Supernus to Acquire Biscayne Neurotherapeutics

September 13, 2018

Adds Phase 1 Novel Epilepsy Development Program

ROCKVILLE, Md., Sept. 13, 2018 (GLOBE NEWSWIRE) -- Supernus Pharmaceuticals, Inc. (NASDAQ:SUPN), a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases, today announced that it entered into a merger agreement to acquire Biscayne Neurotherapeutics (Biscayne), a privately-held company developing a novel treatment for epilepsy.

Supernus will obtain worldwide rights (excluding certain markets in Asia where rights have been out-licensed) to Biscayne's product candidate that is in Phase I clinical development and that has received an Orphan Drug designation from the U.S. Food and Drug Administration (FDA) for the treatment of Dravet Syndrome, a severe form of childhood epilepsy. Supernus will also obtain rights to all the product candidate's underlying and related intellectual property (IP).

The transaction, expected to close in the next few weeks, provides for an upfront payment of $15 million payable by Supernus to the current Biscayne security holders. Additional payments payable by Supernus include $73 million contingent on achieving certain development milestones and up to $95 million contingent upon achieving certain sales milestones. Supernus will pay a low single digit royalty on net sales to Biscayne and any applicable royalties to third parties for the use of in-licensed IP. The maximum combined royalty Supernus will pay to all parties is approximately 12%, depending on the IP covering the marketed product and the applicable tiered sales levels.

The development program which will be referred to as SPN-817 will utilize a novel synthetic form of huperzine A which is a potent acetyl cholinesterase inhibitor with pharmacological activities in CNS conditions such as epilepsy. SPN-817 will have a new chemical entity status (NCE) in the U.S. market, and Supernus expects to have significant IP protecting this product candidate through its own research and development efforts as well as the in-licensed IP.

SPN-817 represents a novel mechanism of action for an anticonvulsant. Development of SPN-817 will initially focus on the drug's anticonvulsant activity that has been shown in preclinical models for partial seizures and Dravet Syndrome. It increases cortical acetylcholine and readily crosses the blood brain barrier showing an increase in gamma-aminobutyric acid (GABA), a seizure inhibitor, in the cortical region of the brain. In a predictive preclinical seizure model, huperzine A demonstrated 57 times more potency than levetiracetam, a leading anti-epilepsy drug.

Supernus will focus on completing and optimizing the synthesis process of the drug and the development of a novel dosage form. Given the potency of huperzine A, a novel extended release oral dosage form is critical to the success of this program because initial studies with immediate release formulations of non-synthetic huperzine A have shown dose-limiting serious side effects.

Supernus plans on studying SPN-817 initially in catastrophic pediatric epilepsy disorders such as Dravet Syndrome. A Phase I proof-of-concept trial is currently underway in adult patients with refractory complex partial seizures to study the safety and pharmacokinetics profile of a new extended release formulation.

Stephen Collins M.D., Ph.D., President & CEO of Biscayne and a well-known neurologist who has been involved over the past three decades with the development of several anti-epilepsy products, will be retained on a consulting basis to assist with the transition and potentially the future development of SPN-817.

"Supernus, with its strong presence in epilepsy and its proven technologies and research and development capabilities, represents an ideal partner for us. Huperzine A has a novel mechanism of action that represents a new approach for the treatment of epilepsy. We look forward to working with Supernus and progressing SPN-817 in the clinic, and eventually to its availability to patients," said Dr. Collins.

"We are excited to add SPN-817 to our portfolio as part of our long term growth strategy. It represents a strong strategic fit with Oxtellar XR and Trokendi XR in neurology. We are committed to epilepsy patients and to bringing to them novel alternative treatment options," said Jack Khattar, President & CEO of Supernus.

Financial Guidance

For full year 2018, Supernus is updating its prior guidance for research and development expenses and operating earnings to account for the one-time upfront expense of $15 million, and is reiterating its prior guidance for net product sales as set forth below:

- Net product sales in the range of $385 million to $400 million.
- Research and development expenses of approximately $95 million, compared to $80 million previously.
- Operating earnings in the range of $115 million to $125 million, compared to the previously expected range of $130 million to $140 million.

About Supernus Pharmaceuticals, Inc.

Supernus Pharmaceuticals, Inc. focuses on developing and commercializing products for the treatment of central nervous system diseases. The Company currently markets Trokendi XR® (extended-release topiramate) for the prophylaxis of migraine and the treatment of epilepsy, and Oxtellar XR® (extended-release oxcarbazepine) for the treatment of epilepsy. The Company is also developing several product candidates to address large market opportunities in psychiatry, including SPN-810 for the treatment of impulsive aggression in ADHD patients and SPN-812 for the treatment of ADHD.

Forward-Looking Statements:

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements do not convey historical information, but relate to predicted or potential future events that are based upon management's current expectations. These statements are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. In addition to the factors mentioned in this press release, such risks and uncertainties include, but are not limited to, the Company's ability to successfully complete the development of its product candidates including SPN-817; the Company's ability to sustain and increase its profitability; the Company's ability to raise sufficient capital to fully implement its corporate strategy; the implementation of the Company's corporate strategy; the Company's future financial performance and projected expenditures; the Company's ability to increase the number of prescriptions written for each of its products; the Company's ability to increase its net revenue; the Company's ability to enter into future collaborations with pharmaceutical companies and academic institutions or to obtain funding from government agencies; the Company's product research and development activities, including the timing and progress of the Company's clinical trials, and projected expenditures; the Company's ability to receive, and the timing of any receipt of, regulatory approvals to develop and commercialize the Company's product candidates; the Company's ability to protect its intellectual property and operate its business without infringing upon the intellectual property rights of others; the Company's expectations regarding federal, state and foreign regulatory requirements; the therapeutic benefits, effectiveness and safety of the Company's product candidates; the accuracy of the Company's estimates of the size and characteristics of the markets that may be addressed by its product candidates; the Company's ability to increase its manufacturing capabilities for its products and product candidates; the Company's projected markets and growth in markets; the Company's product formulations and patient needs and potential funding sources; the Company's staffing needs; and other risk factors set forth from time to time in the Company's SEC filings made pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended. The Company undertakes no obligation to update the information in this press release to reflect events or circumstances after the date hereof or to reflect the occurrence of anticipated or unanticipated events.

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