# Valeant Pharmaceuticals To Acquire Sprout Pharmaceuticals

August 20, 2015

Enters Sexual Health Market with FDA-Approved Addyi™ (flibanserin 100mg) Addyi Expected to Launch in U.S. in the Fourth Quarter of 2015

LAVAL, Quebec and RALEIGH, N.C., Aug. 20, 2015 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX) (TSX: VRX) and Sprout Pharmaceuticals, Inc. today announced that they have entered into a definitive agreement under which a wholly-owned subsidiary of Valeant will acquire Sprout, on a debt-free basis, for approximately \$1 billion in cash, plus a share of future profits based upon the achievement of certain milestones.

On Tuesday, August 18, 2015, Sprout received approval from the U.S. Food and Drug Administration (FDA) on its New Drug Application (NDA) for flibanserin, which will be marketed as Addyi in the U.S. Addyi has demonstrated improvements in desire for sex, reducing distress from the loss of sexual desire and increasing the number of satisfying sexual events. Sprout also has global rights for flibanserin. Valeant will leverage its global scale to register flibanserin internationally.

Sprout is passionate about women's sexual health and has focused solely on the delivery of a treatment option for the unmet need of premenopausal women with acquired, generalized Hypoactive Sexual Desire Disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is not due to a co-existing medical or psychiatric condition, problems within the relationship, or the effects of a medication or other drug substance.

Addyi is not indicated for use in postmenopausal women or men or to enhance sexual function. Addyi was approved with a Boxed Warning. Use of Addyi with alcohol increases the risk of severe hypotension and syncope; therefore, alcohol use is contraindicated. Severe hypotension and syncope occurs when Addyi is used with moderate or strong CYP3A4 inhibitors or in patients with hepatic impairment; therefore use of Addyi in patients with hepatic impairment is also contraindicated. Hypotension, syncope and central nervous system (CNS) depression can occur with Addyi alone. The most common adverse reactions are dizziness, somnolence, nausea, fatigue, insomnia and dry mouth.

Valeant expects Addyi to be available in the United States in the fourth quarter of 2015 through prescribers and pharmacies that have been certified under the U.S. FDA's comprehensive Risk Evaluation and Mitigation Strategy (REMS) program to assure safe use. Following the closing of the transaction, Valeant, under the REMS, will offer physicians and pharmacists the required certification programs for prescribing and dispensing Addyi.

Following the closing of the acquisition, Sprout will remain headquartered in Raleigh, N.C. and become a division of Valeant. Cindy Whitehead, Chief Executive Officer of Sprout, will join Valeant to lead this division dedicated to the introduction and global commercialization of Addyi, reporting to Anne Whitaker, Executive Vice President and Company Group Chairman.

Valeant's Chairman and Chief Executive Officer, J. Michael Pearson, said, "Delivering a first-ever treatment for a commonly reported form of female sexual dysfunction gives us the perfect

opportunity to establish a new portfolio of important medications that uniquely impact women. We applaud the efforts of the Sprout team to address this important area of unmet need and look forward to working with them to bring the benefits of Addyi to additional markets around the world."

Sprout Chief Executive Officer, Cindy Whitehead , said, "I am extremely proud of the commitment and passion of our 34 employees who have been mission driven to get to this breakthrough first for women. This partnership with Valeant allows us the capacity to now ensure broader, more affordable access to all the women who have been waiting for this treatment. Beyond building this in the United States, Valeant also offers us a global footprint that could eventually bring Addyi to women across the globe."

"The Valeant team is excited to be a part of the launch of this critically important treatment for women, and I am personally delighted to welcome Cindy and her colleagues at Sprout to Valeant," added Anne Whitaker, Executive Vice President and Company Group Chairman. "The Sprout team, along with the healthcare providers involved in the Addyi pivotal clinical trials, has delivered on its promise to provide access to a safe and effective treatment for a condition that affects millions of women."

Under terms of the acquisition agreement, Valeant will pay approximately \$500 million, subject to customary purchase price adjustments, upon the closing of the transaction and an additional payment in the amount of \$500 million, payable in the first quarter of 2016, plus a share of future profits based upon the achievement of certain milestones. Valeant expects no impact to 2015 earnings, and moderate accretion to 2016 earnings.

The transaction is subject to customary closing conditions and regulatory approval, including Hart-Scott-Rodino antitrust clearance. The transaction is expected to close in the third quarter of 2015.

Skadden, Arps, Slate, Meagher & Flom LLP served as Valeant's legal counsel. Sprout was advised by Sullivan & Cromwell LLP as its legal counsel and Perella Weinberg Partners as its financial advisor.

#### **About Valeant**

Valeant Pharmaceuticals International, Inc. (NYSE/TSX:VRX) is a multinational specialty pharmaceutical company that develops, manufactures and markets a broad range of pharmaceutical products primarily in the areas of dermatology, gastrointestinal disorder, eye health, neurology and branded generics. More information about Valeant can be found at www.valeant.com

# **About Addyi**

Addyi is a novel, non-hormonal oral pill taken once daily at bedtime. Flibanserin has been studied in over 11,000 women. For premenopausal women with HSDD, Addyi has demonstrated improvements in desire for sex, reducing distress from the loss of sexual desire and increasing the number of satisfying sexual events. The most common adverse events among patients treated with Addyi were dizziness, somnolence, nausea, fatigue, insomnia and dry mouth. Hypotension, syncope, and central nervous system (CNS) depression were seen with Addyi alone and more frequently when Addyi was taken in the morning and when co-administered with alcohol or certain other drugs. Alcohol consumption is contraindicated for women taking Addyi. With the FDA, Sprout Pharmaceuticals developed a comprehensive Risk Evaluation and Mitigation

Strategy (REMS) program, including prescriber and pharmacist certification, to ensure safe use of Addyi.

## **About Sprout Pharmaceuticals**

Sprout Pharmaceuticals, Inc. is passionate about women's sexual health. With a breakthrough concept for women, the company "sprouted" out of Slate Pharmaceuticals in 2011. Based in Raleigh, N.C., the company is focused solely on the delivery of a treatment option for women with HSDD. For more information or the latest news about Sprout Pharmaceuticals, visit <a href="https://www.sproutpharma.com">www.sproutpharma.com</a>

or call 1-844-PINK-PILL (1-844-746-5745).

## **Forward Looking Statements**

This press release may contain forward-looking statements, including, but not limited to, statements regarding the acquisition of Sprout Pharmaceuticals, including the anticipated timing of the closing of such acquisition, the anticipated timing of the launch of the Addyi product and Valeant's marketing and sales plans. Forward-looking statements may generally be identified by the use of the words "anticipates," "expects," "intends," "plans," "should," "could," "would," "may," "will," "believes," "estimates," "potential," "target," or "continue" and variations or similar expressions. These statements are based upon the current expectations and beliefs of management of Valeant and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include the risks and uncertainties discussed in Valeant's most recent annual or quarterly report and detailed from time to time in Valeant's other filings with the Securities and Exchange Commission (the "SEC") and the Canadian Securities Administrators, which factors are incorporated herein by reference. Readers are cautioned not to place undue reliance on any of these forward-looking statements. These forward-looking statements speak only as of the date hereof. Valeant undertakes no obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this press release or to reflect actual outcomes, except as required by law.

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