
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): September 11, 2019

CRYOLIFE, INC.
(Exact name of registrant as specified in its charter)

Florida
(State or Other Jurisdiction
of Incorporation)

1-13165
(Commission File Number)

59-2417093
(IRS Employer
Identification No.)

1655 Roberts Boulevard, N.W., Kennesaw, Georgia 30144
(Address of principal executive office) (zip code)

Registrant's telephone number, including area code: (770) 419-3355

(Former name or former address, if changed since last report)

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.01 par value	CRY	NYSE

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01. Entry into a Material Definitive Agreement.

Exclusive Distribution Agreement

On September 11, 2019, CryoLife, Inc.'s wholly owned subsidiary, JOTEC GmbH, or JOTEC, entered into an Exclusive Distribution Agreement with an Israeli corporation named Endospan Ltd., or Endospan, pursuant to which JOTEC obtained exclusive distribution rights with respect to Endospan's Nexus™ stent graft system and accessories in certain countries in Europe in exchange for a fixed distribution fee in the amount of \$9 million. CryoLife Inc., or Cryolife, also entered into a Securities Purchase Option Agreement with Endospan, providing CryoLife the option to purchase all of the outstanding securities of Endospan from Endospan's existing securityholders, or the option to acquire all of Endospan's assets, with such option expiring 90 days after receiving notice that Endospan has received approval from the U.S. Food and Drug Administration, or the FDA, for its Nexus™ product.

Under the terms of the Exclusive Distribution Agreement, JOTEC agreed to use its best efforts to market, promote, distribute, sell and support the Nexus™ products for approved uses in the territories subject to JOTEC's exclusive distribution rights. JOTEC is obligated to satisfy a minimum purchase amount of EUR 900,000 in 2020, with purchases in 2019 counting toward this minimum purchase amount for 2020. Additional product purchases under the Exclusive Distribution Agreement will be subject to non-binding quarterly rolling forecasts.

The term of JOTEC's exclusive distribution rights expires upon the earliest to occur of (i) the date on which the acquisition contemplated by the Securities Purchase Option Agreement can no longer be consummated under its terms, or (ii) the date on which such Securities Purchase Option Agreement is terminated pursuant to its terms, subject to earlier termination by either party under certain circumstances. JOTEC would be entitled to a termination fee in the event the Exclusive Distribution Agreement is terminated by JOTEC due to a suspension of approvals related to the Nexus™ product lasting more than 6 months or the withdrawal of such approvals, or a temporary injunction on the Nexus™ product lasting 6 months or more or a permanent injunction on the Nexus™ product (unless such injunction resulted solely from an act or omission of JOTEC, its affiliates, or their sub-distributors).

The foregoing description of the Exclusive Distribution Agreement does not purport to be complete and is qualified in its entirety by reference to the Exclusive Distribution Agreement, a copy of which is to be filed with CryoLife's Quarterly Report on Form 10-Q for the quarter ending September 30, 2019.

Loan Agreement & Debenture

CryoLife and Endospan also entered into a Loan Agreement, dated as of September 11, 2019, pursuant to which CryoLife agreed to provide Endospan a secured loan in an amount of up to \$15 million, with the loan to be funded in three tranches in the amount of \$5 million each.

The first tranche of this loan is to be funded within 14 business days of the date of the Loan Agreement, the second tranche is to be funded within 14 business days of Endospan notifying CryoLife that the Nexus™ product received Investigational Device Exemption, or IDE, approval from the FDA, and providing a copy of such IDE approval to CryoLife, and the third tranche is to be funded within 14 business days after the enrolment of at least 50% of the required number of patients in the primary arm of the FDA approved clinical trial for the Nexus™ product, in each case subject to Endospan's continued compliance with the Loan Agreement and certain other conditions. If a termination fee becomes payable by Endospan under the Exclusive Distribution Agreement, it will be added to the amount payable under the Loan Agreement.

The loan is secured pursuant to a Debenture entered into between CryoLife and Endospan dated September 11, 2019, which grants CryoLife a security interest over substantially all of Endospan's assets. Such security interest is a first priority security interest, except as to a pre-existing security interest granted to a third party.

The loan bears interest at a rate of 5% per annum and is subject to acceleration upon an event of default. Interest on the loan is payable upon the closing of the acquisition contemplated in the Securities Purchase Option Agreement, and the principal amount and any additional interest or other obligations are payable upon the first anniversary of the closing of such acquisition.

The foregoing description of the Loan Agreement and Debenture does not purport to be complete and is qualified in its entirety by reference to the Loan Agreement and Debenture, copies of which are to be filed with CryoLife's Quarterly Report on Form 10-Q for the quarter ending September 30, 2019.

References to Nexus™ refer to Endospan's Nexus™ product. All brands, product names, company names, trademarks and service marks are the properties of their respective owners.

