INVIVO THERAPEUTICS HOLDINGS CORP.
Form S-1/A
May 19, 2011
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As filed with the Securities and Exchange Commission on May 19, 2011

Registration No. 333-171998

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 1

to

FORM S-1

REGISTRATION STATEMENT

UNDER THE SECURITIES ACT OF 1933

INVIVO THERAPEUTICS HOLDINGS CORP.

(Exact Name of Registrant as Specified in Its Charter)

Nevada	**3841**	**36-4528166**
(State or other Jurisdiction of Incorporation or Organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

One Broadway, 14th Floor Cambridge, MA 02142 (617) 475-1520

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant s Principal Executive Offices)

Frank M. Reynolds Chief Executive Officer One Broadway, 14th Floor Cambridge, MA 02142 (617) 475-1520

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

Copies to:

Thomas B. Rosedale, Esq. BRL Law Group LLC 425 Boylston Street 3rd Floor Boston, MA 02116 (617) 399-6931

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

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, 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 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. ¨

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.:

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

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, $.00001 par value per Share(1)	26,047,200	$0.83(2)	$21,619,176	$2,510*

(1) Pursuant to Rule 416 under the Securities Act, this registration statement also covers such indeterminate number of additional shares of common stock as may be issuable with respect to the shares being registered hereunder as a result of any stock splits, stock dividends or similar transactions.
(2) Estimated solely for the purpose of calculating the registration fee, and based on the average of the high and low prices of the Common Stock on May 17, 2011 as reported on the Over-the-Counter Bulletin Board operated by the National Association of Securities Dealers Inc. in accordance with Rules 457(c) and 457(h) under the Securities Act of 1933.
* Previously paid.

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

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The information contained in this prospectus is not complete and may be changed. These securities may not be sold 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.

Subject to Completion, Dated May 19, 2011

26,047,200 Shares of Common Stock

INVIVO THERAPEUTICS HOLDINGS CORP.

This prospectus relates to the following offerings by certain of our stockholders and warrantholders, which we refer to as Selling Securityholders :

- the resale of up to 12,848,600 shares of common stock purchased in a private placement;
- the resale of up to 12,848,600 shares of common stock that are issuable on exercise of the investor warrants that were acquired in a private placement; and
- the resale of up to 350,000 shares of common stock that are issuable on exercise of the new bridge warrants that were issued to warrantholders in connection with our recent merger.

Holders of the investor warrants and new bridge warrants may currently purchase one share of common stock for each warrant exercised. The exercise price and number of shares of common stock issuable upon exercise of the warrants is subject to further adjustment in certain circumstances.

We will not receive any proceeds from the sale of these securities, although we will receive the exercise price for any warrants that are exercised. We are registering securities for resale by the Selling Securityholders, but that does not necessarily mean that they will sell any of the securities. Any securities sold by the Selling Securityholders will be offered at market or privately negotiated prices.

The investor warrants and the new bridge warrants are exercisable at $1.40 per warrant and $1.00 per warrant, respectively, at any time on or before the fifth anniversary of the date of issuance.

Our common stock is currently available for trading in the over-the-counter market and is quoted on the OTC Bulletin Board under the symbol NVIV . The last sale price of our common stock on May 17, 2011 was $0.79.

These are speculative securities. Investing in our securities involves significant risks. You should purchase these securities only if you can afford a complete loss of your investment. See Risk Factors beginning on page 6.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is , 2011.

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You should rely only on the information contained in this document or to which we have referred you. We have not authorized anyone to provide you with information that is different. This document may only be used where it is legal to sell these securities. The information contained in this document may only be accurate on the date of this document.

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PROSPECTUS SUMMARY

The following summary highlights selected information contained in this prospectus. This summary does not contain all the information that may be important to you. You should read the more detailed information contained in this prospectus, including but not limited to, the risk factors beginning on page 6. References to we, us, our, or the Company refer to InVivo Therapeutics Holdings Corp., together, with its consolidated subsidiaries where applicable. The term ITHC refers to InVivo Therapeutics Holdings Corp. (f/k/a Design Source, Inc.), the Nevada corporation, before giving effect to the Merger, and the term InVivo refers to InVivo Therapeutics Corporation, the Delaware corporation, before giving effect to the Merger. All share amounts relating to our Common Stock contained in this prospectus give effect to a 2.02898 for 1 forward split of our shares of Common Stock, which was effected on October 22, 2010.

As the result of the Transactions (as defined below) and the change in business and operations of the Company from a shell company to a biotechnology company, a discussion of the past financial results of ITHC is not pertinent, and the financial results of InVivo, the acquirer, are considered the financial results of the Company on a historical and going-forward basis.

