CRYOLIFE INC
Form S-3
February 22, 2012

As filed with the Securities and Exchange Commission on February 22, 2012
Registration No. 333-_____

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

_____

FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

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

Florida	59-2417093
(State or Other Jurisdiction of Incorporation or Organization)	(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

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

If the only securities being represented on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box: [ ]

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box: [X]

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(c) 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 registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box: [ ]

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box: [ ]

Indicate by a 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.

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

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 or until this Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered (1)	Proposed Maximum Aggregate Offering Price (2) (3)	Amount of Registration Fee (2)
Common Stock (including attached preferred share purchase rights)		
Preferred Stock		
Depositary Shares (4)		
Warrants		
Units		
Total	$ 100,000,000	$ 11,460 (5)

(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended, the shares being registered hereunder include such indeterminate number of shares of common stock, preferred stock, depositary shares, warrants and units as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions.

(2) Rule 457(o) under the Securities Act of 1933, as amended, permits the registration fee to be calculated on the basis of the maximum offering price of all of the securities listed and, therefore, the table does not specify by each class information as to the amount to be registered, the proposed maximum offering price per security or the amount of the registration fee. An indeterminate amount of common stock, preferred stock, depositary shares, warrants and units may be issued from time to time at indeterminate prices, with an aggregate offering price not to exceed $100,000,000.

(3) This registration statement also covers an indeterminate amount of securities that may be issued in exchange for, or upon conversion or exercise of, as the case may be, any securities registered hereunder that provide for conversion, exercise or exchange. Any securities registered hereunder may be sold separately or as units with other securities registered hereunder.

(4) The depositary shares registered hereunder will be evidenced by depositary receipts issued pursuant to a depositary agreement. If the Registrant elects to offer to the public fractional interests in shares of preferred stock, then depositary receipts will be distributed to those persons purchasing the fractional interests and the shares will be issued to the depositary under the depositary agreement.

(5) Calculated pursuant to Rule 457(o) at the statutory rate of $114.60 per $1,000,000 of securities registered. Pursuant to Rule 415(a)(6) and Rule 457(p) under the Securities Act of 1933, as amended, the registrant is offsetting $1,965 of the filing fee due hereunder by the amount of the filing fee that relates to $50,000,000 of securities of the registrant registered on the Registration Statement on Form S-3 (File No. 333-155549) filed by the registrant on November 21, 2008, which securities were not sold by the registrant under such registration statement; the associated filing fee of $1,965 for such unsold securities, calculated under Rule 457(o), is hereby used to offset $1,965 of the registration fee due.

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.

Common Stock
Preferred Stock
Depositary Shares
Warrants
Units

This prospectus will allow us to issue, from time to time at prices and on terms to be determined at or prior to the time of the offering, any combination of the securities described in this prospectus, either individually or in units. We may also offer common stock upon conversion of the preferred stock, preferred stock upon conversion of the depositary shares, or common stock, preferred stock or depositary shares upon the exercise of warrants.

This prospectus provides you with a general description of the securities that may be offered. Each time securities are sold, we will provide one or more supplements to this prospectus that will contain additional information about the specific offering and the terms of the securities being offered. The supplements may also add, update or change information contained in this prospectus. You should carefully read this prospectus and any accompanying prospectus supplement before you invest in any of our securities. This prospectus may not be used to offer or sell our securities unless accompanied by a prospectus supplement.

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 February 21, 2012 was $5.29 per share.

This investment involves risks. See “RISK FACTORS” beginning on page 7.

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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You should rely only on the information included or incorporated by reference in this prospectus and any accompanying prospectus supplement. We have not authorized any dealer, salesman or other person to provide you with additional or different information. This prospectus and any accompanying prospectus supplement are not an offer to sell or the solicitation of an offer to buy any securities other than the securities to which they relate and are not 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 an offer or solicitation in that jurisdiction. You should not assume that the information in this prospectus or any accompanying prospectus supplement or in any document incorporated by reference in this prospectus or any accompanying prospectus supplement is accurate as of any date other than the date of the document containing the information.

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 part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, which we refer to as the "SEC," using a "shelf" registration process. Under this shelf process, we may, over time, sell any combination of the securities described in this prospectus in one or more offerings up to a total dollar amount of $100,000,000. 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. You should read both this prospectus and any accompanying prospectus supplement 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

- 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

- 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.

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 October of 2010 CryoLife distributes 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 anticipates refiling its IDE for PerClot in early 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 transmyocardial revascularization, or 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.

