Medtronic News

Spectranetics to Acquire Stellarex™ Drug Coated Balloon Assets From Covidien

Expands Spectranetics' portfolio of solutions to treat complex vascular conditions in projected $700 million drug coated balloon segment

COLORADO SPRINGS, Colo., and DUBLIN, Ireland, Nov. 2, 2014 (GLOBE NEWSWIRE) -- The Spectranetics Corporation (Nasdaq:SPNC) and Covidien plc (NYSE:COV) today announced a definitive agreement under which Spectranetics will acquire Covidien's Stellarex™ drug coated angioplasty balloon (DCB) platform for $30 million.

The transaction is subject to approval by the Federal Trade Commission and other regulatory agencies, as well as closure of the pending acquisition of Covidien by Medtronic, which is expected to occur in early 2015.

It is anticipated that the Stellarex DCB platform will receive European CE mark approval in late 2014 or early 2015. Spectranetics expects a European launch of the product immediately upon CE mark approval, with U.S. commercialization in the 2017 timeframe, following FDA approval.

"This acquisition advances SPNC's objective to provide comprehensive solutions to cross, prepare and treat the most complex vascular conditions," said Scott Drake, president and CEO, Spectranetics. "Drug coated balloons are and will be an integral part of the vascular landscape for many years to come. Global thought leaders believe that primary patency is the most important clinical metric, and Stellarex's feasibility data stands apart. We believe this technology will meaningfully add to our near-term revenue growth and expand operating leverage over time."

"The Stellarex team has made significant progress developing this advanced technology and we are confident that Spectranetics is the right organization to advance the program," said Brian Verrier, president, Peripheral Vascular, Covidien. "Pending completion of the Medtronic transaction, Covidien looks forward to collaborating with Spectranetics to transfer this technology as well as ensure investigators of the ILLUMENATE trial series are transitioned appropriately."

Financial Impact to Spectranetics

Spectranetics management expects the acquisition of the Stellarex platform will provide a revenue growth catalyst beginning in 2015, and has the potential to contribute at least $100 million of revenue within two to three years of commercialization in the United States. The investment required to capitalize on this opportunity will lead to estimated dilution to 2015 earnings per share in the range of $28.0 million to $32.0 million, or $0.65 to $0.75 per share driven primarily by research and development costs associated with the ongoing Stellarex clinical trial program. The Company anticipates the transaction to be accretive to adjusted operating income, excluding special items, in the first full year following U.S. commercialization.

Conference Call

Spectranetics management will host an investment community conference call today beginning at 6:30 a.m. MT/8:30 a.m. ET. Individuals interested in listening to the conference call may dial 877-561-2747 for domestic callers or 973-409-9689 for international callers, or access the webcast on the investor relations section of the Company's website at: www.spectranetics.com. The webcast will be available on the Company's website for 14 days following the completion of the call.

About the Stellarex™ DCB Platform

The Stellarex DCB platform is designed to treat peripheral arterial disease. Stellarex uses EnduraCoat™ technology, a durable, uniform coating designed to prevent drug loss during transit and facilitate controlled, efficient drug delivery to the treatment site.

The Stellarex DCB platform currently is not approved for sale in any market.

About ILLUMENATE First-in-Human (FIH) Study

Data from the ILLUMENATE FIH Study was reported at the EuroPCR Scientific Congress in May 2014. The ILLUMENATE FIH study is a prospective, multi-center, single-arm study designed to assess the clinical performance of the Stellarex DCB. In the study, 58 superficial femoral and/or popliteal lesions (up to 15 cm in length) in 50 patients were pre-dilated with an uncoated angioplasty balloon, followed by treatment with the Stellarex DCB. Clinical events were adjudicated by independent angiographic and sonographic core laboratories. The study found the Stellarex DCB to be safe, with durable results to 24 months reported on 44 patients, including:

- Primary patency (defined as the treated artery remaining open without further treatment required or renewed blockage detected by ultrasound scanning) was 89.5 percent at 12 months and 80.3 percent at 24 months.
- Freedom from clinically driven target lesion revascularization at 24 months was 85.8 percent.
- No amputations or cardiovascular deaths were reported.