Item 7.01 Regulation FD Disclosure

On September 11, 2019, the Company issued a press release announcing the execution of the Exclusive Distribution Agreement, a copy of which is furnished as Exhibit 99.1 hereto and incorporated herein by reference.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to Item 7.01 of this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1**	Press Release of CryoLife, Inc., dated September 11, 2019

** Furnished herewith, not filed.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, CryoLife, Inc. has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CRYOLIFE, INC.

Date: September 11, 2019

By: /s/ Jean F. Holloway
Name: Jean F. Holloway
Title: Senior Vice President, General Counsel, Chief Compliance Officer,
and Corporate Secretary



N E W S R E L E A S E

FOR IMMEDIATE RELEASE**Contacts:****CryoLife**

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CryoLife Enters Into Distribution Agreement with EPIC

Positions the Company for Accelerating Revenue and Non-GAAP Earnings Growth Over the Next Five Years

Conference Call and Webcast Tomorrow, September 12, 2019 at 8:00 a.m. ET

Atlanta, GA – (September 11, 2019) – CryoLife, Inc. (“CryoLife”; NYSE: CRY), a leading cardiac and vascular surgery company focused on aortic disease, announced today that it has entered into distribution and credit facility agreements with Endospan, as well as an option agreement to purchase Endospan. Endospan is an Israeli-based, privately-held developer of NEXUS™, the only endovascular stent graft system approved for the repair of both aneurysms and dissections in the aortic arch. The addition of NEXUS to CryoLife’s highly differentiated branched aortic stent graft portfolio further strengthens the Company’s position as a leader in the growing aortic repair market.

Strategic Rationale for the Transaction

- Provides CryoLife with:
 - Exclusive European distribution rights to NEXUS, the first branched endovascular stent graft system with CE Mark for the repair of aortic arch aneurysms and dissections
 - Significant cross-selling opportunities with CryoLife’s existing JOTEC stent graft portfolio
 - Immediate access to the \$150 million European endovascular aortic arch repair market
 - Option to purchase Endospan for a predetermined price that survives until 90 days following notice of U.S. FDA approval for NEXUS

- o Access to potential \$800 million overall global market opportunity for endovascular aortic arch repair pending regulatory approvals
- Positions the Company for accelerating revenue and non-GAAP earnings growth over the next five years even without exercising the option to purchase Endospan
- Leverages CryoLife's existing 88 person European direct sales organization calling on cardiac and vascular surgeons

“We believe the addition of NEXUS to our product offerings will make a meaningful contribution to our future growth as it gives us immediate access to the \$150 million EU market and has the potential to expand our addressable market by over \$800 million,” said Pat Mackin, Chairman, President, and Chief Executive Officer of CryoLife. “NEXUS is another highly differentiated device that, when included in our European channel, further solidifies our position as a global leader in aortic repair, as it strengthens our highly competitive product portfolio in Europe. As we gain experience with NEXUS over the next few years, we may elect to further capitalize on this opportunity with our option to purchase Endospan.”

Kevin Mayberry, Chief Executive Officer of Endospan, commented, “CryoLife is ideally positioned to accelerate the adoption of NEXUS in Europe through its experienced direct sales force focused on aortic repair and its complementary JOTEC product portfolio. Additionally, the funding supplied through the distribution and credit facility provides us with the working capital needed to support operations in Europe, as well as to complete the U.S. FDA approval process, which we currently anticipate being completed in approximately five years.”

Aortic arch disease includes both aortic aneurysms and aortic dissections, which occur suddenly and usually without warning. Approximately 120,000 patients suffer thoracic aortic arch disease annually in the US and Europe, but only about 30,000 receive treatment. While minimally invasive endovascular repair has been the standard of care for Abdominal Aortic Aneurysm (AAA) and Thoracic Aortic Aneurysms (TAA), aortic arch disease patients with aneurysms or dissections who receive treatment have had little choice but to undergo open-chest surgery with its associated invasiveness and risks, lengthy hospitalizations, and prolonged recuperation.

Endospan has developed NEXUS, the first approved branched endovascular system to treat aortic arch disease, transforming a complex surgical aortic arch repair into a standard endovascular procedure. It is designed for enhanced intra-procedural and long-term stability attributable to its proprietary geometrical design, which reduces arch manipulation and, hence, stroke risks.

Prof. Dr. Nicolas Doll, Sana Cardiac Surgery, Stuttgart, Germany, commented, “NEXUS is a highly differentiated stent graft system that allows physicians to repair aneurysms and dissections in the aortic arch through an endovascular approach. NEXUS is especially important for elderly patients who are not suited for open surgery, and for patients with a prior Type A dissection that was repaired in an open surgical approach.”

