

CRYOLIFE INC  
Form S-4  
June 22, 2012

As filed with the Securities and Exchange Commission on June 22, 2012

Registration No. 333-\_\_\_\_\_

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

FORM S-4

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

CRYOLIFE, INC.

(Exact name of registrant as specified in its charter)

Florida  
(State or Other Jurisdiction of  
Incorporation or Organization)

59-2417093  
(I.R.S. Employer  
Identification No.)

1655 Roberts Boulevard, NW, Kennesaw, Georgia 30144  
(Address, including zip code, of registrant's principal executive offices)

Steven G. Anderson, President, Chief Executive Officer  
and Chairman of the Board of Directors  
CryoLife, Inc.

1655 Roberts Boulevard, NW  
Kennesaw, Georgia 30144  
(770) 419-3355

(Name and address, including zip code, and telephone number, including area code,  
of agent for service)

Copy to:

Jeffrey W. Burris, Esq., Vice President  
and General Counsel  
CryoLife, Inc.  
1655 Roberts Boulevard, NW  
Kennesaw, Georgia 30144  
(770) 419-3355

B. Joseph Alley, Jr., Esq.  
Arnall Golden Gregory LLP  
Suite 2100  
171 17th Street, NW  
Atlanta, Georgia 30363-1031  
(404) 873-8500

Approximate Date of Commencement of Proposed Sale to the Public: From time to time after the effective date of this Registration Statement.

If the securities being registered on this form are being offered in connection with the formation of a holding company and there is compliance with General Instruction G, check the following box. "

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer   
 Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

If applicable, place an X in the box to designate the appropriate rule provision relied upon in conducting this transaction:

Exchange Act Rule 13d-4(i) (Cross-Border Issuer Tender Offer)

Exchange Act Rule 14d-1(d) (Cross-Border Third-Party Tender Offer)

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Share	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock, par value \$0.001 per share (including attached preferred share purchase rights) (1)				
Warrants (2)				
Total (3)	\$100,000,000	100%	\$100,000,000	\$11,460

(1) There is being registered hereunder an indeterminate number of shares of common stock, subject to limitations on the number of shares authorized by the registrant’s Amended and Restated Articles of Incorporation, as amended from time to time, as may be issued from time to time at indeterminate prices, including shares issuable upon exercise of warrants. The securities that may be offered pursuant to this registration statement include, pursuant to Rule 416 of the Securities Act of 1933, as amended (the “Securities Act”), such additional number of common shares that may become issuable as a result of any stock split, stock dividends or similar event. Each share of common stock is accompanied by a Series A Junior Participating Preferred Stock purchase right that trades with the share of common stock. The value attributed to those rights, if any, is reflected in the market price of the common stock. Prior to the occurrence of certain events, none of which has occurred at this date, the rights will not be exercisable or evidenced separately from the common stock.

(2) There is being registered hereunder an indeterminate number of warrants of CryoLife as may be issued from time to time at indeterminate prices entitling the holder to purchase shares of common stock

(3)

Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) under the Securities Act.

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The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is incomplete and may be changed. The registrant may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS

\$100,000,000

CRYOLIFE, INC.

Shares of Common Stock  
Warrants

This prospectus relates to up to \$100,000,000 of our common stock, par value \$0.01, and warrants that we may offer and issue in acquisition transactions that we may make from time to time. These acquisitions of assets, businesses or securities, whether by purchase, merger, or any other form of business combination, will be made at negotiated prices. The consideration for any such acquisition may consist of shares of our common stock or warrants or a combination of common stock, warrants, cash, notes, assumption of liabilities or other consideration. The total number of shares and/or warrants issued to consummate any of these acquisitions will be determined through arms-length negotiations and we expect that the shares of common stock issued in connection with any of these transactions will be valued at a price reasonably related to the prevailing market price of our common stock at the time an acquisition agreement is entered into or at or about the time the acquisition is consummated or during some other negotiated period. We do not expect to receive any cash proceeds when we issue common stock or warrants registered by this prospectus

We expect to pay all expenses of any offerings under this prospectus. We do not expect to pay any underwriting discounts or commissions in connection with issuing the common stock or warrants, although we may pay finder's or similar fees in specific acquisitions, and the fees may be paid through the issuance of shares of common stock and warrants covered by this prospectus. Any person receiving a finder's or similar fee may be deemed an underwriter within the meaning of Section 2(a)(11) of the Securities Act of 1933, as amended.

Our common stock is listed for trading on the New York Stock Exchange under the symbol "CRY." Our executive offices are located at 1655 Roberts Boulevard, NW, Kennesaw, Georgia 30144. Our telephone number is (770) 419-3355. The last reported sale price of the common stock on June 21, 2012 was \$4.63 per share.

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Investing in our securities involves significant risks. You should carefully consider the "Risk Factors" beginning on page \_\_\_ of this prospectus and in the applicable prospectus supplement and in any of the documents we incorporate by reference before determining whether to accept our common stock as to all or part of the purchase price for our acquisition of your business, securities or other assets.

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Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is \_\_\_\_\_, \_\_\_\_.

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## TABLE OF CONTENTS

	Page
SUMMARY	1
ABOUT THIS PROSPECTUS	1
ABOUT CRYOLIFE	1
RISK FACTORS	5
FORWARD LOOKING STATEMENTS	22
USE OF PROCEEDS	23
DESCRIPTION OF CAPITAL STOCK	23
DESCRIPTION OF WARRANTS	27
PLAN OF DISTRIBUTION	28
WHERE YOU CAN FIND MORE INFORMATION	29
LEGAL MATTERS	30
EXPERTS	30

We have not authorized any dealer, salesman or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus and any accompanying supplement to this prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus or any accompanying prospectus supplement. This prospectus and any accompanying supplement to this prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus and any accompanying supplement to this prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus or any prospectus supplement, as well as the information we previously filed with the SEC that is incorporated by reference herein or therein, is accurate as of any date other than its respective date. When we deliver this prospectus or a supplement or make a sale pursuant to this prospectus or a supplement, we are not implying that the information is current as of the date of the delivery or sale.

This prospectus incorporates important business and financial information about us that is not included in or delivered with the prospectus. We will provide you without charge upon your request a copy of any documents incorporated by reference into this prospectus, other than exhibits to those documents that are not specifically incorporated by reference into those documents, or you may obtain copies of such documents from the SEC, in each case as described under “Where You Can Find More Information” below. For a more detailed discussion about the information about us that is incorporated by reference into this prospectus, see “Where You Can Find More Information.” Requests for documents should be submitted in writing to the following address: 1655 Roberts Boulevard, NW, Kennesaw, Georgia 30144, Attention Corporate Secretary. To obtain timely delivery, you must request information no later than five business days before the date you must make your investment decision.





## SUMMARY

This summary highlights information that we believe is especially important concerning our business and this offering. It does not contain all of the information that may be important to your investment decision. You should read the entire prospectus, including the documents incorporated herein by reference, “Risk Factors” and our financial statements and related notes, before deciding to purchase our securities.

## ABOUT THIS PROSPECTUS

This prospectus is a part of a “shelf” registration statement on Form S-4 that we have filed with the United States Securities and Exchange Commission, referred to as the SEC. Under the shelf registration process, we may from time to time offer and sell up to \$100,000,000 of common stock, par value \$0.01 per share, and warrants in connection with the acquisition of assets, stock or businesses, whether by purchase, merger or any other form of business combination. This prospectus incorporates important business and financial information about us that is not included in or delivered with the prospectus. We will provide you without charge upon your request a copy of any documents incorporated by reference into this prospectus, other than exhibits to those documents that are not specifically incorporated by reference into those documents, or you may obtain copies of such documents from the SEC, in each case as described under “Where You Can Find More Information” below. For a more detailed discussion about the information about us that is incorporated by reference into this prospectus, see “Incorporation by Reference.”

This prospectus provides you with a general description of the securities we may offer pursuant to this prospectus. Each time we sell securities, we will provide one or more prospectus supplements that will contain specific information about the terms of that offering. This prospectus does not contain all of the information included in the registration statement. For a complete understanding of the offering of securities, you should refer to the registration statement relating to this prospectus, including its exhibits. A prospectus supplement may also add, update or change information contained in this prospectus. Once we know the actual information concerning a specific acquisition, we may be required to provide further information either by means of a post-effective amendment to the registration statement of which this prospectus is a part, or by means of a prospectus supplement. You should read this prospectus and any accompanying prospectus supplement or any applicable post-effective amendment together with the additional information described under the heading “Where You Can Find More Information.”

## ABOUT CRYOLIFE

CryoLife preserves and distributes human tissues and develops, manufactures, and commercializes medical devices for cardiac and vascular transplant applications. The human tissues distributed by CryoLife include the following:

- CryoValve® SG pulmonary heart valve,
- CryoPatch® SG pulmonary cardiac patch tissue,
- CryoVein and CryoArtery vascular tissues; and
- Other cardiac and vascular tissues.

CryoLife’s medical devices consist primarily of surgical sealants and hemostats, including the following:

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- BioGlue® Surgical Adhesive,
- BioFoam® Surgical Matrix, and
- PerClot®, which CryoLife began distributing for Starch Medical, Inc., or SMI, in October of 2010 in certain international markets.

In addition, following its acquisition of Cardiogenesis Corporation in May 2011, CryoLife markets devices that treat severe angina through a surgical procedure known as transmyocardial revascularization, or TMR. Following its acquisition of Hemosphere, Inc. in May 2012, CryoLife markets the HeRO® (Hemodialysis Reliable Outflow) Graft, a proprietary graft-based solution for end-stage renal disease hemodialysis patients with limited access options and central venous obstruction.

CryoLife's international revenues were 17% of total revenues in 2010 and 20% of total revenues in 2011.

#### Services and Products

**Preservation Services.** CryoLife distributes preserved human cardiac and vascular tissue to implanting institutions throughout the U.S., Canada, and Europe. CryoLife processes and preserves cardiac and vascular tissue using proprietary processing and freezing techniques, or cryopreservation. Management believes the human tissues it distributes offer specific advantages over mechanical, synthetic, and animal-derived alternatives. Depending on the alternative, the advantages of CryoLife's heart valves include more natural blood flow properties, the ability to treat endocarditis, the elimination of a need for long-term drug therapy to prevent excessive blood clotting, and a reduced risk of catastrophic failure, thromboembolism (stroke), or calcification. CryoLife's cardiac tissues include the CryoValve SGPV and the CryoPatch SG, both processed with CryoLife's proprietary SynerGraft technology. CryoLife uses the SynerGraft technology for a portion of its pulmonary valve and pulmonary cardiac patch tissue processing. CryoLife's vascular tissues, including the CryoVein and CryoArtery, have been used to treat a variety of vascular reconstructions such as peripheral bypass, hemodialysis access, and aortic infections which have saved the lives and limbs of patients

**Surgical Sealants and Hemostats.** CryoLife's proprietary product BioGlue, designed for cardiac, vascular, pulmonary, and general surgical applications, is a polymer based on bovine blood protein and an agent for cross-linking proteins. CryoLife distributes BioGlue throughout the U.S. and in more than 75 other countries for designated applications. In the U.S. BioGlue is FDA approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. CryoLife distributes BioGlue for repair of soft tissues (which include cardiac, vascular, pulmonary, and additional soft tissues) in the European Economic Area under Conformité Européene Mark product certification, or CE Mark. In April 2011 CryoLife began distributing BioGlue in Japan for the repair of aortic dissections. Additional marketing approvals have been granted for specified applications in several other countries throughout the world, including Canada, Brazil, and Australia.

CryoLife's proprietary product, BioFoam, is a protein hydrogel biomaterial with an expansion agent which generates a mixed-cell foam. The foam creates a mechanical barrier to decrease blood flow and pores for the blood to enter, leading to cellular aggregation and enhanced hemostasis. BioFoam contains a foaming agent, which has the potential to rapidly seal organs, such as the liver, and may provide hemostasis in penetrating wounds and trauma. CryoLife distributes BioFoam under CE Mark certification for use as an adjunct in the sealing of liver and spleen when cessation of bleeding by ligature or conventional methods is ineffective or impractical. BioFoam has approval by the FDA for an investigational device exemption to conduct a human clinical trial with BioFoam to determine its safety and effectiveness in sealing liver tissues in patients for whom cessation of bleeding by ligature or other conventional methods is ineffective or impractical.

CryoLife has a worldwide distribution agreement (except in China and certain related territories and governing areas) and a license and manufacturing agreement with SMI of San Jose, California for PerClot, a polysaccharide hemostatic agent used in surgery. PerClot is an absorbable powder hemostat that has CE Mark designation allowing commercial distribution into the European Community and other markets. It is indicated for use in surgical procedures, including cardiac, vascular, orthopaedic, spinal, neurological, gynecological, ENT, and trauma surgery as an adjunct hemostat

when control of bleeding from capillary, venous, or arteriolar vessels by pressure, ligature, and other conventional means is either ineffective or impractical. CryoLife filed an investigation device exemption (“IDE”) with the FDA in March 2011 seeking approval to begin clinical trials for the purpose of obtaining Premarket Approval (a “PMA”) to distribute PerClot in the U.S. In April 2011, the FDA disapproved CryoLife’s IDE filing. CryoLife refiled its IDE for PerClot in March 2012.

