CryoLife Acquires Ascyrus Medical

September 2, 2020

Conference Call and Webcast Today, September 2, 2020 at 5:00 pm ET

ATLANTA, Sept. 2, 2020 /PRNewswire/ -- CryoLife, Inc. ("CryoLife"; NYSE: CRY), a leading cardiac and vascular surgery company focused on aortic disease, announced today that it has acquired Ascyrus Medical LLC (Ascyrus). Ascyrus is a Florida-based, privately-held developer of the Ascyrus Medical Dissection Stent (AMDS™), the world's first aortic arch remodeling device used for the treatment of acute Type A aortic dissections. The addition of the AMDS to CryoLife's product portfolio further strengthens the Company's position as a leader in the growing aortic repair market.

Strategic Rationale for the Transaction

- Provides CryoLife with:
  - AMDS, the first aortic arch remodeling system for use in the repair of acute Type A aortic dissections
  - Significant cross-selling opportunities with CryoLife's existing JOTEC® portfolio, BioGlue®, and On-X®
  - Access to an estimated $540 million incremental global market opportunity pending regulatory approvals
- Positions the Company for high single-digit revenue growth beginning in 2021 and non-GAAP earnings growth over the next five years
- Leverages CryoLife's existing world-wide direct sales organization calling on cardiac surgeons

"We believe the addition of the AMDS to our product offerings will make a meaningful contribution to our future growth as it gives us immediate access to the combined $100+ million EU and Canadian markets and has the potential to expand our worldwide addressable market by approximately $540 million," said Pat Mackin, Chairman, President, and Chief Executive Officer of CryoLife. "AMDS is another highly differentiated device that, when included in our commercial channel, will further solidify our position as a global leader in aortic repair, as it will immediately strengthen our highly competitive product portfolio in Europe."

Globally, approximately 48,000 patients suffer from acute Type A aortic dissections. Aortic dissection occurs when the innermost layer of the aorta tears and blood surges through the tear separating the layers of the aorta. In acute Type A aortic dissections, the tear in the wall of the aorta originates in the ascending aorta and continues down into the descending thoracic aorta. Left untreated, aortic dissections can lead to death. The current standard of care for repairing acute Type A aortic dissections is a hemiarch repair which involves open surgery during which the ascending thoracic aorta is replaced. Hemiarch repair typically addresses the most critical and pressing issues resulting from acute Type A dissections. However, stand-alone surgical repair is often not enough, as it does not address downstream re-entry tears or treating the false lumen beyond the ascending aorta, which could lead to issues such as continued blood flow in the false lumen, an enlarged aorta, and malperfusion with subsequent end-organ ischemia resulting from a lack of blood-flow – complications that result in costly and dangerous re-interventions, and often times, death.

Ascyrus has developed the AMDS, the world's first aortic arch remodeling device for use in the treatment of acute Type A aortic dissections. It is used as a complement to, and in conjunction with, hemi-arch replacement without adding technical complexity. The design of the AMDS allows for rapid deployment of the graft in the aortic arch during a standard replacement of the ascending aorta, adding less than five minutes to the procedure time. The deployment of the AMDS preserves the native arch, potentially allowing for the minimally invasive re-interventions, including the repair of additional entry tears, rather than an invasive arch repair. In the clinical trial supporting the CE Mark and Health Canada approvals, the AMDS was shown to reduce mortality, complications and reoperations compared to the standard of care, thereby improving the care of patients and offering significant cost savings for the health care system.

Michael Andrew Borger, MD, PhD, Professor of Cardiac Surgery, University of Leipzig, Director of Cardiac Surgery, Leipzig Heart Center, Leipzig, Germany, commented, "Based on our experience with the AMDS and the published data, I believe the addition of this simple and elegant device to the standard surgical procedure for patients with acute aortic dissection will actually simplify the operation, reduce early and late complications requiring reintervention, and possibly improve survival. It is likely to become the standard of care because of its ease of adoption, simplicity, safety, and effectiveness, particularly with the sickest patients."

