=====
Loss per common share:				
Basic	\$(0.23)	\$(0.34)	\$(1.56)	\$(1.12)
	=====	=====	=====	=====
Diluted	\$(0.23)	\$(0.34)	\$(1.56)	\$(1.12)
	=====	=====	=====	=====
Weighted-average number of common and common equivalent shares:				
Basic	60,922	53,617	58,192	53,479
Diluted	60,922	53,617	58,192	53,479

SAVIENT PHARMACEUTICALS, INC. AND SUBSIDIARIES
RECONCILIATION OF NON-GAAP NET LOSS TO GAAP NET LOSS
(Unaudited)
(In millions, except per share data)

Below is a reconciliation of the non-GAAP net loss and loss per basic and diluted share amounts presented in this press release to the GAAP net loss and loss per basic and diluted share amounts presented in this press release (amounts in millions except per share data):

	Quarter Ended September 30, -----		Nine Months Ended September 30, -----	
	2009	2008	2009	2008
	----	----	----	----
GAAP net loss	\$(13.9)	\$(18.2)	\$(90.6)	\$(60.0)
Impact of change in warrant valuation	11.8	-	(24.1)	-
Non-GAAP net loss	\$(25.7)	\$(18.2)	\$(66.5)	\$(60.0)
	Quarter Ended September 30, -----		Nine Months Ended September 30, -----	

	2009	2008	2009	2008
	----	----	----	----
GAAP loss per basic and diluted share	\$ (0.23)	\$ (0.34)	\$ (1.56)	\$ (1.12)
Impact of change in warrant valuation	0.19	-	(0.41)	-
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Non-GAAP loss per basic and diluted share	\$ (0.42)	\$ (0.34)	\$ (1.15)	\$ (1.12)
	=====	=====	=====	=====

SOURCE Savient Pharmaceuticals, Inc.

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