Revascularization Technology. Following the acquisition of Cardiogenesis in May 2011, CryoLife develops and markets surgical products for the treatment of refractory angina in patients with chronic cardiac ischemia caused by coronary artery disease, which remains a leading cause of death for persons over the age of 65. Its products are used to create transmural laser channels into the myocardium, commonly referred to as TMR, which has proven effective in reducing symptoms in patients with refractory angina compared to optimal medical management. While these products can be employed as a minimally invasive standalone therapy, they are most often used in conjunction with coronary bypass surgery to treat incomplete revascularization, utilizing the technology in areas of myocardium not amenable to coronary bypass. CryoLife believes the clinical effect of transmural laser channeling can be further enhanced by the intramyocardial injection of stem cells. As such, it is developing proprietary catheter-based systems that combine TMR with the delivery of biologics, such as stem cells. CryoLife's PHOENIX Combination Delivery System is the first device developed for this purpose. CryoLife intends to conduct a pilot clinical evaluation in select European countries in 2012 while also investigating requirements to achieve an IDE approval for clinical evaluation of the Phoenix system in the U.S.

HeRO Graft Technology. Following the acquisition of Hemosphere in May 2012, CryoLife, through its Hemosphere subsidiary, develops and markets the HeRO Graft, a proprietary graft-based solution for end-stage renal disease hemodialysis patients with limited access options and central venous obstruction. The HeRO Graft received its initial FDA 510(k) clearance in 2008 and CE Mark approval in 2011. It is indicated for catheter dependent end-stage renal disease ("ESRD") patients on long-term hemodialysis who have exhausted all other access options, such as AV fistulas and grafts. The HeRO Graft has been implanted in more than 5,000 patients to date. The product has established and expanding reimbursement rates in the U.S., with reimbursement codes that are endorsed by the Society for Vascular Surgery and the American Medical Association. Hemosphere has 6 issued patents on the product in the U.S., Europe and Japan and 12 patents pending. Additional details regarding our acquisition of Hemosphere are disclosed in our current report on Form 8-K filed on May 18, 2012, which is incorporated herein by reference.

## Research and Business Development

Through its continuing research and development activities, CryoLife uses its expertise in protein chemistry, biochemistry, cell biology, and engineering, and its understanding of the cardiac and vascular surgery medical specialties to develop useful technologies, services, and products. In addition, CryoLife uses this expertise to acquire and license supplemental and complimentary products and technologies. CryoLife seeks to identify market areas that can benefit from medical devices, preserved tissues, and other related technologies, to develop innovative products and techniques within these areas, to secure their commercial protection, to establish their efficacy, and then to market these products and techniques. In order to expand CryoLife's service and product offerings, CryoLife is in the process of developing or investigating several technologies and products. Some of the products in development have not been subject to completed clinical trials and have not received FDA or other regulatory approval, so CryoLife may not derive any revenues from them. CryoLife generally performs significant research and development work before offering its services and products, building on either existing proprietary and non-proprietary knowledge or acquired technology and know-how. CryoLife's current tissue preservation services were developed internally. CryoLife developed its BioGlue and BioFoam products from a technology originally developed by a third party and acquired by CryoLife. CryoLife purchased the rights to distribute and manufacture PerClot from a third party and is in the process of obtaining FDA approval to distribute PerClot in the U.S. CryoLife acquired the revascularization technologies from a third party.

## Risk Factors

Our business is subject to a number of risks, including:

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- the possibility of FDA actions and other regulatory actions,
  - additional expenses and losses from product recalls,
- possible losses from product liability, securities, and other litigation,

- lower demand for our products and adverse publicity resulting from product recalls and other FDA activity,
  - the possible inability to obtain sufficient insurance coverage,
  - the possible inability to protect our intellectual property rights,
  - the possible inability to obtain necessary regulatory approvals,
- the possible inability to successfully integrate acquired businesses and technologies,
- uncertainties related to patents and protection of proprietary technology that may adversely impact the value of our intellectual property,
- our significant dependence on our revenues from BioGlue and tissues and our exposure to a variety of risks affecting these products and services,
- risks related to our BioGlue product, including competing products, our limited number of suppliers and the future expiration of our BioGlue patents,
- risks related to our acquisition of Cardiogenesis, including our potential inability to maintain revenues and achieve growth in revenues from Cardiogenesis' revascularization technologies in the future due to our dependence upon physician awareness of this technology,
- risks related to our acquisition of Hemosphere, including our potential inability to maintain revenues and achieve growth in revenues from Hemosphere's HeRO Graft product, and risks related to our ability to successfully integrate Hemosphere into our business and operations,
- the potential of impairments to the carrying value of certain investments over which we have limited control,
- challenging domestic and international economic conditions and their constraining effect on hospital budgets,
- the possibility that we will not be able to obtain the necessary regulatory approvals to allow us to distribute PerClot in the United States or other jurisdictions,
- potential limits on our ability to charge fees, and potential additional tax expenses, from recent legislation to reform the U.S. healthcare system, and
  - possible future lack of adequate capital.

See "Risk Factors" below for a more detailed discussion of risks relating to our business and our securities.

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CryoLife, Inc. was incorporated January 19, 1984 in Florida. All references to "CryoLife," the "Company," "we," "us" or "our" in this prospectus mean CryoLife, Inc., a Florida corporation, and all entities owned or controlled by CryoLife, Inc., except where it is made clear that the term means only the parent company.

Our principal executive offices are located at 1655 Roberts Boulevard, NW, Kennesaw, Georgia 30144. Our telephone number is (770) 419-3355 and our Web site is located at [www.cryolife.com](http://www.cryolife.com). Information contained on our Web site is not part of this prospectus.

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## RISK FACTORS

You should carefully consider the following risk factors and all other information contained or incorporated by reference in this prospectus or in any supplement to it before you make any investment decisions with respect to our securities.

If any of the adverse events described in the following factors actually occur, our business, financial condition and operating results could be materially and adversely affected, the value of your securities could decline and you could lose all or part of your investment.

### Risks Relating To Our Business

**We Are Significantly Dependent On Our Revenues From BioGlue And Are Subject To A Variety Of Risks Affecting This Product.**

BioGlue is a significant source of our revenues. Should this product be the subject of adverse developments with regard to its safety, efficacy, or reimbursement practices, or if our rights to manufacture and market this product are challenged, the result could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

**The Continued Introduction Into The Market Of Products That Compete With BioGlue Could Have An Irreversible Adverse Impact On Our Sales Of BioGlue.**

In recent years competitors of BioGlue were able to obtain FDA approval for indications in which BioGlue had been used off-label. The continued introduction of these or similar competitive products could have an irreversible adverse impact on our sales of BioGlue and, therefore, our revenues, financial condition, profitability, and cash flows.

**Our BioGlue Patent Expires In The U.S. In Mid-2012 And In The Rest Of The World In Mid-2013.**

Our U.S. patent for BioGlue expires in mid-2012, and our patents in the rest of the world for BioGlue expire in mid-2013. Following expiration of these patents, competitors may utilize the inventions disclosed in the BioGlue patents in competing products, which could materially reduce our revenues and income from BioGlue, although any competing product would have to be approved by the appropriate regulatory authority, such as the FDA. In addition, the validity of our patent in Germany is being challenged. We filed suit in Germany against Tenaxis because we believe Tenaxis is infringing our main BioGlue patent in Germany. Tenaxis filed a separate nullity suit against this same BioGlue patent in Germany, and the lower court ruled that our BioGlue patent was nullified. We appealed this ruling, and the nullification was stayed pending resolution of the nullification case by the German Supreme Court, which will not occur until 2012 or potentially 2013. If we lose this appeal, we will lose intellectual property protection for our BioGlue product in Germany, potentially sooner than the expiration of our patent in mid-2013, which may cause us to lose revenues in Germany as competitors may legally offer similar products. Any such outcome could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

**Our Tissues And Products Allegedly Have Caused, And May In The Future Cause, Injury To Patients, And We Have Been, And May In The Future Be, Exposed To Tissue Processing And Product Liability Claims, Including One Currently Outstanding Product Liability Lawsuit, And Additional Regulatory Scrutiny As A Result.**

The processing, preservation, and distribution of human tissues, and the manufacture and sale of medical devices entail inherent risks, including the possibility of medical complications for patients, and have resulted, and may in the future result in, tissue processing and product liability claims against us and adverse publicity. From time to time various plaintiffs have asserted that our tissues or medical devices have caused a variety of injuries, including death. We have been, and may be, sued and our insurance coverage has in the past been and may in the future be inadequate. Adverse judgments and settlements in excess of our available insurance coverage could materially adversely impact our financial condition, profitability, and cash flows.

Because medical complications are alleged to have been caused by or occur in connection with medical procedures involving our tissues or products, we have been, and may be, subject to additional FDA and other regulatory scrutiny, inspections, and adverse publicity. For example, in 2002 the FDA issued an order regarding our non-valved cardiac, vascular, and orthopaedic tissues processed by us from October 3, 2001 until August 13, 2002, which we refer to as the FDA Order. Pursuant to the FDA Order, we recalled these tissues or placed them on quarantine hold. Shortly after the FDA Order, the FDA posted a notice, now archived, on its website stating its concerns regarding our heart valve tissues. As a result, some surgeons and hospitals decided not to use our heart valves. Cautionary statements from the FDA or other regulators, adverse publicity, changes to our labeling, required prominent warnings, or negative reviews from the FDA or other regulators of our processing and manufacturing facilities have in the past decreased, and may in the future decrease, demand for our tissues or products and could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

In addition to the recall resulting from the FDA Order, we have in the past suspended the distribution of, or recalled, certain tissues, and in the future may have to suspend the distribution of or recall particular types of tissues or products as a result of reported adverse events. Suspension of the distribution of, or recall of, our tissues or products could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

**Our Investment In Medafor Has Been Impaired Due To Medafor's Termination Of Our Exclusive Distribution Agreement With Medafor And Our Investment Could Be Further Impaired By Risks Associated With Medafor's Business Or By Medafor's Actions, Which Could Have A Material Adverse Impact On Our Financial Condition And Profitability.**

We recorded an impairment of \$3.6 million in the third quarter of 2010 to write down our investment in Medafor common stock that we had purchased in 2009 and 2010. The carrying value of our 2.4 million shares of Medafor common stock after this write down was \$2.6 million. The carrying value of our 2.4 million shares of Medafor common stock remained \$2.6 million as of December 31, 2011.

We will continue to evaluate the carrying value of this investment if changes to impairment factors or additional impairment factors become known to us that indicate that we should evaluate our investment in Medafor common stock for further impairment. Also, our investment in Medafor is subject to certain risks, including business and operational risks of Medafor outside of our control that could further impair the value of our investment, including the issuance of shares of Medafor common stock that could dilute our investment in Medafor. In addition, in June 2012 we settled a lawsuit with Medafor, with the settlement resulting in a \$3.5 million payment by Medafor to us and the dismissal of Medafor's counterclaims against us. We may not be able to fully assess the effect of the settlement on Medafor's financial position. If we subsequently determine that the value of our Medafor common stock has been impaired further or if we decide to sell our Medafor common stock for less than the carrying value, the resulting impairment charge or realized loss on sale of the investment in Medafor could be material.

**We Will Not Fully Realize The Benefit Of Our Investment In Our Distribution And License And Manufacturing Agreements With Starch Medical, Inc. Unless We Are Able To Obtain FDA Approval For PerClot In The U.S., Which Will Require An Additional Commitment Of Funds.**

On September 28, 2010 we entered into a worldwide distribution agreement and a license and manufacturing agreement with SMI pursuant to which we distribute and will, ultimately, manufacture PerClot. We were also authorized to pursue, obtain, and maintain regulatory approval for PerClot in the U.S. If this approval is not obtained prior to October 1, 2017, SMI may terminate our rights with respect to U.S. regulatory approval and require us to

negotiate a reasonable revision to the agreement.

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As part of the transaction, we paid SMI \$6.75 million in cash, which includes \$1.5 million in prepaid royalties, and \$1.25 million in restricted CryoLife common stock. We made an additional contingent payment of \$250,000 in 2011 and will pay additional contingent amounts of up to \$2.5 million to SMI if certain U.S. regulatory and other commercial milestones are achieved and will also pay royalties on sales of PerClot manufactured by us. In September 2011 we entered into an agreement with SMI for an additional \$1.0 million to acquire the technology used to produce the key component in the manufacture of PerClot. We anticipate that we will spend between \$5.0 million and \$6.0 million to gain U.S. regulatory approval in the next several years, most of which we expect to be incurred in 2012. We will incur additional costs to begin manufacturing PerClot and to begin marketing PerClot in the U.S. Our costs may be greater than anticipated, as the costs to obtain FDA approval, begin manufacturing PerClot from plant starch modified by SMI, and begin marketing PerClot are estimates and may ultimately be greater than anticipated.

