



Savient Pharmaceuticals Reports Second Quarter 2009 Financial Results

Ends First half of 2009 with \$76.6M in Cash and Short-term Investments

EAST BRUNSWICK, N.J., Aug 10, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Savient Pharmaceuticals, Inc. (Nasdaq: SVNT) today reported financial results for the three and six months ended June 30, 2009, ending the quarter with \$76.6 million in cash and short-term investments, a reduction of \$2.0 million from December 31, 2008. Excluding the receipt of the \$29.0 million in cash from our registered direct offering in April 2009, our cash burn for the six months ended June 30, 2009 was \$31.0 million, or approximately \$5.0 million per month.

The net loss for the second quarter of 2009 was \$54.8 million or \$0.92 per basic and diluted share on total revenues of \$0.7 million, compared with a net loss of \$24.2 million or \$0.45 per basic and diluted share on total revenues of \$0.4 million for the second quarter of 2008. A significant portion of our net loss for the three months ended June 30, 2009 resulted from a non-cash charge of \$35.8 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, excluding the \$35.8 million non-cash charge due to the valuation adjustment, our net loss for the second quarter of 2009 was \$19.0 million, or \$0.32 per basic and diluted share, compared with a GAAP net loss for the second quarter of 2008 of \$24.2 million, or \$0.45 per basic and diluted share.

As part of our April 2009 registered direct offering, we issued to investors 5.9 million shares of common stock and warrants to purchase up to 5.0 million shares of common stock. We account for the warrants as a liability and are required to record a mark-to-market valuation adjustment at the end of each financial reporting period. Because the value of our common stock price increased between the issuance of the warrants and the end of the quarter, the fair value of the warrants also increased, and we were required to record a non-cash charge of \$35.8 million due to the valuation adjustment, in other expense, net, within our consolidated statements of operations.

The net loss for the first six months of 2009 was \$76.8 million or \$1.35 per basic and diluted share on total revenues of \$1.8 million, compared with a net loss of \$41.8 million or \$0.78 per basic and diluted share on total revenues of \$1.5 million for the same period in 2008. On a non-GAAP basis, excluding the \$35.8 million non-cash charge due to the valuation adjustment on our warrants, our net loss for the first six months of 2009 was \$41.0 million, or \$0.72 per basic and diluted share, compared with a GAAP net loss of \$41.8 million for the second quarter of 2008, or \$0.78 per basic and diluted share.

"Given the delay in a potential approval of our Biologics License Application (BLA) for KRYSTEXXA(TM) (pegloticase), our biologic PEGylated uricase enzyme, we have begun implementing immediate measures to further conserve cash and reduce our cash burn, while we concentrate our efforts to remedy the chemistry, manufacturing and controls (CMC) issues identified in the complete response letter received from the Food and Drug Administration (FDA) on July 31, 2009," said Paul Hamelin, President of Savient. "We will suspend many of our pre-launch commercialization activities and are able to do so without jeopardizing our launch readiness in light of the significant interactions we have already engaged in with the FDA on our package insert which has enabled us to bring to near conclusion many of our pre-launch commercialization activities. Until we regain greater certainty regarding the timing of a potential approval of KRYSTEXXA, our spend on commercialization activities will be reduced to the minimum needed to generally maintain our current state of launch readiness."

Operational Key Events:

- Raised \$31.0 million from a registered direct offering that yielded \$29.0 million in cash, net of \$2.0 million of offering costs

- Elected Ginger D. Constantine, M.D. to the Company's Board of Directors

- FDA appointed Arthritis Advisory Committee recommended marketing approval for KRYSTEXXA

- Presented six abstracts (two oral presentations and four posters) about

KRYSTEXXA at the European League Against Rheumatism (EULAR) 2009 Annual Congress addressing various aspects of treatment failure gout.

- Received a complete response letter from the FDA on July 31, 2009 stating that the FDA cannot at this time approve the BLA for KRYSTEXXA as a treatment for chronic gout in patients refractory to conventional therapy. The complete response letter cited deficiencies with the CMC section of the BLA and also provided the current draft of the proposed labeling and further guidance regarding a Risk Evaluation and Mitigation Strategy (REMS). We expect to resubmit our BLA to the FDA in early 2010 to respond to the FDA's complete response letter.

- Received notification from the FDA of a tentative meeting date scheduled for mid-September 2009 to discuss the complete response letter issued by the FDA in response to the "Type A" Meeting request filed by the Company.

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

Total revenues for the second quarter of 2009 were \$0.7 million compared with \$0.4 million for the second quarter of 2008, an increase of \$0.3 million. The increase is primarily the result of higher product sales of oxandrolone, our authorized generic product that promotes weight gain following involuntary weight loss due to disease or medical condition, due to increased market share achieved by our authorized generic distributor.