About ILLUMENATE Clinical Trials

The Stellarex DCB platform is being studied in an active Investigational Device Exemption (IDE) trial in the United States and internationally. There are four active ILLUMENATE clinical trials in addition to the First-in-Human ILLUMENATE trial, described above:

- ILLUMENATE Pharmacokinetic Study – to evaluate the drug levels in the blood; 25 patients to be enrolled at up to two sites
- ILLUMENATE Pivotal Trial – randomized trial to support PMA in the United States; 360 patients to be enrolled at up to 45 sites
- ILLUMENATE European Randomized Trial – similar to the U.S. Pivotal trial; 360 patients to be enrolled at up to 30 sites
- ILLUMENATE Global Registry – non-randomized; 500 patients to be enrolled at up to 65 sites

These five clinical trials will be used to evaluate the safety and effectiveness of the Stellarex DCB platform and support U.S. and Canada regulatory approval.

About Spectranetics

SPNC develops, manufactures, markets and distributes single-use medical devices used in minimally invasive procedures within the cardiovascular system. The Company's products are sold in over 65 countries and are used to treat arterial blockages in the heart and legs and in the removal of pacemaker and defibrillator leads.

The Company's Vascular Intervention (VI) products include a range of laser catheters for ablation of blockages in arteries above and below the knee as well as the AngioSculpt® scoring balloon used in both peripheral and coronary procedures. The Company also markets support catheters to facilitate crossing of peripheral and coronary arterial blockages, and retrograde access and guidewire retrieval devices used in the treatment of peripheral arterial blockages, including chronic total occlusions. The Company markets aspiration and cardiac laser catheters to treat blockages in the heart.

The Lead Management (LM) product line includes excimer laser sheaths, dilator sheaths, mechanical sheaths and accessories for the removal of pacemaker and defibrillator cardiac leads.

For more information, visit www.spectranetics.com.

About Covidien

Covidien is a global health care leader that understands the challenges faced by providers and their patients and works to address them with innovative medical technology solutions and patient care products. Inspired by patients and caregivers,

Covidien's team of dedicated professionals is privileged to help save and improve lives around the world. With more than 38,000 employees, Covidien operates in 150-plus countries and had 2013 revenue of $10.2 billion. To learn more about our business visit www.covidien.com or connect with us on Twitter.

Cautionary Statement Regarding Forward-Looking Statements

This news release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. You can identify these statements because they do not relate strictly to historical or current facts. Such statements may include words such as "anticipate," "will," "estimate," "expect," "look forward," "strive," "project," "intend," "should," "plan," "believe," "hope," "enable," "potential," and other words and terms of similar meaning in connection with any discussion of, among other things, future operating or financial performance, strategic initiatives and business strategies, clinical trials, regulatory or competitive environments, our intellectual property and product development. These forward-looking statements include, but are not limited to, statements regarding our expectation of continued growth and strength and the reasons for that growth, growth rates, strength, and outlook including projected revenue, net loss and Adjusted EBITDA. Such statements are based on current assumptions that involve risks and uncertainties that could cause actual outcomes and results to differ materially. You are cautioned not to place undue reliance on these forward-looking statements and to note they speak only as of the date of this release. These risks and uncertainties may include financial results differing from guidance, inability to successfully integrate AngioScore and the Stellarex platform into our business, market acceptance of excimer laser atherectomy technology and our vascular intervention and lead removal products, market acceptance of drug coated balloon technology, increasing price and product competition, increased pressure on expense levels resulting from expanded sales, marketing, product development and clinical activities, uncertain success of our strategic direction, dependence on new product development, loss of key personnel, uncertain success of or delays in our clinical trials, adverse results in any ongoing legal proceeding, or any legal proceeding in which we may become involved, adverse impact to our business of the health care reform and related legislation or regulations, including changes in reimbursements, continued or worsening adverse conditions in the general domestic and global economic markets and continued volatility and disruption of the credit markets, which affects the ability of hospitals and other health care systems to obtain credit and may impede our access to capital, intellectual property claims of third parties, availability of inventory from suppliers, adverse outcome of FDA inspections, the receipt of FDA approval to market new products or applications and the timeliness of any approvals, market acceptance of new products or applications, product defects, ability to manufacture sufficient volumes to fulfill customer demand, availability of vendor-sourced components at reasonable prices, unexpected delays or costs associated with any planned improvements to our manufacturing processes, and share price volatility due to the initiation or cessation of coverage, or changes in ratings, by securities analysts. For a further list and description of such risks and uncertainties that could cause our actual results, performance or achievements to materially differ from any anticipated results, performance or achievements, please see our previously filed SEC reports, including those risks set forth in our 2013 Annual Report on Form 10-K. We disclaim any intention or obligation to update or revise any financial or other projections or other forward-looking statements, whether because of new information, future events or otherwise.