We will not be able to fully realize the benefit of our investment in our agreements with SMI in future years unless we are able to obtain the necessary regulatory approvals in the U.S. to distribute PerClot within the timetable anticipated, which is currently 2013 or 2014, or at all, and this failure would materially adversely impact our financial condition, anticipated future revenues and profitability. There is no guarantee that we will obtain this approval when anticipated or at all. Estimates regarding the timing of regulatory approval for PerClot are subject to factors beyond our control, and the approval process may be delayed because of unforeseen scheduling difficulties and unfavorable results at various stages in the process. The FDA rejected our initial IDE application for PerClot and we are working to address its concerns; however, there is no guarantee that we can do so on a timely or cost efficient basis. Our approval efforts for PerClot in the United States are subject to delays and cost overages, and management may decide to terminate or delay its pursuit of U.S. regulatory approval for PerClot at any time due to changing conditions in our company, in the marketplace or in the economy in general.

**The Receipt Of Impaired Materials Or Supplies That Do Not Meet Our Standards Or The Recall Of Materials Or Supplies By Our Vendors Or Suppliers Could Have A Material Adverse Impact On Our Revenues, Financial Condition, Profitability, And Cash Flows.**

The materials and supplies used in our processing of tissue and our manufacturing processes for devices are subject to quality standards and requirements, and many of these supplies and products are subject to regulatory oversight and action. If materials or supplies used in our processes fail to meet these standards and requirements or are subject to recall or other quality action, it is likely the outcome of this event will be the rejection or recall of the processed tissue or devices and/or the immediate expense of the costs of the preservation or manufacturing. For example, in 2011 certain supplies of processing solution used in our processing of tissue did not meet our quality requirements. As a result, we ceased processing the tissues that used this solution and expensed \$674,000 related to the preservation costs for these tissues.

Any of these occurrences or actions could materially adversely impact our revenues, financial condition, profitability, and cash flows.

**Our Sales Are Impacted By Challenging Domestic And International Economic Conditions And Their Constraining Effect On Hospital Budgets And Demand For Our Tissues And Products Could Decrease In The Future, Which Could Have A Material Adverse Impact On Our Business.**

The demand for our tissues and BioGlue has fluctuated recently and may continue to fluctuate. In challenging economic environments, hospitals attempt to control costs by reducing spending on consumable items, which can result in reduced demand for some of our products and services. We believe that our tissues and products will continue to be in demand for the foreseeable future. However, if the economic recession continues or worsens, changes occur in healthcare policies that force or encourage our customers to limit their use of our tissues and

products, or if new competitive tissues or products are introduced, demand for our tissues and products could decrease in the future. If demand for our tissues or products decreases significantly in the future, our revenues and cash flows would likely decrease, possibly materially. In addition, our processing throughput of tissue and our manufacturing throughput of BioGlue would necessarily need to decrease, which would likely adversely impact our margins, and, therefore, our profitability, possibly materially. Further, if demand for our tissues decreases in the future, we may not be able to ship our tissues before they expire, which would cause us to write down our deferred preservation costs. Since our international revenues are currently approximately one-fifth of our total revenues, our sales may be impacted by challenging economic conditions in countries around the world, in addition to the U.S., particularly in Europe and Japan. These factors could materially adversely impact our financial condition and profitability.

#### Healthcare Policy Changes, Including Recent Federal Legislation To Reform The U.S. Healthcare System, May Have A Material Adverse Impact On Us.

In response to perceived increases in health care costs in recent years, there have been, and continue to be, proposals by the federal government, state governments, regulators, and third-party payors to control these costs and, more generally, to reform the U.S. healthcare system. Certain of these proposals could limit the fees we are able to charge for our services, prices we are able to charge for our products, or the amounts of reimbursement available for our services or products and could limit the acceptance and availability of our services and products. In addition, as discussed below, recent federal legislation would impose significant new taxes on medical device makers such as us. The adoption of some or all of these proposals, including the recent federal legislation, could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

On March 23, 2010 President Obama signed the Patient Protection and Affordable Care Act. This legislation imposes a new 2.3% tax on the sale after December 31, 2012 of a taxable medical device by the manufacturer, producer, or importer. We believe that, if this tax had been in effect in 2011, it would likely have cost the Company approximately \$1.1 million. However, the final regulations implementing the new tax have not been promulgated, so we are uncertain about the amount that ultimately will be paid. These taxes will result in a significant increase in the tax burden on us, which could have a material adverse impact on our financial condition, profitability, and cash flows.

#### The Loss Of Any Of Our Sole-Source Suppliers Could Have A Material Adverse Impact On Our Revenues, Financial Condition, Profitability, And Cash Flows.

We purchase certain supplies used in our processing of tissues and our manufacturing of products from single sources due to quality considerations, costs, or constraints resulting from regulatory requirements. With respect to BioGlue, for instance, we have only one supplier for our BioGlue syringe. Additionally, we have only two suppliers of bovine serum albumin, which is necessary for the manufacture of BioGlue. If we lose one or more of these suppliers, our ability to manufacture and sell BioGlue could be adversely impacted. We cannot be sure that we would be able to replace any such loss on a timely basis, if at all.

Agreements with certain suppliers are terminable by either party or may expire. Where a particular single-source supply relationship is terminated, we may not be able to establish additional or replacement suppliers for certain components or materials quickly. This is largely due to the FDA approval system, which mandates validation of materials prior to use in our tissue processing and product manufacturing, and the complex nature of the manufacturing processes employed by many suppliers. In addition, we may lose a sole-source supplier due to, among other things, the acquisition of such supplier by a competitor, which may cause the supplier to stop selling its products to us, or the bankruptcy of such a supplier, which may cause the supplier to cease operations. A reduction or interruption by a sole-source supplier of the supply of materials or key components used in our tissue processing or our product manufacturing or an increase in the price of those materials or components could materially adversely impact our revenues, financial condition, profitability, and cash flows.

#### We May Be Unsuccessful In Our Efforts To Market And Sell PerClot In The U.S. And Internationally.

Even if we are able to obtain FDA approval to distribute PerClot in the U.S. according to our estimated timeline, we may be unsuccessful in our attempts to sell PerClot in the U.S. as other competing products may have penetrated the market by that time. Also, while we do not believe Medafor would have a valid reason to do so, based on our past history with Medafor, it is possible that Medafor may attempt to challenge the legality of our distribution of PerClot in both the U.S. and international markets or file a patent infringement action against us or SMI, the company that manufactures PerClot for us. If we are ultimately unable to distribute PerClot in the U.S., we would not be able to

fully realize the benefit of our investment in PerClot, which could materially adversely impact our financial condition, profitability, and future revenues. If Medafor were successful in its challenge to the legality of our distribution agreement or in a patent infringement action against us or SMI, it could materially adversely impact our revenues, financial condition, profitability and cash flows.



#### We Have Inherited Risks And Uncertainties Related To Cardiogenesis' Business.

In May 2011 we acquired Cardiogenesis, and Cardiogenesis is now operating as a subsidiary of CryoLife. We have inherited certain risks and uncertainties related to Cardiogenesis' business. These risks and uncertainties include the following:

- We may be unable to maintain revenues and achieve growth in revenues from Cardiogenesis' revascularization technologies in the future due to our dependence upon physician awareness of this technology as a safe, efficacious, and appropriate treatment for their patients;
- We will continue to purchase some of Cardiogenesis' key product components from single suppliers, and the loss of these suppliers could prevent or delay shipments of its products, delay its clinical trials, or otherwise adversely affect our Cardiogenesis business;
- If Cardiogenesis' independent contract manufacturers fail to timely deliver sufficient quantities of some of Cardiogenesis' products and components, our Cardiogenesis operations may be harmed;
- Cardiogenesis' contract manufacturers are at locations that may be at risk from earthquakes or other natural disasters;
- Cardiogenesis may have liability for actions that occurred prior to our acquisition of Cardiogenesis which could adversely affect us; and
- Cardiogenesis' internal control over financial reporting may not have been effective prior to the merger, which could impact the value of our investment in Cardiogenesis and potentially lead to lawsuits from former Cardiogenesis shareholders, which could have a significant and adverse effect on us.

Any of these conditions or contingencies could have a material adverse effect on our revenues, financial condition profitability, and cash flows.

#### We Have Inherited Risks And Uncertainties Related To Hemosphere's Business.

In May 2012 we acquired Hemosphere, and Hemosphere is now operating as a subsidiary of CryoLife. We have inherited certain risks and uncertainties related to Hemosphere's business. These risks and uncertainties include the following:

- The expansion of the geographic footprint and acceleration of domestic growth for HeRO Graft sales may require the formation of new relationships and contracts;
  - We may be unable to maintain existing HeRO Graft sales and/or expand into new territories;
- We may be unable to achieve international sales or grow such sales from Hemosphere's HeRO graft products in the future due to our dependence upon physician and patient acceptance, along with international economic conditions, foreign exchange rates and regulatory approvals in various jurisdictions;
- The estimated domestic, European and worldwide market opportunity for HeRO Graft, as well as the total addressable market for CryoLife products in general, may be incorrect and the market opportunity may shrink due

to factors beyond our control, including general economic conditions and government regulations;

- Sales growth via product enhancements will be subject to regulatory approvals and physician and patient acceptance, as well as successful innovation within our research and development department;
- Even if we experience successful sales growth for HeRO Graft, our margins would be impacted if we experience increased costs related to the manufacturing and distribution of HeRO Graft;
- HeRO Graft may not continue to experience continued reimbursement in the U.S. and existing reimbursement rates may not continue to expand due to regulatory or other reasons, and if patients are not able to receive reimbursement from their insurance providers for this product, sales could be materially impacted;
- HeRO Graft may not continue to provide the anticipated medical benefits, including the reduction of infections in patients and improved dialysis treatments;
- If the medical profession and patients do not perceive HeRO Graft to be a safe and effective product, our sales would be materially impacted and we may experience lawsuits as a result;
- Hemosphere integration costs could be much higher than expected or integration could be more time consuming or difficult than anticipated;
- Third-party intellectual property rights may limit the development and protection of intellectual property acquired from Hemosphere, which could adversely affect its value to us;
- Hemosphere's business relies on patent and trade secret laws, which are complex and may be difficult to enforce;
- Hemosphere may have liability for actions that occurred prior to our acquisition of Hemosphere, which could adversely affect us; and
- Hemosphere may have had undisclosed weaknesses in its internal controls, which could impact our internal control over financial reporting or adversely impact the value of the Hemosphere acquisition to us, which could have a material and adverse effect on us.

Any of these conditions or contingencies could have a material adverse effect on our revenues, financial condition, profitability, and cash flows.

We May Expand Through Acquisitions, Or Licenses Of, Or Investments In, Other Companies Or Technologies, Which May Result In Additional Dilution To Our Stockholders And Consume Resources That May Be Necessary To Sustain Our Business.

One of our business strategies is to acquire technologies, products, and licenses to grow our business. In connection with one or more of those transactions, we may:

- Issue additional equity securities that would dilute our stockholders' value;
  - Use cash that we may need in the future to operate our business;
- Incur debt that could have terms unfavorable to us or that we might be unable to repay; and

- Structure the transaction in a manner that has unfavorable tax consequences, such as a stock purchase that does not permit a step-up in the tax basis for the assets acquired.

Business acquisitions also involve the risk of unknown liabilities associated with the acquired business. In addition, we may not realize the anticipated benefits of any acquisition, including securing the services of key employees. Incurring unknown liabilities or the failure to realize the anticipated benefits of an acquisition could materially adversely impact our business.

We May Not Realize The Anticipated Benefits From Acquisitions And We May Find It Difficult To Integrate Recent Or Potential Future Acquisitions Of Technology Or Business Combinations, Which Could Disrupt Our Business, Dilute Stockholder Value, And Adversely Impact Our Operating Results.

Acquisitions involve the integration of companies that have previously operated independently. We expect that future acquisitions may result in financial and operational benefits, including increased revenues, cost savings, and other financial and operating benefits. We cannot be certain, however, that we will be able to realize increased revenues, cost savings, or other benefits from any acquisition, or to the extent such benefits are realized, that they are realized timely. Integration may also be difficult, unpredictable, and subject to delay because of possible cultural conflicts and different opinions on product roadmaps or other strategic matters. We may integrate or, in some cases, replace numerous systems, including those involving purchasing, accounting and finance, sales, billing, employee benefits, payroll, and regulatory compliance, many of which may be dissimilar. Difficulties associated with integrating an acquisition's service and product offering into ours, or with integrating an acquisition's operations into ours, could have a material adverse impact on the combined company and the market price of our common stock. Our integration efforts may not succeed or may distract our management's attention from existing business operations. Our failure to successfully manage and integrate recent technology acquisitions and any future acquisitions could materially adversely impact our business.

We Are Subject To Stringent Domestic And Foreign Regulation Which May Impede The Approval Process Of Our Tissues And Products, Hinder Our Development Activities And Manufacturing Processes, And, In Some Cases, Result In The Recall Or Seizure Of Previously Cleared Or Approved Tissues And Products.