Cost of goods sold for the second quarter of 2009 was \$0.4 million, compared with \$0.2 million for the second quarter of 2008, an increase of \$0.2 million. The increase in cost of goods sold resulted primarily from higher gross sales of oxandrolone.

Research and development expenses for the second quarter of 2009 were \$11.6 million, compared with \$15.7 million for the second quarter of 2008, a decrease of \$4.1 million. The decrease was primarily due to lower technology transfer expenses of \$2.1 million as we near the completion of the technology transfer related to developing our secondary source supplier of pegloticase active pharmaceutical ingredient (API). In addition, manufacturing capacity reservation fees paid to our primary third-party manufacturer of API, BTG-Israel (BTG), clinical trial expenses and manufacturing-related process development expenses decreased by \$2.1 million, \$0.7 million, and \$0.6 million, respectively, as the majority of our research and development activities associated with the development of KRYSTEXXA were incurred in prior years. Partially offsetting the lower expenses was an increase in severance expense of \$1.0 million recorded during the current quarter and \$0.6 million in consulting expenses related to our preparation for the FDA Arthritis Advisory Committee meeting held on June 16, 2009.

Selling, general and administrative expenses for the second quarter of 2009 were \$7.4 million, compared with \$10.5 million for the second quarter of 2008, a decrease of \$3.1 million, primarily due to lower legal fees as the prior year results reflect expenses for Oxandrin-related patent infringement litigation.

Investment income, net, decreased \$0.4 million to an expense of \$27,000 for the second quarter of 2009, from income of \$0.4 million for the second quarter of 2008. The decrease was primarily attributable to lower dividend and interest income from lower cash, cash equivalent and investment balances.

Other expense, net, increased \$35.9 million primarily as a result of a non-cash charge relating to the mark-to-market valuation adjustment to our warrant liability during the second quarter of 2009.

Our income tax benefit decreased \$1.6 million to zero for the second quarter of 2009, as we no longer have the ability to carry back losses to previous years to recover taxes paid and it is uncertain that we will be able to utilize these net operating losses against future income. The 2008 income tax benefit reflects the tax effects of the carry back of our 2008 net operating losses to the 2006 tax year to recover 2006 income taxes paid.

Financial Results of Operations for the Six Months Ended June 30, 2009

Total revenues for the first six months of 2009 were \$1.8 million compared with \$1.5 million for the same period of 2008, an increase of \$0.3 million. The increase was primarily the result of higher sales of oxandrolone, due to increased market share achieved by our authorized generic distributor.

Cost of goods sold for the first six months of 2009 were \$0.9 million compared with \$0.6 million for the same period of 2008, an increase of \$0.3 million. The increase in cost of goods sold resulted primarily from higher gross sales of oxandrolone.

Research and development expenses for the first six months of 2009 were \$24.4 million, compared with \$26.9 million for the same period of 2008, a decrease of \$2.5 million. The decrease was primarily due to lower technology transfer expenses of \$2.4 million as we near the completion of the technology transfer related to developing our secondary source supplier of pegloticase API. In addition, manufacturing capacity reservation fees paid to BTG and expenses related to manufacturing development of KRYSTEXXA decreased by \$2.0 million each, as the majority of our research and development activities associated with the development of KRYSTEXXA were incurred in prior years. Partially offsetting the decreases in research and development expenses were higher costs of \$1.8 million associated with the production of commercial batches of pegloticase API by BTG and \$0.9 million in consulting expenses related to our preparation for the FDA Arthritis Advisory Committee meeting held on June 16, 2009.

Selling, general and administrative expenses for first six months of 2009 were \$16.9 million, compared with \$19.7 million for the same period of 2008, a decrease of \$2.8 million. The decrease was primarily due to lower legal fees of \$2.9 million as the prior year results reflect expenses for Oxandrin-related patent infringement litigation and \$2.0 million of lower compensation and benefits, including share-based compensation, due primarily to decreased headcount and share-based awards. Partially offsetting the lower expenses are higher pre-launch marketing expenses of \$1.1 million incurred in preparation for a potential commercial launch of KRYSTEXXA.

Investment income, net, decreased \$1.6 million to an expense of \$0.2 million for the first six months of 2009, from income of \$1.4 million for the same period of 2008. The decrease was primarily attributable to lower dividend and interest income from lower cash, cash equivalent and investment balances.

Other expense, net, increased \$35.9 million primarily as a result of a non-cash charge relating to the mark-to-market valuation adjustment to our warrant liability during the first six months of 2009.

Our income tax benefit decreased \$2.8 million to zero for the first six months of 2009, as we no longer have the ability to carry back losses to previous years to recover taxes paid and it is uncertain that we will be able to utilize these net operating losses against future income. The 2008 income tax benefit reflects the tax effects of the carry back of our 2008 net operating losses to the 2006 tax year to recover 2006 income taxes paid.

