November 3, 2016

Versartis Reports Third Quarter 2016 Financial Results

MENLO PARK, Calif., Nov. 03, 2016 (GLOBE NEWSWIRE) -- Versartis, Inc. (NASDAQ:VSAR), an endocrine-focused biopharmaceutical company that is developing somavaratan (VRS-317), a novel, long-acting form of recombinant human growth hormone (rhGH) for growth hormone deficiency (GHD), today announced financial results for the third quarter ended September 30, 2016 and provided an update on its clinical development programs.

"Our achievements this past quarter further validate our robust development program for somavaratan and highlight the global demand for a long-acting treatment for growth hormone deficiency," said Jay Shepard, Versartis' President and Chief Executive Officer. "Our recent strategic alliance with Teijin puts somavaratan in the hands of an experienced endocrine partner for commercialization in Japan and offers us strong economics over the life of the agreement. We also completed enrollment in our Phase 3 VELOCITY trial, with data expected in the third quarter of 2017, and have initiated the Phase 3 portion of our Japanese trial in pediatric GHD patients. These trials, in combination with the initiation of our pediatric "switch" study in 2017, will provide us with an extensive data package to support our efforts to gain approval and commercialize somavaratan globally."

Corporate Highlights & Milestones

- Entered strategic alliance with Teijin Limited in which Teijin will have exclusive license to commercialize and further develop somavaratan in the Japanese market in exchange for a $40 million upfront payment and up to $125 million in milestone payments to Versartis
- Presented positive safety, efficacy, and adherence data at the International Congress of Endocrinology (ICE) and the European Society of Paediatric Endocrinology (ESPE) with up to 30 months of somavaratan dosing in the Phase 2a trial and VISTA long-term safety study of children with GHD
- Initiated the Phase 3 portion of the J14VR5 study in Japan following the review of the study's Phase 2 data by the Steering Committee, the Data Safety Monitoring Board, and the Pharmaceuticals and Medical Devices Agency
- Based on data from the Phase 2 VITAL trial in adult GHD patients, the Company selected a lower starting dose and a dosing schedule of twice-monthly for its Phase 3 trial
- Presented details of planned preloaded disposable autoinjector device, intended to provide simplified administration
- Raised gross proceeds of $63.4 million through a follow-on offering of 5,176,545 shares at a price of $12.25, which includes shares issued pursuant to the underwriters' partial exercise of their over-allotment option

Anticipated Milestones and Other Key Events

- Top-line data from the pediatric Phase 3 VELOCITY trial in Q3 2017
- Initiation of Phase 3 trial in adult GHD patients by the end of 2017

Third Quarter 2016 Financial Results

For the third quarter ended September 30, 2016, Versartis reported a net loss of approximately $27.3 million, or $0.92 per share, basic and diluted, compared to a net loss for the quarter ended September 30, 2015 of $20.4 million, or $0.69 per share, basic and diluted.

Total operating expenses for the quarter ended September 30, 2016 were $27.4 million compared to $20.5 million for the quarter ended September 30, 2015.

Research and development (R&D) expenses for the quarter ended September 30, 2016 were $20.7 million, compared to $15.4 million for the quarter ended September 30, 2015. The increase in R&D expenses was primarily due to an increase in manufacturing and clinical costs to support our ongoing Phase 2 and 3 clinical trials for somavaratan, including the Phase 3 VELOCITY pediatric trial, the Phase 2 VITAL adult trial, and the Phase 2/3 pediatric GHD trial in Japan.

General and administrative (G&A) expenses were $6.8 million for the quarter ended September 30, 2016, compared to $5.1 million for the quarter ended September 30, 2015. The increase in G&A expenses was primarily due to additional fees related to consulting and professional services to support our continued growth, including the work associated with our strategic alliance with Teijin.