Our tissues, products, development activities, tissue processing, and manufacturing processes are subject to extensive and rigorous regulation by the FDA, by comparable agencies in foreign countries, and by other regulatory agencies and governing bodies. Under applicable law, processors of human tissues and manufacturers of medical devices must comply with certain regulations that cover the composition, labeling, testing, clinical study, manufacturing, packaging, and distribution of tissues and products. In addition, medical devices must receive FDA clearance or approval before they can be commercially marketed in the U.S., and the FDA may require testing and surveillance programs to monitor the effects of approved products that have been commercialized and can prevent or limit further marketing of a product based on the results of these post-marketing programs. The process of obtaining marketing approval or clearance can take a significant period of time, require expenditure of substantial resources, and result in limitations on the indicated uses of the tissues and products. Furthermore, most major markets for tissues and products outside of the U.S. require clearance, approval, or compliance with certain standards before tissues and products can be commercially available. We cannot be certain that we will receive these required clearances or approvals from the FDA and foreign regulatory agencies on a timely basis. The failure to receive clearance or approval for significant new tissues and products on a timely basis could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

The FDA may conduct periodic inspections to determine compliance with applicable tissue and product regulations for any of our marketed tissues and products. Approvals by the FDA can be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial approval. In addition, the FDA could reevaluate our tissues or products, or the processes or solutions used with our tissues or products, and determine that they must go through additional approvals or require approvals where none were previously required. The failure to comply with regulatory standards, the discovery of previously unknown problems with tissues or products, or reevaluation of our tissues and products or the processes and solutions used with our tissues and products could result in fines; delays or suspensions of regulatory clearances; seizures or recalls of tissues, products, or solutions; the banning of a particular device; operating restrictions; or criminal prosecution. The related expenses and decreased revenues as a result of negative publicity and legal claims could have a material adverse impact on our revenues,

financial condition, profitability, and cash flows.

For example, in 2002 the FDA issued the FDA Order discussed above at “Our Tissues And Products Allegedly Have Caused And May In The Future Cause, Injury To Patients, And We Have Been, And May In The Future Be, Exposed To Tissue Processing And Product Liability Claims, Including One Currently Outstanding Product Liability Lawsuit, And Additional Regulatory Scrutiny As A Result.”

Our HemoStase Sales Ceased In Late March 2011, And We Will Not Be Able To Participate In The Hemostats Market In The U.S. Or Other Markets Where We Lack Regulatory Approval Unless We Can Obtain FDA Or Other Regulatory Approval For PerClot.

On September 27, 2010 Medafor, Inc. sent CryoLife a letter stating that Medafor was “fully, finally and immediately terminating” our exclusive distribution agreement, or EDA.

We have not had any revenues from HemoStase since first quarter of 2011. We began selling PerClot internationally in the fourth quarter of 2010, but unlike HemoStase, PerClot is not approved for sales in the U.S. where we sold the majority of our HemoStase product. In addition, PerClot is not approved for sales in all countries of the world in which HemoStase was approved. As a result, our anticipated 2012 revenues from PerClot will be materially lower than our 2010 HemoStase revenues. The FDA approval process for U.S. sales of PerClot is expected to be expensive and time-consuming, is not expected to be completed any sooner than 2013 or 2014, and is subject to many risks that could increase the costs or time involved or even prevent sales from ever occurring in the United States. See “We Will Not Fully Realize The Benefit Of Our Investment In Our Distribution And License And Manufacturing Agreements With Starch Medical, Inc. Unless We Are Able To Obtain FDA Approval For PerClot In The U.S., Which Will Require An Additional Commitment Of Funds,” above, for a discussion of these risks. The reduction in our revenues due to the loss of the HemoStase product, together with the uncertainty surrounding our ability to obtain FDA approval to market PerClot in the U.S., is expected to continue to materially adversely impact our revenues, financial condition, profitability, and cash flows.

We May Not Be Successful In Obtaining Necessary Clinical Results And Regulatory Approvals For Services And Products In Development, And Our New Services And Products May Not Achieve Market Acceptance.

Our growth and profitability will depend, in part, upon our ability to complete development of, and successfully introduce, new services and products. We are uncertain whether we can develop commercially acceptable new services and products. We must also expend significant time and resources to obtain the required regulatory approvals. Although we have conducted preclinical studies on certain services and products under development which indicate that such services and products may be effective in a particular application, we cannot be certain that the results we obtain from expanded clinical studies will be consistent with earlier trial results or be sufficient for us to obtain any required regulatory approvals or clearances. We cannot give assurance that we will not experience difficulties that could delay or prevent us from successfully developing, introducing, and marketing new services and products. We also cannot give assurance that the regulatory agencies will clear or approve these or any new services and products on a timely basis, if ever, or that the new services and products will adequately meet the requirements of the applicable market or achieve market acceptance.

Our ability to complete the development of any of our services and products is subject to all of the risks associated with the commercialization of new services and products based on innovative technologies. Such risks include unanticipated technical or other problems, processing or manufacturing difficulties, and the possibility that we have allocated insufficient funds to complete such development. Consequently, we may not be able to successfully introduce and market our services or products which are under development, or we may not be able to do so on a timely basis. These services and products may not meet price or performance objectives and may not prove to be as effective as competing services and products. If we are unable to successfully complete the development of a service, product, or application, or if we determine for financial, technical, or other reasons not to complete development or obtain regulatory approval or clearance of any service, product, or application, particularly in instances when we have expended significant capital, this could have a material adverse impact on our revenues, financial condition, profitability, and cash flows. Research and development efforts are time consuming and expensive, and we cannot be sure that these efforts will lead to commercially successful services or products. Even the successful

commercialization of a new service or product in the medical industry can be characterized by slow growth and high costs associated with marketing, under-utilized production capacity, and continuing research and development and education costs. The introduction of new services or products may require significant physician training and years of clinical evidence derived from follow-up studies on human implant recipients in order to gain acceptance in the medical community. Our potential new services or products currently under development include the following:



- PerClot in the U.S. and other jurisdictions,
  - CryoValve SGAV,
  - BioFoam in the U.S.,
- Cardiogenesis' Phoenix System, for combining TMR with the delivery of biologics, such as stem cells, ProPatch and related products,
  - HeRO Graft modifications,
  - SynerGraft processed tissues, and
  - New indications for BioGlue.

Uncertainties Related To Patents And Other Proprietary Technology Rights May Adversely Impact The Value Of Our Intellectual Property Or May Result In Our Payment Of Significant Monetary Damages and/or Royalty Payments, Negatively Impact Our Ability To Sell Current Or Future Products, Or Prohibit Us From Enforcing Our Patent and Other Proprietary Technology Rights Against Others.

We operate in an industry characterized by extensive patent litigation. We own several patents, patent applications, and licenses relating to our technologies, which we believe provide us with important competitive advantages. In addition, we have certain proprietary technologies and methods that provide us with important competitive advantages. We cannot be certain that our pending patent applications will issue as patents or that no one will challenge the validity or enforceability of any patent that we own. We also cannot be certain that if anyone does make such a challenge, that we will be able to successfully defend that challenge. We may have to incur substantial litigation costs to uphold the validity and prevent infringement of a patent or to protect our proprietary technologies and methods. Furthermore, competitors may independently develop similar technologies or duplicate our technologies or design around the patented aspects of such technologies. In addition, our technologies or products or services could infringe patents or other rights owned by others. If we are sued for patent infringement or violation of other proprietary technology rights owned by others, an adverse result could result in significant damage awards and injunctions that could prevent our manufacture and sale of affected products or services or require us to pay significant royalties in order to continue to manufacture or sell affected products or services. Patent litigation, whether we are enforcing our patents or are being sued for patent infringement, is expensive and along with any adverse judgment or settlement could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

Intense Competition May Impact Our Ability To Operate Profitably.

We face competition from other companies engaged in the following lines of business:

- The processing and preservation of human tissue,
- The marketing of mechanical, synthetic, and animal-based tissue valves for implantation,
  - The marketing of surgical adhesives, surgical sealants, and hemostatic agents,
  - The marketing of products to treat coronary artery disease, and

- The marketing of products to treat end-stage renal disease.

Management believes that at least two domestic tissue banks offer preserved human heart valves and many companies offer porcine, bovine, and mechanical heart valves, including St. Jude Medical, Inc., Medtronic, Inc., and Edwards Life Sciences.

Our BioGlue product competes with other surgical adhesives and surgical sealants, including Baxter International, Inc.'s Tisseel, CoSeal, and TachoSil; Ethicon, Inc.'s, (a Johnson & Johnson Company), Evicel and Omnex; Covidien, Ltd.'s U.S. Surgical Division's Duraseal product; Tenaxis's ArterX; and Neomend, Inc.'s ProGel. Other large medical device, pharmaceutical, and biopharmaceutical companies may also be developing competitive products. Our BioGlue product competes on the basis of its high tensile strength and ease of use.

Our BioFoam product competes with other surgical hemostatic agents that include Pfizer, Inc.'s Gelfoam; Baxter International, Inc.'s FloSeal; Ethicon, Inc.'s Spongostan, Instat, Surgicel, and Surgicel Nu-Knit; C.R. Bard, Inc.'s Avitene; Nycomed's TachoSil; and Orthovita, Inc.'s Vitagel. Other medical device, pharmaceutical, and biopharmaceutical companies may also develop competitive products. Our BioFoam product competes on the basis of its clinical efficacy and ease of use.

Our PerClot product competes with thrombin products, including King Pharmaceuticals, Inc.'s Thrombin JMI; ZymoGenetics, Inc.'s Recothrom; and Omrix Biopharmaceuticals, Inc.'s, (a Johnson & Johnson Company), Evithrom; and surgical hemostats, including Pfizer, Inc.'s Gelfoam; C.R. Bard, Inc.'s Avitene; Baxter International, Inc.'s FloSeal; Ethicon, Inc.'s Surgicel, Surgiflo, and Surgifoam; and Medafor's Arista, which we previously distributed as HemoStase. We are also aware that a few companies have surgical hemostat products under development. Other medical device, pharmaceutical, and biopharmaceutical companies may also be developing competitive products. Our PerClot product competes on the basis of its safety profile, clinical efficacy, absorption rates, and ease of use.

Our HeRO Graft product competes with other products on the market that treat central venous stenosis, such as balloon angioplasty, bare metal and covered stents, as well as competing with open surgical venous reconstruction procedures. Tunneled Dialysis Catheters (TDCs) are the main competitor to HeRO Graft in treating end-stage renal disease patients who have exhausted all of their options with AV fistulas and/or grafts. TDCs are manufactured by several major medical device companies such as C.R. Bard, Medcomp, Arrow (a Teflex Company), Covidien, and AngioDynamics. Other medical device, pharmaceutical, and biopharmaceutical companies may also be developing competitive products. Our HeRO graft product competes on the basis of its reduced infection rates, clinical efficacy, and overall cost savings.

Many of our competitors have greater financial, technical, manufacturing, and marketing resources than we do and are well established in their markets. We have increased fees and prices on some of our international services and products since January 1, 2011. This increase may provide an opportunity for our competitors to gain market share. If we are unable to continue to increase prices as planned and retain or improve our market share, our ability to grow revenues and profits may be materially adversely impacted.

We cannot give assurance that our tissues and products will be able to compete successfully. Any products that we develop that gain regulatory clearance or approval will have to compete for market acceptance and market share. In addition, our competitors may gain competitive advantages that may be difficult to overcome. If we fail to compete effectively, this could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

If We Are Not Successful In Expanding Our Business Activities In International Markets, We May Be Unable To Increase Our Revenues.

Our international operations are subject to a number of risks which may vary from the risks we face in the U.S., including:

- Difficulties and costs associated with staffing and managing foreign operations, including foreign distributor relationships,
- Longer accounts receivable collection cycles in certain foreign countries and additional cost of collection of those receivables,
  - More limited protection for intellectual property in some countries,

- Changes in currency exchange rates,

- Adverse economic or political changes,
- Unexpected changes in regulatory requirements and tariffs,
- Potential trade restrictions, exchange controls, and import and export licensing requirements, and
- Potentially adverse tax consequences of overlapping tax structures.

Our failure to adequately address these risks could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

#### We Are Dependent On The Availability Of Sufficient Quantities Of Tissue From Human Donors.

The success of our tissue preservation services depends upon, among other factors, the availability of sufficient quantities of tissue from human donors. We rely primarily upon the efforts of third party procurement organizations, tissue banks, most of which are not-for-profit, and others to educate the public and foster a willingness to donate tissue. If the supply of donated human tissue is materially reduced, this would restrict our growth and could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

#### Key Growth Strategies May Not Generate The Anticipated Benefits.

The key elements of our strategy related to growing our business and leveraging our strength and expertise in our core marketplaces to generate revenue and earnings growth are to:

- Identify and evaluate acquisition opportunities of and investments in complementary product lines and companies,
  - Expand our core business,
  - Develop our pipeline of services and products,
    - License Company technology to third parties for non-competing uses, and
    - Analyze and identify underperforming assets for potential sale or disposal.

Although management has begun implementing these strategies, we cannot be certain that they will ultimately enhance shareholder value.