Univ. Prof. Dr. Hubert Schelzig, Clinic for Vascular and Endovascular Surgery, University Clinic Düsseldorf, Germany, commented. “The NEXUS system has the potential to cross the next frontier in aortic surgery, namely a safe, therapeutic, minimally invasive procedure in aortic arch pathology. Not only does it provide a platform to treat the aortic arch, but it is a perfect fit with

CryoLife's highly differentiated and comprehensive portfolio of products that treat the entire aorta.”

Terms of the Agreements

Under terms of the agreements, CryoLife will acquire the European distribution rights for Nexus and an option to purchase Endospan for a total upfront payment of \$10 million. Additionally, CryoLife will provide up to \$15 million in additional debt financing to Endospan subject to Endospan's progress on its U.S. clinical trial in support of an FDA approval for NEXUS. CryoLife expects to finance the acquisition of the distribution and option rights and debt financing out of available cash on hand.

Under the purchase option, CryoLife has the right to acquire Endospan at any time until 90 days after receiving notice of U.S. FDA approval of the NEXUS stent graft system for a total consideration of \$250 million, plus a guaranteed \$100 million payment and up to an additional \$100 million based upon commercial success of NEXUS in the first year post-option exercise.

The distribution agreement, credit facility, and securities purchase option agreement have been approved by both companies' boards of directors and Endospan's Security Holders. The purchase obligations of the securities purchase agreement will become effective if, and only when, CryoLife exercises its purchase option and are subject to customary conditions to closing.

Financial Commentary

The Company does not anticipate the transaction with Endospan to have a material impact on its 2019 financial guidance. Management will update its 2019 financial guidance, if necessary, in its third quarter financial conference call.

Advisors

In connection with the transaction, Vinson & Elkins, LLP is acting as lead legal counsel to CryoLife. GKH Law Offices is acting as lead legal counsel to Endospan.

Webcast and Conference Call Information

CryoLife will hold a teleconference call and live webcast tomorrow at 8:00 a.m. Eastern Time to discuss the proposed 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 8:00 a.m. A replay of the teleconference will be available September 12 through September 19 and can be accessed by calling (toll free) 877-660-6853 or 201-612-7415. The conference number for the replay is 13694487.

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 Endospan

Privately held Endospan, headquartered in Herzlia (Tel Aviv), Israel, is a pioneer in the endovascular repair of Aortic Arch Disease including aneurysms and dissections. Endospan has received CE-Mark to commercialize in Europe the NEXUS™ Stent Graft System, the first endovascular off-the shelf system to treat Aortic Arch Disease which affects a greatly underserved group of patients diagnosed with a dilative lesion in, or near, the aortic arch. While minimally invasive endovascular repair has been the standard of care for Abdominal Aortic Aneurysm (AAA), Aortic Arch Disease patients with aneurysms or dissections have not been as fortunate and have had little choice but to undergo open-chest surgery with its invasiveness and risks, lengthy hospitalization periods, and prolonged recuperation. For additional information about Endospan, visit their website, www.endospan.com.

Forward Looking Statements

Statements made in this press release and the accompanying presentation that look forward in time or that express management's beliefs, expectations, or hope 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 those regarding the worldwide, including international and US, market opportunities for endovascular aortic arch repair products; and the number of patients that suffer thoracic aortic arch disease annually in the US and Europe and the number of those patients who receive treatment; the ability to leverage CryoLife's existing direct sales force in Europe and to create significant cross-selling opportunities with CryoLife's existing JO TEC stent graft portfolios; the positioning of CryoLife for accelerating revenue and non-GAAP earnings growth over the next five years; and the CryoLife loan to Endospan will provide Endospan with the working capital needed to support operations in Europe, as well as complete the U.S. FDA approval process; and the anticipated completion of U.S. FDA approval process in approximately five years. They also include our beliefs that the addition of NEXUS to our product offerings will make a meaningful contribution to our future growth; give us immediate access to a \$150 million EU market and has the potential to expand our addressable market by over \$800 million; the distribution agreement further solidifies our position as a global leader in aortic repair and strengthens our highly competitive product portfolio in the EU; as we gain experience with NEXUS over the next few years, we will be able to further capitalize on this opportunity by exercising our option to purchase Endospan at any time up until 90 days following notice of U.S. FDA approval of NEXUS. 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 may be incorrect or may change over time; we may be unable to capitalize on cross-selling opportunities of the distribution agreement in the EU at all or as well as anticipated and anticipated portfolio synergies may be less than expected or may not materialize at all; competitive dynamics may be different than anticipated; regulatory approvals may take longer than expected or may not be obtained at all; we may be unable or unwilling to exercise the option, if US regulatory approval is not secured for NEXUS or not secured within the anticipated timeframe or even if US regulatory approval is secured for NEXUS. We may also be faced with unforeseen risks and uncertainties related to Endospan's business, particularly if the information received by CryoLife during the due diligence phase of this transaction now or upon exercise of the option is incomplete or inaccurate.

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, 2018, and our subsequent filings with the SEC. CryoLife does not undertake to update its forward-looking statements.