Total operating expenses for the nine months ended September 30, 2016 were $73.8 million compared to $62.3 million for the nine months ended September 30, 2015. R&D expenses for the nine months ended September 30, 2016 were $55.3 million, compared with $44.4 million for the nine months ended September 30, 2015, reflecting the increase in manufacturing and clinical costs to support our ongoing Phase 2 and 3 clinical trials for somavaratan noted above. G&A expenses were $18.6 million for the nine months ended September 30, 2016, compared to $17.9 million for the nine months ended September 30, 2015. The increase in G&A expenses was primarily due to the additional fees related to consulting and professional services to support our continued growth, including the work associated with our strategic alliance with Teijin noted above, partially offset by a one-time non-recurring expense of $2.4 million associated with our CEO transition in May 2015.

Total operating expenses for the quarter ended September 30, 2016 include non-cash stock-based compensation expense of $2.7 million compared to $2.3 million of non-cash stock-based compensation expense for the quarter ended September 30, 2015. For the nine-months ended September 30, 2016, operating expenses include $8.0 million of non-cash stock-based compensation expense compared to $8.5 million for the nine-months ended September 30, 2015. The nine-month period ended September 30, 2015 includes a one-time non-recurring stock-based compensation charge of $2.0 million associated with the CEO transition.

Cash and cash equivalents were $160.4 million as of September 30, 2016, which excludes net proceeds of approximately $59.2 million from the public offering received in October and November.

About Versartis, Inc.

Versartis, Inc. is an endocrine-focused biopharmaceutical company initially developing somavaratan (VRS-317), a novel, long-acting form of recombinant human growth hormone in late-stage clinical trials for the treatment of GHD in children and adults. Somavaratan is intended to reduce the burden of daily injection therapy by requiring significantly fewer injections, potentially improving compliance and, therefore, treatment outcomes. For more information on Versartis and Versartis sponsored clinical trials, visit www.versartis.com.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding our intentions or current expectations concerning, among other things, plans and timing of our clinical trials and the potential for eventual regulatory approval of somavaratan. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, risks and uncertainties related to: our success being heavily dependent on somavaratan; somavaratan being a new molecular entity; the risk that somavaratan may not have favorable results in clinical trials or receive regulatory approval; potential delays in our clinical trials due to regulatory requirements or difficulty identifying qualified investigators or enrolling patients; the risk that somavaratan may cause serious side effects or have properties that delay or prevent regulatory approval or limit its commercial potential; the risk that we may encounter difficulties in manufacturing somavaratan; if somavaratan is approved, risks associated with its market acceptance, including pricing and reimbursement; potential difficulties enforcing our intellectual property rights; our reliance on our license of intellectual property from Amunix Operating, Inc. and our need for additional funds to support our operations. We discuss many of these risks in greater detail under the heading "Risk Factors" contained in our Annual Report on Form 10-K for the year ended December 31, 2015, in our Quarterly Report on Form 10-Q for the three months ended June 30, 2016 and in the Prospectus Supplement dated September 28, 2016, which are on file with the Securities and Exchange Commission (SEC). Forward-looking statements are not guarantees of future performance, and our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

Versartis, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015

Operating expenses				
Research and development	$ 20,664	$ 15,400	$ 55,253	$ 44,440
General and administrative	6,752	5,124	18,575	17,861
Total operating expenses	27,416	20,524	73,828	62,301
Loss from operations	(27,416)	(20,524)	(73,828)	(62,301)
Interest income	120	54	354	168
Other income (expense), net	(39)	91	(210)	81
Net loss	(27,335)	(20,379)	(73,684)	(62,052)
Net loss per share- basic and diluted	$ (0.92)	$ (0.69)	$ (2.50)	$ (2.15)
Weighted-average common shares used to compute basic and diluted net loss per share	29,574	29,354	29,495	28,825

Versartis, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands)

	September 30, 2016	December 31, 2015
Assets:		
Cash and cash equivalents	$ 160,434	$ 182,069
Other assets	4,774	3,258
Total assets	**$ 165,208**	**$ 185,327**
Liabilities and stockholders' equity:		
Accounts payable and other current liabilities	$ 14,207	$ 8,827
Upfront payment from collaboration partner	40,000	—
Total liabilities	54,207	8,827
Total stockholders' equity	111,001	176,500
Total liabilities and stockholders' equity	**$ 165,208**	**$ 185,327**

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