#### Investments In New Technologies And Acquisitions Of Products Or Distribution Rights May Not Be Successful.

We may invest in new technology licenses and acquire products or distribution rights that may not succeed in the marketplace. In such cases we may be unable to recover our initial investment, which could include the cost of acquiring license or distribution rights, acquiring products, purchasing initial inventory, or investments in early stage companies. Inability to recover our investment or any write off of such investment may materially adversely impact our financial condition and profitability.

**Regulatory Action Outside Of The U.S. Has Affected Our Business In The Past And May Affect Our Business In The Future.**

After the FDA issued the FDA Order, discussed above at “Our Tissues And Products Allegedly Have Caused, And May In The Future Cause, Injury To Patients, And We Have Been, And May In The Future Be, Exposed To Tissue Processing And Product Liability Claims, Including One Currently Outstanding Product Liability Lawsuit, And Additional Regulatory Scrutiny As A Result,” Health Canada also issued a recall of the same types of tissue. In addition, other countries have made inquiries regarding the tissues that we export, although these inquiries are now, to our knowledge, complete. In the event other countries raise additional regulatory concerns, we may be unable to export tissues to those countries. Regulatory concerns could also be raised regarding the products we market internationally, including BioGlue, BioFoam and PerClot. Revenues from international tissue preservation services were approximately \$2.7 million, \$2.3 million, and \$1.6 million, for the years ended December 31, 2011, 2010, and 2009, respectively. International revenues from product sales, which includes international BioGlue, BioFoam, HemoStase, and PerClot revenues, were approximately \$21.0 million, \$17.3 million, and \$16.0 million, for the years ended December 31, 2011, 2010, and 2009, respectively. Loss of all or a material portion of our international revenues would have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

Consolidation In The Healthcare Industry Could Continue To Result In Demands For Price Concessions, Limits On The Use Of Our Tissues And Products, And Limitations On Our Ability To Sell To Certain Of Our Significant Market Segments.

The cost of healthcare has risen significantly over the past decade and numerous initiatives and reforms initiated by legislators, regulators, and third-party payors to curb these costs have resulted in a consolidation trend in the medical device industry as well as among our customers, including healthcare providers. This in turn has resulted in greater pricing pressures and limitations on our ability to sell to important market segments, as group purchasing organizations, independent delivery networks, and large single accounts continue to consolidate purchasing decisions for some of our customers. We expect that market demand, government regulation, third-party reimbursement policies, and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances which may exert further downward pressure on the fees charged for our tissues and prices for our products, which could materially adversely impact our revenues, financial condition, profitability, and cash flows.

Extensive Government Regulation May Adversely Impact Our Ability To Develop And Market Services And Products.

Government regulation in the U.S., Europe, Asia and other jurisdictions can determine the success of our efforts and our competitors' efforts to market and develop services and products. Most of our services and products in development, if successfully developed, will require regulatory approvals from the FDA and perhaps other regulatory authorities before they may be commercially distributed, including in most instances a PMA. The process of obtaining a PMA from the FDA normally involves clinical trials as well as an extensive PMA application and often takes many years. Some products may qualify for clearance to be marketed under a Section 510(k) process, in which the manufacturer provides a premarket notification that it intends to begin marketing a product, and shows that the product is substantially equivalent to another legally marketed predicate product. While more streamlined than the full PMA process, the 510(k) notification process may also require clinical trials and take many years. For example, the 510(k) clearance for the CryoValve SGPV took four years. The process for approval or clearance from the FDA is expensive and can vary significantly based on the type, complexity, and novelty of the product. We cannot give any assurance that any services and products developed by us, independently or in collaboration with others, will receive the required approvals or clearances for processing or manufacturing and marketing.

Delays in obtaining U.S. or foreign approvals could result in substantial additional costs and adversely impact our competitive position. The FDA may also place conditions on service or product approvals that could restrict commercial applications of our services or products. The FDA may withdraw service and product marketing approvals or clearances if we do not maintain compliance with regulatory standards, if problems occur following initial marketing, or based on the results of post-market studies. Delays imposed by the governmental approval and clearance process may materially reduce the period during which we have the exclusive right to commercialize patented services and products.

Delays or rejections may also be encountered by us during any stage of the regulatory approval process if clinical or other data fails to satisfactorily demonstrate compliance with, or if the service or product fails to meet, the regulatory agency's requirements for safety, efficacy, and quality. Those requirements may become more stringent due to changes in applicable laws, regulatory agency policies, or the adoption of new regulations. Clinical trials may also be delayed due to the following:





- Unanticipated side effects,
  - Lack of funding,
- Inability to locate or recruit clinical investigators,
- Inability to locate, recruit, and qualify sufficient numbers of patients,
  - Redesign of clinical trial programs,
- Inability to manufacture or acquire sufficient quantities of the particular tissue, product, or any other components required for clinical trials,
  - Changes in development focus, and
  - Disclosure of trial results by competitors.

Even if we are able to obtain regulatory approval for any services or products offered, the scope of the approval may significantly limit the indicated usage for which such services or products may be marketed. The unapproved use of our tissues or products could adversely impact the reputation of our Company and our services and products. Services or products marketed pursuant to FDA or foreign oversight or foreign approvals are subject to continuing regulation and periodic inspections. Labeling and promotional activities are also subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The export of devices and biologics is also subject to regulation and may require FDA approval. From time to time, the FDA may modify such regulations, imposing additional or different requirements. If we fail to comply with applicable FDA requirements, which may be ambiguous, we could face civil and criminal enforcement actions, warnings, citations, product recalls or detentions, and other penalties. This could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

In addition, the National Organ Transplant Act of 1984, or “NOTA,” prohibits the acquisition or transfer of human organs for valuable consideration for use in human transplantation. NOTA permits the payment of reasonable expenses associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of human organs. Congress could adopt more restrictive interpretations of NOTA in the future that challenge one or more aspects of industry methods of charging for preservation services. Our laboratory operations, and those of our competitors, are subject to the U.S. Department of Labor, Occupational Safety and Health Administration, and U.S. Environmental Protection Agency requirements for prevention of occupational exposure to infectious agents and hazardous chemicals and protection of the environment. Some states have enacted statutes and regulations which govern the processing, transportation, and storage of human organs and tissue.

The EU has three separate directives called the EUCTD that establish a benchmark standard for the regulation of tissues and cells to be implanted in humans. The EUCTD requires that countries in the European Economic Area take responsibility for regulating tissues and cells through a Competent Authority. Although Europa, our subsidiary, has a license to ship tissue into the United Kingdom and a provisional license to distribute tissue into Germany through those countries’ Competent Authorities, these countries could change their regulations or processes, and, thereby, increase the cost to us of distribution, or modify or eliminate our ability and Europa’s ability to distribute tissue into the United Kingdom and Germany. In addition, Europa ships tissue into Austria, which currently has no Competent Authority. When Austria puts in place its Competent Authority, it could cause CryoLife and Europa to cease distribution of tissue into Austria temporarily or permanently or increase the costs to do so materially.

In addition, U.S. and foreign governments and regulatory agencies may adopt more restrictive laws or regulations in the future that could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

#### The Success Of Many Of Our Tissues And Products Depends Upon Strong Relationships With Physicians.

If we fail to maintain our working relationships with physicians, many of our tissues and products may not be developed and marketed to appropriately meet the needs and expectations of the professionals who use and support our tissues and products. The research, development, marketing, and sales of many of our new and improved tissues and products are dependent upon our maintaining working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding our tissues and products and their marketing. Physicians assist us as researchers, marketing consultants, product consultants, and public speakers.

Certain states have begun to regulate interactions with physicians and other healthcare professionals. There is existing legislation and regulations that govern interactions with physicians and other healthcare professionals, and there is proposed legislation and regulations that govern interactions with physicians and other healthcare professionals that are currently before state legislatures and the U.S. Congress. For example, unless implementation is further delayed by the Department of Health and Human Services, Congress, or the courts, beginning in 2013, we will have to disclose payments made to physicians for meals or other services in 2012 to the Department of Health and Human Services. These existing regulations and legislation currently impact our ability to maintain strong relationships with physicians, and may in the future, further impact our relationships with physicians and the proposed regulations and legislation, if passed or implemented, may impact our ability to maintain strong relationships with physicians in the future. If we are unable to maintain our strong relationships with these professionals and do not continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

#### Our Existing Insurance Policies May Not Be Sufficient To Cover Our Actual Claims Liability.

Our tissues and products allegedly have caused, and may in the future cause, injury to patients using our tissues or products, and we have been, and may be, exposed to tissue processing and product liability claims. We maintain claims-made insurance policies to mitigate our financial exposure to tissue processing and product liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. Thus, a claims-made policy does not generally represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier during the policy period.

Our December 31, 2011 Consolidated Balance Sheet reflects a \$2.0 million liability for the estimated cost of resolving unreported tissue processing and product liability claims. We believe that the liability could be estimated to be as high as \$3.7 million, after including a reasonable margin for statistical fluctuations. Based on an actuarial valuation, we estimated that as of December 31, 2011, \$700,000 of the accrual for unreported liability claims would be recoverable under our insurance policies. These amounts represent management's estimate of the probable losses and anticipated recoveries for unreported liability claims related to services performed and products sold prior to December 31, 2011. Actual results may differ from this estimate. Our tissue processing and product liability insurance policies do not include coverage for any punitive damages.

If we are unsuccessful in arranging acceptable settlements of future tissue processing or product liability claims or future securities class action or derivative claims, we may not have sufficient insurance coverage and liquid assets to meet these obligations. Additionally, if one or more claims with respect to which we become hereafter a defendant should be tried with a substantial verdict rendered in favor of the plaintiff(s), such verdict(s) could exceed our available insurance coverage and liquid assets. If we are unable to meet required future cash payments to resolve any outstanding or any future claims, this will materially adversely impact our financial condition, profitability, and cash flows. Further, if the costs of pending or incurred but unreported tissue processing and product liability claims exceed

our current estimates, our financial condition, profitability, and cash flows may be materially adversely impacted. If we do not have sufficient resources to pay any future verdicts rendered against us, we may be forced to cease operations or seek protection under applicable bankruptcy laws.

#### We May Be Unable To Obtain Adequate Insurance At A Reasonable Cost, If At All.

If we are unable to obtain satisfactory insurance coverage in the future, we may be subject to additional future exposure from tissue processing and product liability claims. Additionally, insurance rates may be significantly higher than in the past, and insurers may provide less coverage, which may materially adversely impact our financial condition, profitability, and cash flows. In addition, should we be subject to liability, whether imposed by a court or due to a settlement that results in a large insurance claim, our insurance rates could increase significantly. Our current tissue processing and product liability insurance policy is a ten-year claims-made policy covering claims incurred during the period April 1, 2003 through March 31, 2013 and reported during the period April 1, 2012 through March 31, 2013. Claims incurred prior to April 2003 that have not been reported are uninsured. Any punitive damage components of claims are also uninsured.

#### We Are Not Insured Against All Potential Losses. Natural Disasters Or Other Catastrophes Could Adversely Impact Our Business, Financial Condition, And Profitability.

Our facilities could be materially damaged by tornadoes, flooding, other natural disasters, or catastrophic circumstances. For example, our current facility in Kennesaw, Georgia, is the central location for all of our tissue processing and most of our BioGlue manufacturing. If this facility were to be materially damaged by a natural disaster it would cause a loss of processing and production and additional expenses to us to the extent any such damage is not fully covered by our business interruption and disaster insurance.

Even with insurance coverage, natural disasters or other catastrophic events could cause us to suffer substantial losses in our operational capacity and could also lead to a loss of opportunity and to a potential adverse impact on our relationships with our existing customers resulting from our inability to process tissues or produce products for them, for which we would not be compensated by existing insurance. This in turn could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

#### Our Credit Facility, Which Expires In October Of 2014, Limits Our Ability To Pursue Significant Acquisitions.

Our credit facility, which expires in October of 2014, prohibits mergers and acquisitions other than certain permitted acquisitions. Permitted acquisitions include certain stock acquisitions and non-hostile acquisitions that have been approved by the Board of Directors and/or the stockholders of the target company if, after giving effect to the acquisition, there is no event of default under the credit facility and there is still at least \$1.5 million available to be borrowed under the credit facility. The total consideration that we pay or are obligated to pay for all acquisitions consummated during the term of the credit facility, less the portion of any such consideration funded by the issuance of common or preferred stock, may not exceed an aggregate of \$15.0 million. As a result, our ability to consummate acquisitions and fully realize our growth strategy may be materially adversely impacted while this credit facility remains in effect. Any credit facility we subsequently enter into may have similar or more stringent restrictions on our ability to pursue significant acquisitions.

#### Our Ability To Borrow Under Our Credit Facility May Be Limited.

Our credit facility contains a number of affirmative covenants that we must satisfy before we can borrow. For example, we must satisfy specified leverage ratios, and there are also varying levels of adjusted earnings before interest, taxes, depreciation, and amortization under the credit facility that we have covenanted to maintain during the term of the credit facility. Failure to satisfy any of these requirements could limit our borrowing ability and materially adversely impact our liquidity.

Continued Fluctuation Of Foreign Currencies Relative To The U.S. Dollar Could Materially Adversely Impact Our Business.

