



Anika Announces FDA 510(k) Clearance for its WristMotion® Total Arthroplasty System for the Replacement of Painful Wrist Joints

System designed to alleviate pain and restore function and mobility of the wrist joint



BEDFORD, Mass., Oct. 21, 2020 (GLOBE NEWSWIRE) -- [Anika Therapeutics, Inc.](#) (NASDAQ: ANIK), a global joint preservation company that creates and delivers meaningful advancements in early intervention orthopedic care, today announced that the Company's WristMotion Total Arthroplasty System received 510(k) clearance from the U.S. Food and

Drug Administration. The WristMotion Total Arthroplasty System is indicated for replacement of the painful wrist joint due to rheumatoid arthritis, osteoarthritis, or post-traumatic arthritis.

"We are delighted to receive clearance for this innovative wrist device as it is another step forward in our mission to provide motion preserving technologies. This is an underserved market and our solution is in response to demand from both orthopedic surgeons and patients for solutions that avoid fusion and preserve as much natural motion and anatomy as possible," said Cheryl R. Blanchard, Ph.D., President and Chief Executive Officer of Anika. "For Anika, this is another new product category coming from our recently acquired Arthrosurface business, which has a storied history of introducing orthopedic innovations that are minimally invasive, bone-sparing, and motion preserving. All too often, painful wrists caused by arthritis or trauma are treated by fusing the joint. We want to provide alternatives to that outcome that preserve joint motion for the patient. While fusions alleviate pain, the loss of motion in a wrist can be quite life changing, perhaps more than patients initially realize. Anika is committed to doing all that we can to allow patients to remain active and truly live life to the fullest."

The WristMotion Total Arthroplasty System is a modular joint restoration system that replaces both the radial and carpal portions of the joint. The system is unique in that it combines the patented and proven fixation and dual curvature implant geometries with a unique instrumentation system that allows for precise implant placement and joint tensioning. A design philosophy for the system was to preserve the complex kinematics of the joint, often referred to as the 'dart throwers' motion.

"With new kinematic information on implant design and function, the anatomic WristMotion Total Arthroplasty System utilizes an innovative articulating design for greater range of motion in both flexion/extension and radial/ulnar deviation. The WristMotion platform also allows intraoperative decision making with regards to performing a hemi or total arthroplasty to treat all stages of wrist arthritis. The R&D team worked extremely hard to design this new solution for wrist arthritis and I'm thrilled to see this device come to market and benefit patients," said Arnold-Peter C. Weiss, M.D., Chief - Hand, Upper Extremity & Microvascular Surgery, Vice Chairman and Professor of Orthopaedics, Warren Alpert Medical School, Brown University. With over 30 years of clinical experience in total wrist arthroplasty, Dr. Weiss provided his expertise as the lead surgeon designer of the WristMotion Total Arthroplasty System.

The 510(k) clearance for the WristMotion system triggers a one-time \$5 million earnout payment as a result of the achievement of a regulatory milestone set forth in the merger agreement executed among Anika and Arthrosurface, Incorporated on January 4, 2020. This earnout payment will be paid in the fourth quarter of 2020.

About Anika Therapeutics, Inc.

[Anika Therapeutics, Inc.](#) (NASDAQ: ANIK), is a global joint preservation company that creates and delivers meaningful advancements in early intervention orthopedic care. We partner with physicians to understand what they need most to treat their patients and we develop minimally invasive products that restore active living for people around the world. We are committed to leading in high opportunity spaces within orthopedics, including osteoarthritis pain management, regenerative solutions, soft tissue repair and bone preserving joint technologies. For more information, please visit www.anika.com.

Forward-Looking Statements

This press release may contain 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, concerning the Company's expectations, anticipations, intentions, beliefs or strategies regarding the future which are not statements of historical fact. These statements may include, but are not limited to, those relating to the potential market for, and revenue growth opportunity for the Company associated with, this product. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks, uncertainties, and other factors. The Company's actual results could differ materially from any anticipated future results, performance, or achievements described in the forward-looking statements as a result of a number of factors including, but not limited to, (i) the Company's ability to successfully commence and/or complete clinical trials of its products on a timely basis or at all; (ii) the Company's ability to obtain pre-clinical or clinical data to support domestic and international pre-market approval applications, 510(k) applications, or new drug applications, or to timely file and receive FDA or other regulatory approvals or clearances of its products; (iii) that such approvals will not be obtained in a timely manner or without the need for additional clinical trials, other testing or regulatory submissions, as applicable; (iv) the Company's research and product development efforts and their relative success, including whether we have any meaningful sales of any new products resulting from such efforts; (v) the cost effectiveness and efficiency of the Company's clinical studies, manufacturing operations, and production planning; (vi) the strength of the economies in which the Company operates or will be operating, as well as the political stability of any of those geographic areas; (vii) future determinations by the Company to allocate resources to products and in directions not presently contemplated; (viii) the Company's ability to successfully commercialize its products, in the U.S. and abroad; (ix) the Company's ability to provide an adequate and timely supply of its products to its customers; and (x) the Company's ability to achieve its growth targets. Additional factors and risks are described in the Company's periodic reports filed with the Securities and Exchange Commission, and they are available on the SEC's website at www.sec.gov. Forward-looking statements are made based on information available to the Company on the date of this press release, and the Company assumes no obligation to update the information contained in this press release.

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