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:

- 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,
- our subsidiary, Cardiogenesis Corporation, has been named in a patent infringement lawsuit,
- uncertainties related to patents and protection of proprietary technology that may adversely impact the value of our intellectual property,
- significant litigation with Medafor and related litigation cost that may have a material adverse impact on our profitability,
- 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;
- 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.

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. Information contained on our Web site is not part of this prospectus.

SECURITIES REGISTERED HEREBY THAT WE MAY OFFER

We may offer any of the following securities with a total value of up to $100,000,000 from time to time under this prospectus at prices and on terms to be determined by market conditions at the time of the offering:

- common stock;
- preferred stock, in one or more series;
- depositary shares;
- warrants to purchase shares of common stock, shares of preferred stock or depositary shares; or
- any combination of the foregoing securities, in units.

We refer to our common stock, preferred stock, depositary shares, warrants and units collectively in this prospectus as the “securities.” This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities, including, to the extent applicable:

- designation or classification;
- aggregate offering price;
- rates and times of payment of dividends, if any;
- redemption, conversion or sinking fund terms, if any;
- voting or other rights, if any;

- conversion prices, if any; and
- important federal income tax considerations.

Common Stock. We may offer shares of our common stock. Our common stock currently is listed on the New York Stock Exchange under the symbol “CRY.” Shares of common stock that may be offered in this offering will, when issued and paid for, be fully paid and non-assessable.

Preferred Stock. We may offer shares of our preferred stock, in one or more series. Our board of directors will determine the rights, preferences, privileges and restrictions of the preferred stock, including any dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of any series. Convertible preferred stock will be convertible into shares of our common stock. Conversion may be mandatory or at your option and would be at prescribed conversion rates. Shares of preferred stock that may be offered in this offering will, when issued and paid for, be fully paid and non-assessable. The terms of the preferred stock we may offer under this prospectus and any prospectus supplement will be set forth in a certificate of designations relating to that series and will be incorporated by reference into the registration statement of which this prospectus is a part. We urge you to read the complete certificate of designations containing the terms of the applicable series of preferred stock, as well as the applicable prospectus supplement, and any related free writing prospectus that we may authorize to be provided to you, related to such series.

Depositary Shares. We may from time to time issue receipts for depositary shares representing fractional shares of our preferred stock. Any depositary shares that we sell under this prospectus will be evidenced by depositary receipts issued under a deposit agreement between us and a depositary with whom we deposit the shares of the applicable series of preferred stock that underlie the depositary shares that are sold. Subject to the terms of the deposit agreement, each holder of a depositary share will be entitled, in proportion to the applicable fraction of a share of the preferred stock underlying the depositary share, to all of the rights, preferences and privileges, and be subject to the qualifications and restrictions, of the preferred stock underlying that depositary share. We will incorporate by reference into the registration statement of which this prospectus is a part the form of deposit agreement, including a form of depositary receipt that describes the terms of any depositary shares that we are offering before the issuance of the related depositary shares. We urge you to read the prospectus supplements, and any related free writing prospectus that we may authorize to be provided to you, related to any depositary shares being offered, as well as the complete depositary agreement and depositary receipt that contains the terms of the depositary shares.

Warrants. We may issue warrants for the purchase of common stock, preferred stock in one or more series, and/or depositary shares in one or more series. We may issue warrants independently or in combination with common stock, preferred stock, and/or depositary shares. In this prospectus, we have summarized certain general features of the warrants under “Description of Warrants.” We urge you, however, to read the applicable prospectus supplement, and any related free writing prospectus that we may authorize to be provided to you, related to the particular series of warrants being offered, as well as the form of warrant and/or the warrant agreement and warrant certificate, as applicable, that contain the terms of the warrants. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of warrant and/or the warrant agreement and warrant certificate, as applicable, that describe the terms of the particular series of warrants we are offering, and any supplemental agreements, before the issuance of such warrants.

Warrants may be issued under a warrant agreement that we enter into with a warrant agent. We will indicate the name and address of the warrant agent, if any, in the applicable prospectus supplement relating to a particular series of warrants.

Units. We may issue units representing any combination of common stock, preferred stock, depositary shares and/or warrants from time to time. The units may be issued under one or more unit agreements. In this prospectus, we have summarized certain general features of the units.

We will incorporate by reference into the registration statement of which this prospectus is a part the form of unit agreement under which the units are designated, if any, describing the terms of the units we are offering before the issuance of the related units. We urge you to read the prospectus supplements related to any units being offered, as well as the complete unit agreement, if any, designating the units.

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