NO OFFER OR SOLICITATION

This communication is not intended to and does not constitute an offer to sell or the solicitation of an offer to subscribe for or buy or an invitation to purchase or subscribe for any securities or the solicitation of any vote or approval in any jurisdiction pursuant to the acquisition, the merger or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

IMPORTANT ADDITIONAL INFORMATION WILL BE FILED WITH THE SEC

Medtronic Holdings Limited ("New Medtronic") has filed with the Securities and Exchange Commission (the "SEC") a registration statement on Form S-4 that includes the preliminary Joint Proxy Statement of Medtronic, Inc. ("Medtronic") and Covidien plc ("Covidien") that also constitutes a preliminary Prospectus of New Medtronic. The registration statement is not complete and will be further amended. Medtronic and Covidien plan to mail to their respective shareholders the final Joint Proxy Statement/Prospectus (including the Scheme) in connection with the transactions. INVESTORS AND SHAREHOLDERS ARE URGED TO READ THE PRELIMINARY JOINT PROXY STATEMENT/PROSPECTUS (INCLUDING THE SCHEME) AND OTHER RELEVANT DOCUMENTS FILED OR TO BE FILED WITH THE SEC CAREFULLY WHEN THEY BECOME AVAILABLE BECAUSE THEY CONTAIN OR WILL CONTAIN IMPORTANT INFORMATION ABOUT MEDTRONIC, COVIDIEN, NEW MEDTRONIC, THE TRANSACTIONS AND RELATED MATTERS. Investors and security holders are able to obtain free copies of the preliminary Joint Proxy Statement/Prospectus (including the Scheme) and other documents filed with the SEC by New Medtronic, Medtronic and Covidien through the website maintained by the SEC at www.sec.gov. In addition, investors and shareholders are able to obtain free copies of the preliminary Joint Proxy Statement/Prospectus (including the Scheme) and other documents filed by Medtronic and New Medtronic with the SEC by contacting Medtronic Investor Relations at investor.relations@medtronic.com or by calling 763-505-2696, and will be able to obtain free copies of the preliminary Joint Proxy Statement/Prospectus (including the Scheme) and other documents filed by Covidien by contacting Covidien Investor Relations at investor.relations@covidien.com or by calling 508-452-4650.

PARTICIPANTS IN THE SOLICITATION

Medtronic, New Medtronic and Covidien and certain of their respective directors and executive officers and employees may be considered participants in the solicitation of proxies from the respective shareholders of Medtronic and Covidien in respect of the transactions contemplated by the Joint Proxy Statement/Prospectus. Information regarding the persons who may, under the rules of the SEC, be deemed participants in the solicitation of the respective shareholders of Medtronic and Covidien in connection with the proposed transactions, including a description of their direct or indirect interests, by security holdings or otherwise, will be set forth in the final Joint Proxy Statement/Prospectus when it is filed with the SEC. Information regarding Medtronic's directors and executive officers is contained in Medtronic's Annual Report on Form 10-K for the fiscal year ended April 25, 2014, and its Proxy Statement on Schedule 14A, dated July 11, 2014, which are filed with the SEC. Information regarding Covidien's directors and executive officers is contained in Covidien's Annual Report on Form 10-K for the fiscal year ended September 27, 2013, and its Proxy Statement on Schedule 14A, dated January 24, 2014, which are filed with the SEC.

Statement Required by the Irish Takeover Rules

The directors of Covidien plc accept responsibility for the information contained in this communication. To the best of the knowledge and belief of the directors (who have taken all reasonable care to ensure that such is the case) the information contained in this communication is in accordance with the facts and does not omit anything likely to affect the import of such information.

No statement in this announcement is intended to constitute a profit forecast for any period, nor should any statements be interpreted to mean that earnings or earnings per share will necessarily be greater or lesser than those for the relevant preceding financial periods for Medtronic or Covidien or New Medtronic as appropriate. No statement in this announcement constitutes an asset valuation.

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