

FORM 8-K

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 22, 2001

AVI BioPharma, Inc.

(Exact name of registrant as specified in its charter)

Oregon

*(State or other jurisdiction of
incorporation or organization)*

0-22613

*(Commission
File Number)*

93-0797222

*(IRS Employer
Identification Number)*

One S.W. Columbia, Suite 1105

Portland, OR 97258

(Address of principal executive offices)

(503) 227-0554

Registrant's telephone number, including area code

Item 5. Other Events.

This report and the attached press release contain forward-looking statements that are made pursuant to the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that such forward-looking statements involve risks and uncertainties, including, but not limited to, the results of research and development efforts, the results of pre-clinical and clinical testing, the effect of regulation by the FDA and other governmental agencies, the impact of competitive products, product development, commercialization and technical difficulties, and other risks detailed in the Company's Securities and Exchange filings

Strategic Relationship with Medtronic, Inc. Announced

On May 22, 2001, AVI BioPharma, Inc. ("Company") (NASDAQ: AVII, AVIIW, AVIIZ) and Medtronic, Inc. (NYSE: MDT) ("Medtronic") announced, with the release of the joint press release attached hereto as Exhibit 1 hereto, the initiation of an exclusive worldwide agreement to license a family of antisense compounds, including Resten-NG™, which Medtronic expects to load on medical devices, including stents, for use in treating vascular disease. The relationship is subject to certain pre-closing conditions which are presently expected to be met in June 2001. The relationship will involve an initial purchase by Medtronic subsidiary at an expected June closing (the "Closing") of approximately 1,408,450 shares of the Company's Common Stock (par value \$0.0001) at a price of \$7.10 per share and the issuance of a Warrant to acquire 3,000,000 shares of the Company's Common Stock at an exercise price of \$10.00 per share to that Medtronic affiliate. If certain milestones are met, there may be additional future sales of the Company's Common Stock to the Medtronic subsidiary. Certain license and development and supply agreements will also be entered at the Closing to facilitate the strategic relationship between the parties and the development of the antisense compounds for use in treating vascular disease. More detailed information regarding the expected transactions will be filed following the Closing.

Item 7. Financial Statements, Pro Forma Financial Information and Exhibits.

1. Press release dated May 22, 2001 issued by AVI BioPharma, Inc. and Medtronic, Inc.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Portland, State of Oregon, on June 6, 2001.

AVI BioPharma, Inc.

By: /s/ Alan P. Timmins

Alan P. Timmins
President and Chief Operating Officer
(Principal Operating Officer)

EXHIBIT INDEX

Exhibit No.

Document Description

1

Press release dated May 22, 2001 issued by AVI BioPharma, Inc. and Medtronic, Inc.

TEXT OF JOINT PRESS RELEASE OF AVI BioPharma, INC.
AND MEDTRONIC, INC.

Press Release

MEDTRONIC AND AVI BIOPHARMA, INC. ANNOUNCE EXCLUSIVE AGREEMENT FOR A STENT COATING DESIGNED TO PREVENT RESTENOSIS

Rationally Designed, Highly Selective and Targeted Antisense Compound Shows Promise in Early Clinical Evaluations

On May 22, 2001, AVI BioPharma, Inc. (NASDAQ: AVII, AVI IW, AVI IZ) (the "Company") and Medtronic, Inc. (NYSE: MDT) ("Medtronic"), today announced the initiation of an exclusive worldwide agreement to license a family of antisense compounds, including Resten NG™, which Medtronic expects to load on medical devices, including stents.

Restenosis is the renarrowing or relogging of arteries following balloon angioplasty or placement of a stent. More than 800,000 patients in the United States are treated with coronary angioplasty each year, and more than 1.8 million angioplasties take place annually worldwide. Rates of restenosis following either balloon angioplasty or placement of a stent can range between 10 percent and 40 percent, depending on the type of vessel and patient history.

Following cellular injury incurred during an intervention, elevated expression of a gene called c-myc occurs, resulting in increased cellular proliferation and the growth of tissue that can lead to reclosure of the treated vessel. While a number of conventional pharmaceutical compounds currently under evaluation may retard certain aspects of the restenosis response, Resten-NG, a third-generation NeuGene® antisense compound, is designed to address the underlying genetic mechanism that leads to restenosis. The result is that this compound can selectively target multiple aspects of the restenosis response, specifically cellular proliferation, secretion of matrix proteins and inflammation, potentially without impeding vascular healing.

