



## CryoLife Acquires Distribution Rights and Purchase Option for ProCol® Vascular Bioprosthesis for Hemodialysis Access

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**Provides access for dialysis patients; complementary to HeRO® Graft**

ATLANTA, March 27, 2014 /PRNewswire/ -- **CryoLife, Inc. (NYSE: CRY)**, a leading medical device and tissue processing company focused on cardiac and vascular surgery, announced today that it has acquired the exclusive worldwide distribution rights for the ProCol Vascular Bioprosthesis ("ProCol") from Hancock Jaffe Laboratories, Inc. In addition, beginning 24 months after execution of the agreement, CryoLife has the right to acquire the ProCol product line from Hancock Jaffe.



ProCol, which is approved for sale in the United States, is a natural biological graft derived from a bovine mesenteric vein that provides vascular access for end-stage renal disease ("ESRD") hemodialysis patients. It is intended for the creation of a bridge graft for vascular access subsequent to at least one previously failed prosthetic access graft. ProCol is complementary to CryoLife's HeRO Graft (Hemodialysis Reliable Outflow), which also serves patients with ESRD. ProCol provides vascular access for earlier-stage ESRD patients, while HeRO Graft is designed for patients with limited access options and central venous obstruction.

### Key Aspects of Transaction

- CryoLife will reimburse Hancock Jaffe for up to \$2.3 million of its ProCol production costs over the next four quarters, beginning with the second quarter of 2014, with no more than \$650,000 payable in any quarter.
- In exchange for these payments, CryoLife will receive exclusive worldwide distribution rights for ProCol for up to five years (a three-year term with two one-year renewal terms at CryoLife's option), a purchase option on the ProCol product line, first right of refusal on certain other applications of the ProCol technology, and approximately 4,000 units of ProCol inventory. The 4,000 units are comprised of approximately 200 units of existing commercially saleable ProCol inventory, which will be transferred to CryoLife immediately, while the remaining units of inventory will be transferred when Hancock Jaffe receives FDA approval of the PMA Supplement associated with its new manufacturing facilities.
- Profits from CryoLife's sales of ProCol after the initial approximately 4,000 units will be shared equally by the parties, after taking into account the transfer price paid to Hancock Jaffe and a distribution fee earned by CryoLife.
- After 24 months, CryoLife has the option, during the term of the distribution agreement, to acquire the ProCol product line.

Steven G. Anderson, chairman, president, and CEO of CryoLife, said, "The ProCol Vascular Bioprosthesis is an excellent product for vascular access, with a small but loyal base of existing customers. We believe it has significant potential to gain market share when sold through our established commercial organization, which includes 36 sales representatives selling into the cardiovascular and vascular access markets. In addition, ProCol is complementary to the HeRO Graft, and many of its existing customers are also HeRO Graft users. We look forward to working with Hancock Jaffe, and we are eager to launch ProCol through our team in the second half of 2014."

Norman Jaffe, co-founder of Hancock Jaffe Laboratories, said, "We are excited to enter a distribution agreement with CryoLife. We expect both companies to benefit from the reintroduction of ProCol through CryoLife's established sales and marketing organization, which has a significant presence in the cardiovascular and vascular access markets. The ProCol vascular bioprosthesis has been shown to provide patients with ESRD with a viable access option. In U.S. clinical studies ProCol demonstrated improved patency compared with ePTFE grafts. We believe CryoLife is in a strong position to drive utilization of ProCol with its existing customers as well as to expand awareness with new customers through its commercial presence and physician education events, such as their Central Venous Pathology Summit."

Marc H. Glickman, MD, FACS, chief of vascular surgery, Sentara Healthcare, said, "There is an increasing demand for vascular access options to address the growing number of end-stage renal disease hemodialysis patients. The ProCol Vascular Bioprosthesis is an excellent option for these patients, and clinical data shows that it provides excellent patency when patients are faced with repeated failures of other grafts. In addition, ProCol is flexible and easy to suture, making it easy to implant in difficult cases, and it can be used in a variety of configurations and access sites."

### Financial Guidance

CryoLife intends to sell the currently available units of ProCol to existing ProCol customers beginning in the second quarter of 2014, with sales of additional units beginning immediately following FDA approval of the PMA Supplement associated with Hancock Jaffe's new manufacturing facilities, which is expected to occur during the second half of 2014. The Company expects to complete the training of its cardiovascular sales team by July, with the full U.S. commercial launch in the second half of 2014, pending FDA approval of Hancock Jaffe's PMA Supplement. CryoLife will provide

additional details on the distribution agreement and updated financial guidance in conjunction with its first quarter 2014 financial results conference call in April 2014.