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.

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 June 30		Six Months Ended June 30	
	2009	2008	2009	2008
GAAP net loss	\$(54.8)	\$(24.2)	\$(76.8)	\$(41.8)
Impact of change in warrant valuation	(35.8)	\$-	\$(35.8)	\$-
Non-GAAP net loss	\$(19.0)	\$(24.2)	\$(41.0)	\$(41.8)

	Quarter Ended June 30 2009	Quarter Ended June 30 2008	Six Months Ended June 30 2009	Six Months Ended June 30 2008
GAAP loss per basic and diluted share	\$(0.92)	\$(0.45)	\$(1.35)	\$(0.78)
Impact of change in warrant valuation	(0.60)	\$-	\$(0.63)	\$-
Non-GAAP loss per basic and diluted share	\$(0.32)	\$(0.45)	\$(0.72)	\$(0.78)

ABOUT SAVIENT PHARMACEUTICALS, INC.

Savient Pharmaceuticals, Inc. is a specialty biopharmaceutical company focused on developing and marketing pharmaceutical products that target unmet medical needs in both niche and broader specialty markets. Savient has developed one product: KRYSTEXXA(TM) (pegloticase) which is a PEGylated uricase enzyme intended 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. Further information on Savient can be accessed by visiting: <http://www.savient.com>. 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 help identify forward-looking statements, although not all forward-looking statements contain these identifying words. In particular, any statements regarding our efforts to reduce our burn rate and conserve cash, potential FDA marketing approval for KRYSTEXXA(TM) (pegloticase), a meeting with the FDA to discuss the complete response letter, the reversion to and revalidation of the Phase 3 manufacturing process, the terms of a REMS program, 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; the delay or failure in completing development of KRYSTEXXA and developing other product candidates; our stock price and market conditions; varying interpretations of our clinical and CMC data by the FDA; delay achieving or failure to achieve FDA approval of KRYSTEXXA; inability to manufacture commercial quantities of our products; inability to gain market acceptance sufficient to justify development and commercialization costs if our products are approved for marketing; our continuing to incur substantial net losses for the foreseeable future; 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 ongoing or future 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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SAVIENT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands, except share data)

	June 30, 2009 ----	December 31, 2008 ----
ASSETS		
Current Assets:		
Cash and cash equivalents	\$74,749	\$76,315
Short-term investments (including restricted investments)	1,806	2,282
Accounts receivable, net	798	822
Inventories, net	1,240	1,892
Recoverable income taxes	-	5,526
Prepaid expenses and other current assets	3,055	2,782
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Total current assets	81,648	89,619
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Deferred income taxes, net	4,801	4,200
Property and equipment, net	1,163	1,393
Other assets (including restricted cash and investments)	2,100	3,010
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Total assets	\$89,712	\$98,222
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$3,001	\$5,888
Deferred revenues	249	451
Warrant liability	48,442	-
Other current liabilities	16,406	18,650
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Total current liabilities	68,098	24,989
Other liabilities	10,712	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; 61,376,000 issued and outstanding at June 30, 2009 and 54,654,000 shares issued and outstanding at December 31, 2008	613	547
Additional paid-in-capital	238,201	214,467
Accumulated deficit	(228,372)	(151,614)
Accumulated other comprehensive income	460	24
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Total stockholders' equity	10,902	63,424
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Total liabilities and stockholders' equity	\$89,712	\$98,222
	=====	=====

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Revenues:				
Product sales, net	\$679	\$315	\$1,764	\$1,459
Other revenues	1	38	4	82
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	680	353	1,768	1,541
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Cost and expenses:				
Cost of goods sold	372	219	863	552
Research and development	11,638	15,726	24,401	26,887
Selling, general and administrative	7,397	10,450	16,865	19,714
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	19,407	26,395	42,129	47,153
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Operating loss	(18,727)	(26,042)	(40,361)	(45,612)
Investment income (expense), net	(27)	411	(229)	1,364
Other expense, net	(36,055)	(162)	(36,168)	(312)
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Loss before income taxes	(54,809)	(25,793)	(76,758)	(44,560)
Income tax benefit	-	(1,595)	-	(2,810)
	-----	-----	-----	-----
Net loss	\$(54,809)	\$(24,198)	\$(76,758)	\$(41,750)
	=====	=====	=====	=====
Loss per common share:				
Basic and diluted	\$(0.92)	\$(0.45)	\$(1.35)	\$(0.78)
	=====	=====	=====	=====
Weighted-average number of common and common equivalent shares:				
Basic and diluted	59,594	53,542	56,804	53,409

SOURCE Savient Pharmaceuticals, Inc.

<http://www.savient.com>

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