Anika Therapeutics Announces Monovisc PMA News

Anika Therapeutics Announces Monovisc PMA News BEDFORD, Mass. --(BUSINESS WIRE)--Dec. 4, 2012-- Anika Therapeutics, Inc. (Nasdaq: ANIK) announced today that it has received correspondence from the Chief Scientific Officer of the Center for Devices and Radiological Health of the U.S. FDA upholding the non-approvable decision for the Monovisc PMA that was previously disclosed. The company had utilized the FDA's appeal process to continue to discuss the Monovisc PMA with the FDA .

The company plans to schedule a meeting with the FDA as soon as possible to determine the next steps concerning the Monovisc product.

About Anika Therapeutics, Inc.

Headquartered in Bedford, Mass., Anika Therapeutics, Inc. develops, manufactures and commercializes therapeutic products for tissue protection, healing, and repair. These products are based on hyaluronic acid (HA), a naturally occurring, biocompatible polymer found throughout the body. Anika's products range from orthopedic/joint health solutions led by Orthovisc, a treatment for osteoarthritis of the knee, to surgical aids in the ophthalmic and anti-adhesion fields. The company also offers aesthetic dermal fillers for the correction of facial wrinkles. Anika's Italian subsidiary, Anika S.r.l., provides complementary HA products in orthopedic/joint health and anti-adhesion, as well as therapeutics in new areas such as advanced wound treatment and ear, nose and throat care. Anika S.r.l.'s regenerative tissue technology advances Anika's vision to offer therapeutic products that go beyond pain relief to protect and restore damaged tissue.

The statements made in this press release which are not statements of historical fact are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements include, but are not limited to, those relating to: (i) the company's ability to obtain FDA approval of the Monovisc PMA, including the design, timing, cost and similar uncertainties related to additional clinical studies that the FDA may require for such approval and the related expenses associated therewith; (ii) the company's expectations regarding the likelihood of our obtaining FDA approval of Monovisc and/or the anticipated timing thereof; (iii) the company's ability to launch Monovisc in the U.S., if at all; and (iv) our distribution partner's right to terminate a license agreement with the company in accordance with the terms thereof. Certain other factors that might cause the company's actual results to differ materially from those in the forward-looking statements include those set forth under the headings "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the company's Annual Report on Form 10-K for the year ended December 31, 2011, as well as those described in the company's other press releases and SEC filings.

Source: Anika Therapeutics, Inc.

Anika Therapeutics, Inc.
Charles H. Sherwood, Ph.D., 781-457-9000
CEO
or
Kevin W. Quinlan, 781-457-9000
CFO