The majority of our foreign tissue processing and product revenues are denominated in British Pounds and Euros and, as such, are sensitive to changes in exchange rates. In addition, a portion of our dollar-denominated product sales are made to customers in other countries who must convert local currencies into U.S. Dollars in order to purchase these products. We also have balances, such as cash, accounts receivable, accounts payable, and accruals that are denominated in foreign currencies. These foreign currency transactions and balances are sensitive to changes in exchange rates. Fluctuations in exchange rates of British Pounds and Euros or other local currencies in relation to the U.S. Dollar could materially reduce our future revenues as compared to the comparable prior periods. Should this occur, it could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

#### Rapid Technological Change Could Cause Our Services And Products To Become Obsolete.

The technologies underlying our services and products are subject to rapid and profound technological change. Competition intensifies as technical advances in each field are made and become more widely known. We can give no assurance that others will not develop services, products, or processes with significant advantages over the services, products, and processes that we offer or are seeking to develop. Any such occurrence could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

#### Our CryoValve SGPV Post-Clearance Study May Not Provide Expected Results.

At the FDA's request, we are conducting a post-clearance study to seek evidence for the potential and implied long-term benefits of the SynerGraft process used to process the CryoValve SGPV. The data to be collected includes long-term information on safety, hemodynamic function, immune response, and explant analysis. Although we believe that this information may help us ascertain whether the SynerGraft process reduces the immune response of the transplanted human heart valve and allows for the collagen matrix to recellularize with the recipient's own cells, it is possible that the results of the study will not be as expected. If this study shows that the SynerGraft process does not reduce immune response and/or cause the collagen matrix to recellularize with the recipient's cells, we may be unable to realize some or all of the long-term benefits that we anticipated for the use of this process, and the Company may not be able to continue to process a portion of its human pulmonary valves and cardiac patch tissues with the SynerGraft technology.

#### Our Investment In ValveXchange, Inc. May Become Impaired, Which Could Have A Material Adverse Impact On Our Earnings.

In July 2011 we purchased approximately 2.4 million shares of Series A Preferred Stock of ValveXchange, Inc. ("ValveXchange") for approximately \$3.5 million. ValveXchange is a private medical device company that was spun off from Cleveland Clinic to develop a lifetime heart valve replacement technology platform featuring exchangeable bioprosthetic leaflets. CryoLife's carrying value of this investment includes the purchase price and certain transaction costs, and CryoLife's investment represents an approximate 19% equity ownership in ValveXchange.

In accordance with accounting principles generally accepted in the U.S. ("GAAP"), we regularly review our investments based on available information and make determinations regarding the value of our investments. While we are not currently aware of any factors that would require us to reevaluate our investment in ValveXchange or record an impairment of this investment, we have in the past recorded an impairment of our investment in Medafor, as described above at "Our Investment In Medafor May Have Been Further Impaired Due To Medafor's Termination Of Our Exclusive Distribution Agreement With It, Which Could Have A Material Adverse Impact On Our Financial Condition And Profitability." In the future, factors beyond our control could cause us to take similar action with respect to our ValveXchange investment. In such an event, if we ultimately determined that we were required to write down the carrying value of our investment in ValveXchange, our earnings could be materially adversely impacted, depending on the extent of the impairment.

#### We Are Dependent On Our Key Personnel.

Our business and future operating results depend in significant part upon the continued contributions of our key field personnel and senior management, many of whom would be difficult to replace, including our Chief Executive Officer, Steven G. Anderson, whose employment agreement expires in December 2012. Our business and future operating results also depend in significant part upon our ability to attract and retain qualified management, processing, marketing, sales, and support personnel for our operations. Competition for such personnel is intense, and

we cannot ensure that we will be successful in attracting and retaining such personnel. We do not have key life insurance policies on any of our key personnel. If we lose any key employees, if any of our key employees fail to perform adequately, or if we are unable to attract and retain skilled employees as needed, this could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.



### Risks Related To Our Common Stock

Trading Prices For Our Common Stock, And For The Securities Of Biotechnology Companies In General, Have Been, And May Continue To Be, Volatile.

The trading price of our common stock has been subject to wide fluctuations and may continue to be volatile in the future. Trading price fluctuations can be caused by a variety of factors, many of which are beyond our control, including:

- Governmental regulatory acts,
- Regulatory actions such as adverse FDA activity,
- Other actions taken by government regulators,
- General conditions in the medical device or service industries,
- Announcement of technological innovations or new products by us or our competitors,
- Tissue processing and product liability claims,
- Developments with respect to patents or proprietary rights,
- Variations in operating results, and
- Changes in earnings estimates by securities analysts.

If our revenues or operating results in future quarters fall below the expectations of securities analysts and investors, the price of our common stock would likely decline, perhaps substantially. If our share prices do not meet the requirements of the New York Stock Exchange, our shares may be delisted. The closing price of our common stock has ranged from a high of \$16.35 to a low of \$4.00 in the period from January 1, 2008 to June 21, 2012.

In addition, changes in the trading price of our common stock may bear no relation to our actual operational or financial results. The market prices of the securities of biotechnology companies have been highly volatile and are likely to remain highly volatile in the future. This volatility has often been unrelated to the operating performance of particular companies. In the past, companies that experienced volatility in the market price of their securities have often faced securities class-action litigation. Moreover, market prices for stocks of biotechnology and technology companies frequently reach levels that bear no relationship to the operating performance of these companies. These market prices generally are not sustainable and are highly volatile. Whether or not meritorious, litigation brought against us could result in substantial costs, divert our management's attention and resources, and materially adversely impact our financial condition, profitability, and cash flows.

Anti-Takeover Provisions May Discourage Or Make More Difficult An Attempt To Obtain Control Of Us.

Our Articles of Incorporation and Bylaws contain provisions that may discourage or make more difficult any attempt by a person or group to obtain control of our Company, including provisions authorizing the issuance of preferred stock without shareholder approval, restricting the persons who may call a special meeting of the shareholders, and prohibiting shareholders from taking action by written consent. In addition, we are subject to certain provisions of

Florida law that may discourage or make more difficult takeover attempts or acquisitions of substantial amounts of our common stock. Further, pursuant to the terms of a shareholder rights plan adopted in 1995 and amended in 2005, each outstanding share of common stock has one attached right. The rights will cause substantial dilution of the ownership of a person or group that attempts to acquire our Company on terms not approved by the Board of Directors and may deter hostile takeover attempts. These provisions could potentially deprive our stockholders of opportunities to sell shares of our stock at above-market prices.

We Have Not Paid Cash Dividends On Our Common Stock And May Be Unable To Do So Due To Contractual Restrictions.

We have not paid cash dividends on our common stock. In addition, our credit agreement prohibits us from paying cash dividends without the lender's approval. The terms of any future financing arrangements that we may enter into may also restrict our ability to pay dividends.

## FORWARD LOOKING STATEMENTS

This prospectus includes and incorporates by reference "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act. Forward-looking statements give our current expectations or forecasts of future events. The words "could," "may," "might," "will," "would," "shall," "should," "pro forma," "potential," "pending," "intend," "expect," "anticipate," "estimate," "plan," "future" and other similar expressions generally identify forward-looking statements including, in particular, statements regarding future services, market expansion, revenues, cost savings, regulatory activity, available funds and capital resources, and pending litigation. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned not to place undue reliance on these forward-looking statements, which are as of their respective dates. Such forward-looking statements reflect the views of our management at the time such statements are made and are subject to a number of risks, uncertainties, estimates and assumptions, including, without limitation, in addition to those identified in the text surrounding such statements, those identified under "Risk Factors" and elsewhere in this prospectus.

All statements, other than statements of historical facts, included herein that address activities, events or developments that CryoLife expects or anticipates will or may occur in the future, are forward-looking statements, including statements regarding:

- Advantages of the human tissues CryoLife distributes;
- Plans regarding regulatory approval of PerClot and the PHOENIX Combination Delivery System;
  - Beliefs regarding the potential benefits of combining TMR with the delivery of biologics;
- Our expectations regarding continued and expanding reimbursement rates for our HeRO Graft product;
  - CryoLife's continuing research and development activities;
- Intentions regarding the use of the net proceeds from the sale of securities offered in this prospectus;
- Our expectations regarding the effects of recent and potential future acquisitions of businesses and technologies;
- Our expectations regarding the effects of recent healthcare reform legislation, including the amounts of taxes we may pay, which are uncertain because the government has not released the final implementing regulations; and
  - Other statements regarding future plans and strategies, anticipated events, or trends.

These statements are based on certain assumptions and analyses made by CryoLife in light of its experience and its perception of historical trends, current conditions, and expected future developments as well as other factors it believes are appropriate in the circumstances. However, whether actual results and developments will conform with CryoLife's expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially from CryoLife's expectations, including the risk factors discussed in this prospectus and other factors, many of which are beyond the control of CryoLife. Consequently, all of the forward-looking statements made or incorporated by reference in this prospectus are qualified by these cautionary statements and there can be no assurance that the actual results or developments anticipated by CryoLife will be realized or, even if substantially realized, that they will have the expected consequences to or effects on CryoLife or its business or

operations. CryoLife assumes no obligation to update publicly any such forward-looking statements, whether as a result of new information, future events, or otherwise.

## USE OF PROCEEDS

Unless otherwise indicated in any prospectus supplement, we do not expect to receive proceeds from the offering of any common stock or warrants pursuant to this prospectus other than the businesses, assets or securities acquired in a business combination transaction.

## DESCRIPTION OF CAPITAL STOCK

### Description of Capital Stock

The Company is authorized to issue up to 75,000,000 shares of Common Stock, \$.01 par value, and 5,000,000 shares of Preferred Stock, \$.01 par value. As of June 22, 2012, there were 27,415,618 shares of Common Stock outstanding net of 2,687,074 treasury shares. They were held by approximately 413 shareholders of record. There were no shares of Preferred Stock outstanding as of June 22, 2012.

The following summary is qualified in its entirety by reference to the Company's Amended and Restated Articles of Incorporation, the Company's Amended and Restated Bylaws and the Florida Business Corporation Act (the "FBCA").

### Common Stock

Holders of Common Stock are entitled to one vote per share of Common Stock held of record on all matters to be voted upon by the Company's shareholders generally. Holders of Common Stock are not entitled to cumulative voting rights. As a result, the holders of a majority of the shares of Common Stock voting for the election of directors may elect all of the Company's directors if they choose to do so, and, in such event, the holders of the remaining shares of Common Stock will not be able to elect any person or persons to the Board of Directors.

Holders of Common Stock are entitled to receive, on a pro rata basis, such dividends and distributions, if any, as may be declared from time to time by the Board of Directors out of funds legally available therefor, subject to any preferential dividend right of any issued and outstanding shares of Preferred Stock. In the event of liquidation, dissolution or winding up of the Company, after payment of creditors, holders of Common Stock are entitled to share ratably in all assets, subject to the payment of any liquidation preference of any issued and outstanding shares of Preferred Stock. The shares of Common Stock currently outstanding are validly issued, fully paid and non-assessable.

### Preferred Stock

The Board of Directors of the Company is empowered, without approval of the Company's shareholders, to cause shares of Preferred Stock (the "Preferred Stock") to be issued in one or more series and to fix and determine the relative rights and preferences of the shares of any such series, subject to the limits of Florida law. Because the Board of Directors has the power to establish the preferences and rights of each series, it may afford the holders of any series of Preferred Stock preferences, powers and rights, voting or otherwise, senior to the rights of holders of Common Stock.



While providing desirable flexibility for possible acquisitions and other corporate purposes, and eliminating delays associated with a shareholder vote on specific issuances, the issuance of Preferred Stock could adversely affect the voting power of holders of common stock, as well as dividend and liquidation payments on both Common Stock and Preferred Stock. It also could have the effect of delaying, deferring or preventing a change in control of CryoLife. 2,000,000 shares of authorized but unissued preferred stock have been reserved for issuance as Series A Junior Participating Preferred Stock in connection with our shareholder rights plan, as described at “—Shareholder Rights Plan” below.

#### Stock Options and Restricted Stock Awards

As of June 22, 2012, the Company had issued and outstanding options to purchase an aggregate of approximately 2,147,099 shares of Common Stock (net of forfeitures, expirations and cancellations) pursuant to its stock incentive plans, at exercise prices between \$4.83 and \$13.37. Of such options, approximately 1,488,633 were exercisable as of June 22, 2012. The Company’s stock incentive plans also provide for grants of restricted stock awards (“RSA”s), restricted stock units (“RSU”s) and performance shares. The RSAs, and RSUs granted by the Company typically vest over a one to three-year period. The performance shares issued by the Company vest based on the achievement of Company performance criteria as well as the passage of time. As of June 22, 2012, the Company had issued and outstanding approximately 639,007 shares of restricted stock that are subject to future time-based vesting and a risk of forfeiture. As of June 22, 2012, under the incentive plans, the Company has granted outstanding RSUs representing 95,798 shares of common stock and performance shares representing 158,671 shares of common stock at target levels, and may grant additional RSAs, RSUs and performance shares representing up to 2,947,637 shares of common stock, assuming that no performance shares earn common stock in excess of the target number of shares.