## About CryoLife

CryoLife, Inc. is a leader in medical device manufacturing and distribution and in the processing and distribution of implantable living human tissues for use in cardiac and vascular surgeries. It operates throughout the U.S. and internationally. CryoLife manufactures and distributes BioGlue<sup>®</sup> Surgical Adhesive, an FDA-approved adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. BioGlue is also CE marked in Europe for use in soft tissue repair and has received additional marketing approvals in several other countries throughout the world. CryoLife's BioFoam<sup>®</sup> Surgical Matrix is CE marked in Europe for use as an adjunct in the sealing of abdominal parenchymal tissues (liver and spleen) when cessation of bleeding by ligature or other conventional methods is ineffective or impractical. CryoLife distributes PerClot<sup>®</sup>, an absorbable powdered hemostat, in Europe and other select international countries. CryoLife, through its subsidiary Cardiogenesis Corporation, specializes in the treatment of coronary artery disease for severe angina using a laser console system and single-use, fiber-optic handpieces to perform a surgical procedure known as Transmyocardial Revascularization (TMR). CryoLife and its subsidiary Hemosphere, Inc. market the HeRO<sup>®</sup> Graft, which is a solution for end-stage renal disease in certain hemodialysis patients. CryoLife's CryoValve<sup>®</sup> SG pulmonary heart valve, processed using CryoLife's proprietary SynerGraft<sup>®</sup> technology, has FDA 510(k) clearance for the replacement of diseased, damaged, malformed, or malfunctioning native or prosthetic pulmonary valves. CryoLife's CryoPatch<sup>®</sup> SG pulmonary cardiac patch has FDA 510(k) clearance for the repair or reconstruction of the right ventricular outflow tract (RVOT), which is a surgery commonly performed in children with congenital heart defects.

*Statements made in this press release that look forward in time or that express management's beliefs, expectations, or hopes are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements reflect the views of management at the time such statements are made and are subject to a number of risks, uncertainties, estimates, and assumptions that may cause actual results to differ materially from current expectations. These statements include those regarding anticipated timing of receipt of ProCol inventories; anticipated timing of FDA approval of Hancock Jaffe's PMA Supplement associated with its new manufacturing facilities; anticipated sales and the timing of such sales to existing ProCol customers and to existing HeRO Graft customers; plans related to the U.S. commercial launch of ProCol and the training and utilization of the cardiovascular sales team; profitability of ProCol sales; and the expansion of ProCol market share. The risks and uncertainties affecting these statements include that the success of efforts related to ProCol is subject to factors beyond our control, including general economic conditions, physician and patient acceptance, the potential inability to maintain reimbursement approvals and maintain and expand reimbursement rates, and regulatory approvals and scrutiny. Competing products -- those already in the market and those that may be introduced in the future -- may materially affect sales growth of ProCol. We are relying on Hancock Jaffe to provide our ProCol inventories; therefore, we may experience delays, shortages, or outages of product, or quality issues with respect to such product, if Hancock Jaffe experiences financial, operational, or other challenges with its business. Any such events could have a significant adverse effect on our sales of ProCol and our ability to establish and grow it as a product offering. We may not receive all of the anticipated volumes of currently available product, and/or we may determine, upon receipt of the product, that some or all of it is not suitable for sale. We will not fully realize the potential benefits of the distribution agreement if Hancock Jaffe fails to obtain FDA approval of its PMA Supplement associated with its new manufacturing facilities. Hancock Jaffe may experience delays and/or difficulties in obtaining the FDA approval, or events could transpire that prevent Hancock Jaffe from making the manufacturing facilities operational at all. We may experience currently unforeseen difficulties related to our ability to successfully market and distribute ProCol. Our beliefs regarding the market opportunity for ProCol may be incorrect, and even if correct, there is no guarantee that we will successfully grow ProCol sales or fully realize the potential benefits of any clinical advantages of the product. Our ProCol sales efforts and our ability to expand ProCol market share could be less successful than anticipated if our sales representatives are not timely and adequately trained on ProCol or if they are otherwise unable to capitalize on the established network of ProCol customers and/or leverage our existing network of HeRO Graft customers. Also, our profits from ProCol sales could be lower than anticipated if we are not able to achieve our desired pricing levels. For a discussion of additional factors impacting CryoLife's business, see our Form 10-K for the year ended December 31, 2013, as filed with the SEC, and subsequent filings with the SEC. CryoLife does not undertake to update its forward-looking statements.*

For additional information about the company, visit CryoLife's Web site:  
<http://www.cryolife.com>.

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