The Merger and Related Transactions

On October 4, 2010, we merged into our newly formed, wholly owned subsidiary, InVivo Therapeutics Holdings Corp. (ITHC). The sole purpose of this merger was to effect a change of our name from Design Source, Inc. to InVivo Therapeutics Holdings Corp. in anticipation of a business acquisition. Our common stock par value $0.00001 per share (the Common Stock) was forward-split on a 2.02898 for 1 basis effective October 22, 2010.

On October 26, 2010, InVivo Therapeutics Acquisition Corp., our wholly-owned subsidiary, merged (the Merger) with and into InVivo Therapeutics Corporation, a Delaware corporation (InVivo). InVivo was the surviving corporation of that Merger. As a result of the Merger, we acquired the business of InVivo, and will continue the existing business operations of InVivo, as a wholly-owned subsidiary.

Simultaneously with the Merger, all of the issued and outstanding shares of InVivo common stock converted, on a 13.7706 for 1 basis, into shares of our Common Stock. All of the issued and outstanding options to purchase shares of InVivo common stock, and the issued and outstanding Bridge Warrants (as defined below) to purchase shares of InVivo common stock, converted, respectively, into options (the New Options) and new bridge warrants (the New Bridge Warrants) to purchase shares of our Common Stock. The number of shares of Common Stock issuable under, and the price per share upon exercise of, the New Options and the New Bridge Warrants were calculated based on the terms of the original options and warrants of InVivo, as adjusted by the conversion ratio in the Merger, which is described in the Merger Agreement. The New Options will be administered under InVivo s 2007 Stock Incentive Plan, which the Company assumed and adopted in connection with the Merger.

An aggregate of 31,647,190 shares of Common Stock were issued to former InVivo stockholders and options for the purchase of 5,915,557 shares of Common Stock and New Bridge Warrants for the purchase of 600,000 shares of Common Stock were issued to holders of outstanding InVivo options and warrants. Our stockholders before the Merger, without giving effect to the Offering (as defined below), retained 6,999,981 shares of Common Stock.

The Merger was a reverse merger, and InVivo is deemed to be the acquirer and ongoing operating company. The Merger was recorded as a recapitalization of InVivo, equivalent to the issuance of common stock by InVivo for the net monetary assets of ITHC accompanied by a recapitalization. At the date of the Merger, the 6,999,981 outstanding ITHC shares are reflected as an issuance of InVivo common stock to the prior shareholders of ITHC. ITHC had no net monetary assets as of the Merger so this issuance was recorded as a reclassification between additional paid-in capital and par value of Common Stock. In connection with the Merger, we adopted the fiscal year end of InVivo, thereby changing our fiscal year end from March 31 to December 31.

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In connection with the Merger, on October 26, November 10 and December 3, 2010, we completed a private offering (the Offering) of 13,000,000 units of our securities (Units), at a price of $1.00 per Unit. Each Unit consists of one share of Common Stock and a warrant to purchase one share of Common Stock. The warrants (the Investor Warrants) are exercisable for a period of five years at a purchase price of $1.40 per share of Common Stock. The Offering was made only to accredited investors, as defined under Regulation D, Rule 501(a). The investors in the Offering collectively purchased 13,000,000 Units for total cash consideration of $13,000,000, which includes the conversion of $504,597 of principal of, and accrued interest on, Bridge Notes (as defined below) and we received net proceeds after expenses of $10,914,044.

We paid Spencer Trask Ventures, Inc., our placement agent in the Offering (the Placement Agent), a commission of 10% of the funds raised from investors in the Offering. In addition, the Placement Agent received a non-accountable expense allowance equal to 3% of the proceeds raised in the Offering as well as warrants to purchase a number of shares of Common Stock equal to 20% of the Common Stock and 20% of the Common Stock underlying the Investor Warrants sold to investors in the Offering. As a result of the foregoing arrangement, the Placement Agent was paid commissions and expenses of $1,690,000 and was issued warrants to purchase (i) 2,600,000 shares of Common Stock at an exercise price of $1.00 per share and (ii) 2,600,000 shares of Common Stock at an exercise price of $1.40 per share. Neither the warrants nor the shares issuable upon exercise of the warrants issued to the Placement Agent have registration rights and such securities are not being registered on this registration statement. The warrants contain weighted average anti-dilution and immediate cashless exercise provisions. In September 2010, several related parties to the Placement Agent purchased an aggregate of 3,895,643 shares of our Common Stock from various shareholders of the Company at an aggregate cost of $49,000.

Prior to the Merger, InVivo completed a Bridge Financing, wherein it sold $500,000 in principal amount of its bridge notes (the Bridge Notes) and 36,310 bridge warrants (the Bridge Warrants) to accredited investors (the Bridge Financing). The Bridge Notes converted into 504,597 Units in the Offering. The 36,310 Bridge Warrants converted into 500,000 New Bridge Warrants, each exercisable at a price of $1.00 per share of Common Stock, upon the closing of the Merger. As consideration for identifying investors to participate in the Bridge Financing, the Placement Agent received Warrants from InVivo that were exchanged on the closing of the Merger for Warrants to purchase 100,000 shares of our Common Stock at a price of $1.00 per share. The Placement Agent also received, upon conversion of the Bridge Notes, compensation in the same amount as it received for other Units sold in the Offering. The Merger, the Offering, the Bridge Financing and the related transactions are collectively referred to in this prospectus as the Transactions.