Terms of the Agreements

Under terms of the agreements, CryoLife will acquire Ascyrus Medical for up to $200 million, consisting of:

- $80 million upfront payment, consisting of $60 million in cash and $20 million in CryoLife common stock
- Up to $120 million in milestone payments, consisting of:
  - $20 million upon U.S. IDE approval, consisting of $10 million in cash and $10 million in CryoLife common stock

- $25 million upon U.S. PMA
- $10 million upon Japan approval on or before June 30, 2027
- $10 million upon China approval on or before June 30, 2027
- Up to $55 million (or up to $65M-$75M if Japanese or Chinese approval are not secured on or before June 30, 2027) based on 2 times non-European based incremental sales in the 36 months subsequent to U.S. FDA approval

Advisors
In connection with the transaction, Vinson and Elkins are acting as legal counsel to CryoLife. UBS Investment Bank is acting as exclusive financial advisor to Ascyrus Medical and Wyrick Robbins is acting as legal counsel.

Webcast and Conference Call Information
CryoLife will hold a teleconference call and live webcast today at 5:00 p.m. Eastern Time to discuss the transaction, followed by a question and answer session hosted by Mr. Mackin.

To listen to the live teleconference, please dial 201-689-8261 a few minutes prior to 5:00 p.m. A replay of the teleconference will be available September 2 through September 9 and can be accessed by calling (toll free) 877-660-6853 or 201-612-7415. The conference number for the replay is 13709191.

The live webcast and replay and the accompanying presentation can be accessed by going to the Investor Relations section of the CryoLife website at www.cryolife.com and selecting the heading Webcasts & Presentations.

About CryoLife
Headquartered in suburban Atlanta, Georgia, CryoLife is a leader in the manufacturing, processing, and distribution of medical devices and implantable tissues used in cardiac and vascular surgical procedures focused on aortic repair. CryoLife markets and sells products in more than 100 countries worldwide. For additional information about CryoLife, visit our website, www.cryolife.com.

About Ascyrus Medical
Privately held Ascyrus Medical, headquartered in Florida, has developed the AMDS, the world's first aortic arch remodeling device for use in the repair of acute Type A aortic dissections. It is used as a complement to, and in conjunction with, hemi-arch replacement which is the current standard of care. Ascyrus received CE-Mark to commercialize in Europe the AMDS, and received Health Canada approval allowing for distribution in Canada. For additional information about Ascyrus, visit their website, www.ascyrus.com.

Forward Looking Statements
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. These statements include that the Ascyrus Medical transaction further strengthens CryoLife's position as a leader in the growing aortic repair market; creates significant cross selling opportunities with CryoLife's existing JOTEC product portfolio, BioGlue, and On-X; provides CryoLife access to the Acute Type A Aortic Dissection surgical repair market; positions the Company for high single-digit revenue growth beginning in 2021 and non-GAAP earnings growth over the next five years; and leverages CryoLife's existing world-wide direct sales organization calling on cardiac surgeons. They also include our beliefs that the addition of the AMDS to CryoLife's product offerings will make a meaningful contribution to our future growth by giving us immediate access to the EU and Canadian markets; that the combined EU and Canadian markets are in excess of $100M; that the worldwide addressable market for Acute Type A Aortic Dissection surgical repair is approximately $540 million; that the AMDS will further solidify our position as a global leader in aortic repair and immediately strengthen our highly competitive product portfolio in Europe; that AMDS will simplify the surgical repair operation, reduce early and late complications requiring reintervention, possibly improve survival; and is likely to become the standard of care due to its ease of adoption, simplicity, safety, and effectiveness, particularly with the sickest patients. These forward-looking statements are subject to a number of risks, uncertainties, estimates, and assumptions that may cause actual results to differ materially from current expectations. These risks and uncertainties include that the estimated market opportunities and addressable markets may be incorrect or may change over time; we may be unable to capitalize on cross-selling opportunities at all or as well as anticipated and anticipated portfolio synergies may be less than expected or may not materialize at all; IP protection, device adoption, surgical techniques, and competitive dynamics may be different than anticipated; and regulatory approvals may take longer than expected or may not be obtained at all. We may also be faced with unforeseen risks and uncertainties related to AMDS's business, particularly if the information received by CryoLife during the due diligence phase of this transaction is incomplete or inaccurate. Any of these risks could cause the financial impact of the acquisition to be less beneficial than currently anticipated. These risks and uncertainties include the risk factors detailed in our Securities and Exchange Commission filings, including our Form 10-K for the year ended December 31, 2019, and our subsequent filings with the SEC. CryoLife does not undertake to update its forward-looking statements.

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