AVI BioPharma's third-generation NeuGene® antisense compounds are a significant departure from previous generations of antisense compounds, in that they include a patented synthetic "backbone" that does not succumb to degradation. The improved compounds are designed to demonstrate a higher degree of binding affinity, sequence specificity, cellular uptake and hydrolytic stability. Based upon the successful completion of Phase I clinical studies, it is believed that Resten-NG is safe and non-toxic.

Resten-NG is currently in Phase II clinical trials. Patient enrollment for the Phase II trials began in October 2000. AVI BioPharma presented preclinical data about the effectiveness of Resten-NG at a local drug delivery conference in Geneva, Switzerland earlier this year, where the data demonstrated that Resten-NG significantly reduced restenosis. Resten-NG has been successfully evaluated in four different animal species for the reduction of restenosis.

"Our partnership with AVI BioPharma makes perfect sense, in that we are both striving for solutions that will provide the best long-term patient outcomes without compromising safety or the natural healing process following an intervention," said Andy Rasdal, president of Medtronic Vascular. "Antisense compounds are already demonstrating notable results in various applications. We believe Resten-NG shows great promise as a highly-selective, targeted solution for restenosis that can prove itself over the long term."

Art Collins, president and chief executive officer of Medtronic, added that "Resten-NG is just one of several solutions that Medtronic is evaluating for the prevention of restenosis. Medtronic was the first company to introduce a number of coated stents, starting in the 1990s. Since then efforts have continued, resulting in a broadened intellectual property portfolio, which currently consists of more than 55 patent families. We believe that a number of approaches hold promise, and we will continue to evaluate several options, including traditional pharmaceuticals for stents, photodynamic therapy and intravascular radiation, among others."

"We're excited about the synergy between our companies — Resten-NG is our most advanced NeuGene program and Medtronic AVE is a leader in delivering high performance products to vascular interventionalists," concluded Denis R. Burger, Ph.D. and chief executive officer of AVI BioPharma. "Resten-NG is the first third-generation antisense drug to reach late-stage clinical development, which we believe is a key milestone towards fulfilling the original expectations of antisense. As we think about the future together, we see multiple ways that our expertise in gene-targeted drug development can complement Medtronic AVE's excellence in device engineering — we are truly energized by the possibilities."

Going forward, AVI BioPharma will partner exclusively with Medtronic AVE to evaluate the use of its antisense compounds loaded on medical devices, including stents for the treatment of vascular disease. AVI BioPharma and Medtronic AVE will work with regulatory agencies to amend the current Phase II trial going forward.

"AVI BioPharma, of Portland, OR, develops therapeutic products for the treatment of life-threatening diseases using two technology platforms: immunotherapy and gene-targeting drugs. Its lead clinical agent Avicine™, a therapeutic cancer vaccine, has completed enrollment in a Phase II trial in pancreatic cancer and is in a Phase III pivotal trial in colorectal cancer. The first application of its NeuGene compounds is designed to treat cancer, cardiovascular restenosis and other cell proliferation disorders. Resten-NG is currently in Phase II trials for the treatment of restenosis. More information about AVI BioPharma is available on the Company's website at www.avibio.com.

Medtronic, Inc., headquartered in Minneapolis, is the world's leading medical technology company, providing lifelong solutions for people with chronic disease. Its Internet address is www.medtronic.com. Medtronic AVE, formerly Arterial Vascular Engineering, is headquartered in Santa Rosa, CA.

Any statements made regarding each company's anticipated financial results and regulatory approvals are forward-looking statements subject to risks and uncertainties, such as those described in each company's Annual Report and on Form 10K for the most recently completed fiscal year. Actual results may differ materially from anticipated results.

Note: Medtronic will host two relevant events:

Fourth Quarter Conference Call and Webcast: Tuesday, May 22, 2001 — 3:30 p.m. CT / 4:30 p.m. ET. Dial-in numbers: 612-332-0107 / 651-224-7472 / 612-288-0329. Replay (available until midnight CT May 24, 2001): 320-365-3844 / Access Code 587216. Webcast access: www.medtronic.com/corporate/invest.

Vascular Update from Paris Course on Revascularization: Thursday, May 24, 2001 — 1:30 p.m. Paris time / 7:30 a.m. ET / 6:30 a.m. CT. Featured Speaker: Andy Rasdal, Senior Vice President and President, Medtronic Vascular. Dial-in numbers: 612-332-0107 / 612-288-0329. Replay (available until midnight CT May 29, 2001): 320-365-3844 / Access code 587215. Webcast access: www.medtronic.com/corporate/invest.

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