#### Articles of Incorporation and Bylaws

Certain provisions of the Articles of Incorporation and Bylaws of the Company and of Florida law, which are summarized below, could have the effect of making it more difficult to change the composition of the Company’s Board of Directors or for any person or entity to acquire control of the Company.

#### Special Meetings

Pursuant to the Company’s Articles of Incorporation and Bylaws, special meetings of the shareholders may be called only by the President or Secretary at the request in writing of a majority of the Board of Directors then in office or at the request in writing of shareholders owning not less than 50% of all votes entitled to be cast at the special meeting.

#### Prohibition of Shareholder Action Without Meeting

Under the Company’s Articles of Incorporation, the shareholders may not take action by written consent. Any and all action by the shareholders is required to be taken at the annual shareholders’ meeting or at a special shareholders’ meeting.

#### Anti-Takeover Statute

The Company is subject to FBCA Section 607.0901, which provides that, subject to certain exceptions, an “affiliated transaction” must be approved by the holders of two-thirds of the voting shares other than those beneficially owned by an “interested shareholder” unless the corporation has elected to opt out of this requirement in its Articles of Incorporation or its Bylaws. The Company has not elected to opt out of this requirement, which may have the effect

of making it more difficult for any person or group to acquire the Company or substantial amounts of the Company's Common Stock.



### Ability to Consider Other Constituencies

The Directors of the Company are subject to the “general standards for Directors” provisions set forth in Section 607.0830 of the FBCA. These provisions provide that, among other things, in discharging his or her duties and determining what is in the best interests of the Company, a Director may consider such factors as the Director deems relevant, including the long-term prospects and interests of the Company and its shareholders, and the social, economic, legal or other effects of any proposed action on the employees, suppliers or customers of the Company, the communities in which the Company operates and the economy in general. Consequently, in connection with any proposed corporate action, the Board of Directors is empowered to consider interests of other constituencies in addition to the interests of the Company’s shareholders. Shareholders should be aware that Directors who take into account these other factors may make decisions which are less beneficial to the shareholders than if the law did not permit consideration of such other factors.

### Shareholder Rights Plan

In November 1995, the Board of Directors of the Company established a rights plan, pursuant to which one preferred share purchase right (a “Right”) is attached to each outstanding share of Common Stock. The description and terms of the Rights were set forth in a rights agreement dated as of November 27, 1995, between the Company and Chemical Mellon Shareholder Services, the original “Rights Agent.” The agreement was amended effective June 1, 1997, when the Company’s Board appointed American Stock Transfer and Trust Company successor Rights Agent. On November 2, 2005, the Company amended and restated the agreement to extend its expiration date to November 23, 2015, and make other changes. The First Amended and Restated Rights Agreement (the “Rights Agreement”) between the Company and American Stock Transfer and Trust Company became effective as of November 23, 2005.

Each share of Common Stock outstanding on December 11, 1995 (the "First Record Date") is entitled to one Right, as defined in and subject to the terms and conditions of the Rights Agreement. Under the Rights Agreement, a Right entitles the holder to purchase from the Company one one-hundredth of a share of Series A Junior Participating Preferred Stock, par value \$.01 per Share (the "Preferred Shares") at a price of \$33.33 per one one-hundredth of a Preferred Share (the "Purchase Price"), subject to adjustment. Each share of Common Stock that becomes outstanding after the First Record Date is also entitled to a Right, subject to the terms of the Rights Agreement.

Currently, each Right is non-exercisable and is evidenced only by the certificate of Common Stock to which it is attached. The Rights will not be exercisable and will not be evidenced by separate certificates (“Right Certificates”, as further defined below) until the Distribution Date. Rights Certificates will be issued upon the “Distribution Date,” which will occur on the earlier of:

- 10 days following a public announcement that a person or group of affiliated or associated persons (with certain exceptions, an “Acquiring Person”) has acquired beneficial ownership of 15% or more of the outstanding Common Stock; or
- 10 business days following the commencement of, or announcement of an intention to make, a tender offer or exchange offer the consummation of which would result in the beneficial ownership by a person or group of 15% or more of the outstanding Common Stock (except that the Board of Directors may extend the 10-business-day period before a person or group becomes an Acquiring Person).

Until the Distribution Date (or earlier redemption, exchange or expiration of the Rights), the Rights will be transferred with and only with the shares of common stock that are entitled to receive rights under the Rights Agreement (“Eligible Shares”).

The Rights entitle holders to acquire company securities under defined circumstances after the Distribution Date. Rights beneficially owned by an Acquiring Person (and its affiliates, associates, and transferees (collectively, the "Acquiring Persons")), however, become void from and after the time such persons become Acquiring Persons, and Acquiring Persons have no rights whatsoever under the Rights Agreement. The benefits of the Rights held by shareholders that are not Acquiring Persons and that are not so voided are described below. All references to Rights that follow refer only to Rights held by persons who are not Acquiring Persons.

As soon as practicable following the Distribution Date, separate certificates evidencing the Rights ("Right Certificates") will be mailed to holders of record of the Eligible Shares as of the close of business on the Distribution Date, and such separate Right Certificates will thereafter alone evidence the Rights. The Rights are not exercisable until the Distribution Date and expire on November 23, 2015 (the "Final Expiration Date"), unless the Final Expiration Date is advanced or extended or unless the Rights are earlier redeemed or exchanged by the Company, in each case, as described below. Until a Right is exercised, the Right confers no rights as a stockholder of the Company, including, without limitation, the right to vote or to receive dividends.

The Rights entitle holders to purchase Preferred Shares in certain circumstances. The Purchase Price payable, and the number of Preferred Shares or other securities or property issuable, upon exercise of the Rights are subject to adjustment from time to time to prevent dilution upon any of the following events:

- in the event of a stock dividend on, or a subdivision, combination or reclassification of, the Preferred Shares;
- upon the grant to holders of the Preferred Shares of certain rights or warrants to subscribe for or purchase Preferred Shares at a price, or securities convertible into Preferred Shares with a conversion price, less than the then-current market price of the Preferred Shares; or
  - upon the distribution to holders of the Preferred Shares of evidences of indebtedness or assets (excluding regular periodic cash dividends or dividends payable in Preferred Shares) or of subscription rights or warrants (other than those referred to above).

The number of outstanding Rights and the number of one one-hundredths of a Preferred Share issuable upon exercise of each Right are also subject to adjustment in the event of a stock dividend on the Common Shares payable in Common Shares or subdivisions, consolidations or combinations of the Common Shares occurring, in any such case, prior to the Distribution Date.

Preferred Shares purchasable upon exercise of the Rights will not be redeemable. Each Preferred Share will be entitled, when, as and if declared, to a minimum preferential quarterly dividend payment of \$1.00 per share but will be entitled to an aggregate dividend of 100 times the dividend declared per Common Share. In the event of liquidation, the holders of the Preferred Shares will be entitled to a minimum preferential liquidation payment of \$1.00 per share but will be entitled to an aggregate payment of 100 times the payment made per Common Share. Each Preferred Share will have 100 votes, voting together with the Common Shares. Finally, in the event of any merger, consolidation or other transaction in which Common Shares are exchanged, each Preferred Share will be entitled to receive 100 times the amount received per Common Share. These rights are protected by customary antidilution provisions.

Because of the nature of the Preferred Shares, dividend, liquidation and voting rights, the value of the one one-hundredth interest in a Preferred Share purchasable upon exercise of each Right should approximate the value of one Common Share. In the event that any person or group becomes an Acquiring Person, each holder of a Right will have the right to receive upon exercise of a Right, and in lieu of Preferred Shares, that number of Common Shares having a market value of two times the exercise price of the Right.

In the event that, after a person or group has become an Acquiring Person, the Company is acquired in a merger or other business combination transaction or 50% or more of its consolidated assets or earning power are sold, proper provision will be made so that each holder of a Right will thereafter have the right to receive, upon the exercise of a Right and in lieu of Preferred Shares or Common Shares of the Company, that number of shares of common stock of the person with whom the Company has engaged in the foregoing transaction (or its parent) that at the time of

such transaction will have a market value of two times the exercise price of the Right.

At any time after any person or group becomes an Acquiring Person and prior to the acquisition by any person or group of 50% or more of the outstanding Common Shares, the Board of Directors of the Company may exchange the Rights, in whole or in part, at an exchange ratio of one Common Share, or a fractional share of Preferred Shares (or other preferred stock) equivalent in value thereto, per Right (subject to adjustment).

With certain exceptions, no adjustment in the Purchase Price will be required until cumulative adjustments require an adjustment of at least 1% in such Purchase Price. No fractional Preferred Shares will be issued (other than fractions which are integral multiples of one one-hundredth of a Preferred Share, which may, at the election of the Company, be evidenced by depository receipts) and in lieu thereof, an adjustment in cash will be made based on the current market price of the Preferred Shares or the Common Shares.

At any time prior to the time an Acquiring Person becomes such, the Board of Directors of the Company may redeem the Rights in whole, but not in part, at a price of \$.001 per Right (the "Redemption Price") payable, at the option of the Company, in cash, Common Shares or such other form of consideration as the Board of Directors of the Company shall determine. The redemption of the Rights may be made effective at such time on such basis with such conditions as the Board of Directors in its sole discretion may establish. Immediately upon any redemption of the Rights, the right to exercise the Rights will terminate and the only right of the holders of Rights will be to receive the Redemption Price.

The Company may amend the Rights Agreement in any manner, provided, after (a) such time as a person or group becomes an Acquiring Person, or (b) the Distribution Date, whichever is earlier, the Company may not amend the Rights Agreement in any manner that adversely affects the interests of the holders of the Rights (other than the interests of an Acquiring Person or an affiliate or associate of an Acquiring Person).

The description of the Rights contained herein is qualified in its entirety by reference to the First Amended and Restated Rights Agreement, which is incorporated by reference into the registration statement of which this Prospectus forms a part.

#### Shareholder Action

Except as otherwise provided by law or in our articles of incorporation or bylaws, the approval by holders of a majority of the shares of common stock present in person or represented by proxy at a meeting and entitled to vote is sufficient to authorize, affirm, ratify or consent to a matter voted on by shareholders. The FBCA requires the approval of the holders of a majority of the outstanding stock entitled to vote for certain extraordinary corporate transactions, such as a merger, sale of substantially all assets, dissolution or amendment of the articles of incorporation.

#### Transfer Agent and Registrar

The Transfer Agent and Registrar for the Common Stock is American Stock Transfer & Trust Company. It is located at 6201 15th Avenue, Brooklyn, NY 11219, and its telephone number is (718) 921-8124.

### DESCRIPTION OF WARRANTS

We may issue warrants for the purchase of our common stock. Warrants may be issued independently or together with common stock and may be attached to or separate from these securities. Each series of warrants will be issued under a separate warrant agreement. We will distribute a prospectus supplement with regard to each issue or series of warrants.



Each prospectus supplement for warrants to purchase preferred stock or common stock, will describe:

- the title of the warrants;
- the price or prices at which the warrants will be issued;
- if applicable, the number of the warrants issued with each share of our common stock;
- if applicable, the date on and after which such warrants and the related securities will be separately transferable;
- any provisions for adjustment of the number or amount of shares of our common stock receivable upon exercise of the warrants or the exercise price of the warrants;
- if applicable, a discussion of material federal income tax considerations; and
- any other material terms of such warrants, including terms, procedures and limitations relating to the exchange and exercise of such warrants.

#### Exercise of Warrants

Each warrant will entitle the holder of the warrant to purchase shares of common stock at the exercise price as shall in each case be set forth in, or be determinable as set forth in, the prospectus supplement relating to the warrants offered in the applicable prospectus supplement. Warrants may be exercised at any time up to the close of business on the expiration date set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Upon receipt of payment and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the prospectus supplement, we will, as soon as reasonably practicable, unless otherwise specified in the warrant and the related prospectus supplement, forward the shares of common stock to be purchased upon such exercise. If less than all of the warrants represented by a warrant certificate are exercised, a new warrant certificate will be issued for the remaining warrants.

Prior to the exercise of any warrants to purchase common stock, holders of the warrants will not have any of the rights of holders of the common stock purchasable upon exercise, including the right to vote or to receive any payments of dividends on the common stock purchasable upon exercise.

#### PLAN OF DISTRIBUTION

The common stock and warrants covered by this prospectus are available for use in connection with acquisitions by us of other businesses, assets or securities in business combination transactions. The consideration for any such acquisition may consist of shares of our common stock or warrants or a combination of common stock, warrants, cash,

notes, assumption of liabilities or other consideration. The amount and type of consideration we will offer and the other specific terms of each acquisition will be determined by negotiations with the owners or the persons who control the businesses, assets or securities to be acquired after taking into account the current and anticipated future value of such businesses, assets or securities, along with all other relevant factors. We may structure business acquisitions in a variety of ways, including acquiring stock, other equity interests or assets of the acquired business or merging the acquired business with us or one of our subsidiaries. The common stock and warrants issued to the owners of the businesses, assets or securities to be acquired normally are valued at a price reasonably related to the market value of such common stock or warrants either at the time an agreement is reached regarding the terms of the acquisition, at the time we issue the shares or warrants, or during some other negotiated period.



This prospectus may be supplemented to furnish the information necessary for a particular negotiated transaction, and the registration statement of which this prospectus is a part will be amended or supplemented, where appropriate, to supply information concerning an acquisition.

In addition, we may issue our common stock and warrants pursuant to this prospectus and applicable prospectus supplement, or post-effective amendment, to acquire the assets, stock or business of debtors in cases under the United States Bankruptcy Code, which may constitute all or a portion of the debtor's assets, stock or business. The common stock and warrants we issue in these transactions may be sold by the debtor or its stockholders for cash from time to time in market transactions or it may be transferred by the debtor in satisfaction of claims by creditors under a plan of reorganization approved by the applicable United States Bankruptcy Court or otherwise transferred in accordance with the Bankruptcy Code.

All expenses of this registration will be paid by us. It is not expected that underwriting discounts or commissions will be paid by us in connection with issuances of shares of common stock under this prospectus. However, finders' or similar fees may be paid from time to time in connection with specific acquisitions, and the fees may be paid through the issuance of common stock or warrants covered by this prospectus. Any person receiving a fee may be deemed to be an underwriter within the meaning of the Securities Act of 1933, as amended. We may also pay certain financial advisory or similar fees or reimburse certain expenses of investment banking firms that advise us from time to time generally or regarding a specific acquisition.

#### WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy and information statements and other information with the Securities and Exchange Commission. We have filed a registration statement on Form S-4 with the SEC to register under the Securities Act of 1933 the securities offered hereby. This prospectus constitutes a part of that registration statement. As allowed by the SEC's rules, this prospectus does not contain all of the information set forth in the registration statement, certain parts of which have been omitted in accordance with the rules and regulations of the SEC. Please refer to the registration statement and related exhibits and schedules filed therewith for further information with respect to us and the securities offered hereby. Although the prospectus describes the material provisions of documents referenced herein and filed as exhibits, statements contained herein concerning the provisions of any such document are not necessarily complete. In each instance, reference is made to the copy of such document filed as an exhibit to the registration statement or otherwise filed by us with the SEC and each such statement is qualified in its entirety by such reference.

The following documents, which we have filed with the SEC (file number 001-13165), are incorporated by reference in and made a part of this prospectus:

- Our Annual Report on Form 10-K filed with respect to our fiscal year ended December 31, 2011;
- Our Quarterly Report on Form 10-Q filed with respect to our fiscal quarter ended March 31, 2012;
- Our Current Reports on Form 8-K filed on January 18, 2012, January 30, 2012, March 13, 2012, March 22, 2012, May 16, 2012, May 18, 2012, May 21, 2012, June 14, 2012, and June 22, 2012;



- The description of our Common Stock contained in our Registration Statement filed under Section 12 of the Securities Exchange Act of 1934, including any amendment or report filed for the purpose of updating such description.

We are also incorporating by reference any future filings we make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of the offering. These documents will be deemed to be incorporated by reference in this prospectus and to be a part of it from the date they are filed with the SEC. Unless specifically stated to the contrary, none of the information that we disclose under Items 2.02 or 7.01 of any Current Report on Form 8-K that we may from time to time furnish to the SEC will be incorporated by reference into, or otherwise included in, this prospectus. You may read and copy any document we file at the SEC's public reference room located at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room.

Our SEC filings are also available to the public from commercial document retrieval services and at the Web site maintained by the SEC at <http://www.sec.gov>. This information is also available without charge upon written or oral request to:

CryoLife, Inc.  
Attn: Secretary  
1655 Roberts Boulevard, NW  
Kennesaw, Georgia 30144  
(770) 419-3355

You should rely only on the information contained or incorporated by reference in this prospectus or any prospectus supplement. We have not authorized anyone else to provide you with different information. We may not make an offer of securities in any state where the offer is not permitted. The delivery of this prospectus does not, under any circumstances, mean that there has not been a change in our affairs since the date of this prospectus. It also does not mean that the information in this prospectus is correct after this date.

#### LEGAL MATTERS

The validity of the securities offered by this prospectus has been passed upon for us by Arnall Golden Gregory LLP.

#### EXPERTS

The consolidated financial statements incorporated in this Registration Statement on Form S-4 by reference from Cryolife, Inc.'s Annual Report on Form 10-K and the effectiveness of Cryolife, Inc.'s internal control over financial reporting have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their reports, which are incorporated herein by reference. Such consolidated financial statements have been so incorporated in reliance upon the reports of such firm given upon their authority as experts in accounting and auditing.

CRYOLIFE, INC.

\$100,000,000

Common Stock  
Warrants

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PROSPECTUS

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PART II  
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 20. Indemnification of Directors and Officers

The Registrant is a Florida corporation. The following summary is qualified in its entirety by reference to the complete text of the Florida Business Corporation Act (the "FBCA"), the Registrant's Amended and Restated Articles of Incorporation, and the Registrant's Amended and Restated Bylaws.

Under Section 607.0850(1) of the FBCA, a corporation may indemnify any of its directors and officers against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding (including any appeal thereof) (i) if such person acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, and (ii) with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. In actions brought by or in the right of the corporation, however, Section 607.0850(2) provides that no indemnification shall be made in respect of any claim, issue or matter as to which the director or officer shall have been adjudged to be liable unless, and only to the extent that, the court in which such proceeding was brought, or any other court of competent jurisdiction, shall determine upon application that, despite the adjudication of liability but in view of all circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which such court shall deem proper. Article X of the Registrant's Restated Articles of Incorporation requires that, if in the judgment of the majority of the Board of Directors (excluding from such majority any director under consideration for indemnification) the criteria set forth under Section 607.0850 have been met, then the Registrant shall indemnify its directors and officers for certain liabilities incurred in the performance of their duties on behalf of the Registrant in the manner and to the extent contemplated by Section 607.0850 of the FBCA (formerly Section 607.014 of the Florida General Corporation Act). Article VI of the Registrant's Amended and Restated Bylaws provides that indemnification is available to directors and officers only if the person to be indemnified acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interest of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was unlawful. The Registrant will have no obligation to provide indemnification until a determination has been made that the applicable standard of conduct has been met and that indemnification is not prohibited by relevant law. With respect to proceedings brought by or in the right of the Registrant, no indemnification shall be made if the officer or director is adjudged to be liable unless, and only to the extent that, a court of competent jurisdiction shall determine that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnification. The Registrant's Amended and Restated Bylaws also state that the rights to indemnification are binding contract rights which are binding on the Registrant with respect to any conduct that takes place while the provision remains in place, even if the provision is later amended, and that the rights continue as to a person who has ceased to be an officer or director. Expenses, including reasonable attorneys' fees, paralegals' fees and court costs, incurred by a director or officer in defending a proceeding for which indemnification is provided will be paid by the Registrant in advance of the final disposition of such proceeding provided that the director or officer represents that he or she has met the applicable standard of conduct in relation to the proceeding and will repay such amount if he or she is ultimately found not to be entitled to indemnification.

The Registrant has purchased insurance to insure (i) the Registrant's directors and officers against damages from actions and claims incurred in the course of their duties, and (ii) the Registrant against expenses incurred in defending lawsuits arising from certain alleged acts of its directors and officers.

The Registrant has entered into indemnification agreements with each of its directors and its Executive Vice President, Chief Operating Officer and Chief Financial Officer ("Indemnitees"). Pursuant to such agreements, the Registrant shall indemnify each Indemnitee whenever he or she is or was a party or is threatened to be made a party to any proceeding, including without limitation any such proceeding brought by or in the right of the Registrant, because he or she is or was a director or officer of the Registrant or is or was serving at the request of the Registrant as a director or officer of another corporation, partnership, joint venture, trust or other enterprise, or because of anything done or not done by the Indemnitee in such capacity, against expenses and liabilities (including the costs of any investigation, defense, settlement or appeal) actually and reasonably incurred by the Indemnitee or on his or her behalf in connection with such proceeding, if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the Registrant, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that an Indemnitee did not act in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the Registrant, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his or her conduct was unlawful. Unless a determination has been made that the Indemnitee is not entitled to indemnification pursuant to the agreement, all reasonable expenses incurred by or on behalf of such Indemnitee shall be advanced from time to time by the Registrant to the Indemnitee within thirty (30) days after the Registrant's receipt of a written request for an advance of expenses by such Indemnitee, whether prior to or after final disposition of a proceeding. Indemnitee shall agree, at the time of such advance, to repay the amounts advanced if it is ultimately determined that Indemnitee is not entitled to be indemnified under the terms of the agreement. Any advances made shall be unsecured and no interest shall be charged thereon.

Item 21. Exhibits

See the Exhibit Index attached to this registration statement and incorporated herein by reference.

Item 22. Undertakings

(a) The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
  - (i) to include any prospectus required by Section 10(a)(3) of the Securities Act of 1933, as amended (the "Securities Act");
  - (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and
  - (iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;
- (2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) That, for the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A of this chapter), shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify



any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use;

II-2

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- (5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities: the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
- (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
  - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
  - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
  - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- (b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (c) The undersigned registrant hereby undertakes as follows: that prior to any public reoffering of the securities registered hereunder through the use of a prospectus which is a part of this registration statement, by any person or party who is deemed to be an underwriter within the meaning of Rule 145(c), the registrant undertakes that such reoffering prospectus will contain the information called for by the applicable registration form with respect to reofferings by persons who may be deemed underwriters, in addition to the information called for by the other items of the applicable form.
- (d) The registrant undertakes that every prospectus: (i) that is filed pursuant to the immediately preceding paragraph or (ii) that purports to meet the requirements of Section 10(a)(3) of the Securities Act and is used in connection with an offering of securities subject to Rule 415, will be filed as a part of an amendment to the registration statement and will not be used until such amendment is effective, and that, for purposes of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (e)

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions described in Item 15 above, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

- (f) The undersigned registrant hereby undertakes to respond to requests for information that is incorporated by reference into the prospectus pursuant to Items 4, 10(b), 11, or 13 of Form S-4, within one business day of receipt of such request, and to send the incorporated documents by first class mail or other equally prompt means. This includes information contained in documents filed subsequent to the effective date of the registration statement through the date of responding to the request.
- (g) The undersigned registrant hereby undertakes to supply by means of a post-effective amendment all information concerning a transaction, and the company being acquired involved therein, that was not the subject of and included in the registration statement when it became effective.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-4 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Kennesaw, State of Georgia on June 22, 2012.

CRYOLIFE, INC.

By: /s/ Steven G. Anderson  
 Steven G. Anderson  
 President, Chief Executive Officer  
 and Chairman of the  
 Board of Directors

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints D. Ashley Lee and Jeffrey W. Burris and each of them, his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments and amendments pursuant to Rule 462(b)) to this Registration Statement, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

PRINCIPAL EXECUTIVE, FINANCIAL & ACCOUNTING OFFICERS AND DIRECTORS:

Name	Title	Date
/s/ Steven G. Anderson Steven G. Anderson	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	June 22, 2012
/s/ D.Ashley Lee D. Ashley Lee	Executive Vice President, Chief Operating Officer and Chief Financial Officer (Principal Financial Officer)	June 22, 2012
/s/ Amy D. Horton		June 22, 2012

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Chief Accounting Officer  
(Principal Accounting Officer)

Amy D. Horton

/s/ Thomas F. Ackerman  
Thomas F. Ackerman

Director

June 22, 2012

/s/ James S. Benson  
James S. Benson

Director

June 22, 2012

/s/ Daniel J. Bevevino  
Daniel J. Bevevino

Director

June 22, 2012

II-5

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/s/ Ronald C. Elkins Ronald C. Elkins, M.D.	Director	June 22, 2012
/s/ Ronald D. McCall Ronald D. McCall	Director	June 22, 2012
/s/ Harvey Morgan Harvey Morgan	Director	June 22, 2012
/s/ Jon W. Salveson Jon W. Salveson	Director	June 22, 2012

EXHIBIT INDEX

ExhibitExhibit  
No.

- 3.1 Amended and Restated Articles of Incorporation of the Company. (Restated solely for the purpose of filing with the Commission.) (Incorporated herein by reference to Exhibit 3.1 to the Form S-3 filed by Registrant on February 22, 2012.)
- 3.2 Amended and Restated ByLaws of the Company. (Incorporated by reference to Exhibit 3.1 to the Registrant's Report on Form 8-K filed July 27, 2011.)
- 4.1 Form of Certificate for the Company's Common Stock. (Incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1997.)
- 4.2 First Amended and Restated Rights Agreement, dated as of November 2, 2005, between CryoLife, Inc. and American Stock Transfer & Trust Company. (Incorporated herein by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K filed November 3, 2005.)
- 4.3\*\* Form of Warrant
- 5.1\* Opinion of Arnall Golden Gregory LLP regarding legality of the common stock.
- 23.1\* Consent of Arnall Golden Gregory LLP (included as part of Exhibit 5.1 hereto.)
- 23.2\* Consent of Deloitte & Touche LLP.
- 24.1\* Power of Attorney (included in the signature pages of this registration statement.)

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\* Filed with this Form S-4

\*\* To be filed by amendment