Simultaneously with the closing of the Merger on October 26, 2010, ITHC transferred all of its operating assets and liabilities to its wholly-owned subsidiary, D Source Split Corp., a company organized under the laws of Nevada (DSSC). DSSC was then split-off from ITHC through the sale of all outstanding shares of DSSC (the Split-Off). In connection with the Split-Off, 14,747,554 shares of our Common Stock held by Peter Reichard, Lawrence Reichard and Peter Coker (the Split-Off Shareholders) were surrendered and cancelled without further consideration, other than the shares of DSSC. An additional 1,014,490 shares of our Common Stock were cancelled by a shareholder for no additional consideration. The assets and liabilities of ITHC were transferred to the Split-Off Shareholders in the Split-Off. ITHC executed a split off agreement with the Split-Off Shareholders which obligates the Split-Off Shareholders to assume all prior liabilities associated with ITHC before the Merger.

Please see Description of Capital Stock on page 59 for a reconciliation of the outstanding shares of InVivo and ITHC common stock on a pre and post Merger basis.

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Business Overview

InVivo was founded in 2005 to develop and commercialize new technologies for the treatment of spinal cord injuries. InVivo s proprietary technology was co-invented by Robert S. Langer, ScD, Professor at Massachusetts Institute of Technology and Joseph P. Vacanti, MD, affiliated with Massachusetts General Hospital. The intellectual property rights that are the basis for our products are licensed under an exclusive, world-wide license from Children s Medical Center Corporation (CMCC) and Massachusetts Institute of Technology (MIT).

We intend to create new treatments for spinal cord injury. Current treatments consist of a collection of approaches that only focus on symptoms of spinal cord injury. To date, we are not aware of any product on the market that addresses the underlying pathology of spinal cord injury.

Currently, there are no successful spinal cord injury treatment options for spinal cord injury patients. We take a different approach to spinal cord injury and focus on protection of the spinal cord and prevention of secondary injury rather than regeneration. Our platform technologies focus on minimizing tissue damage sustained following acute injury and promoting neural plasticity of the spared healthy tissue, which may result in full or partial functional recovery. The technologies encompass multiple strategies involving biomaterials, U.S. Food & Drug Administration (FDA) approved drugs, growth factors, and human neural stem cells. We believe our approach could become a standard treatment for both acute and chronic spinal cord injuries.

We intend to leverage our primary platform technology to develop and commercialize three products as follows:

1. A biocompatible polymer scaffolding device to treat acute spinal cord injuries.

2. A biocompatible hydrogel for local controlled release of methylprednisolone to treat acute spinal cord injuries.

3. A biocompatible polymer scaffolding device seeded with autologous human neural stem cells to treat acute and chronic spinal cord injuries.

Our biopolymer-based devices are surgically implanted or injected into the lesion created during traumatic injury, or the primary injury . This biopolymer scaffolding protects the damaged spinal cord by mitigating the progression of secondary injury resulting from the body s inflammatory and immune response to injury, and promotes neuroplasticity, a process where functional recovery (the recovery of motor movement or sensation) may occur through the rerouting of signaling pathways to the spared healthy tissue. Achieving these results is essential to the recovery process, as secondary injury can significantly worsen the immediate damage sustained during trauma. The additional damage dramatically reduces patient quality of life post-injury.

Additional applications of our platform technologies include the potential treatment for, spinal cord injury following tumor removal, peripheral nerve damage, and postsurgical treatment of any transected nerve. Our first product, the biocompatible scaffolding device for the treatment of acute spinal cord injury, is regulated as a Class III medical device by the FDA. The product has been evaluated in animal studies and the Company intends to submit an Investigational Device Exemption with the FDA during 2011 that if approved by the FDA will permit the commencement of human clinical studies.

The biocompatible hydrogel for the local release of methylprednisolone to treat acute spinal cord injuries and the biocompatible polymer scaffolding device seeded with autologous human neural stem cells to treat acute and chronic spinal cord injuries are likely to be regulated as combination drug/devices and as such will require significantly longer regulatory approval times than the biopolymer scaffolding device.

At December 31, 2010, the Company had total assets of $9,379,000 and total liabilities of $11,232,000, resulting in a stockholders deficit of $1,853,000. At March 31, 2011, the Company had total assets of approximately $7,984,000 and total liabilities of approximately $11,005,000, resulting in a stockholders deficit of $3,021,000.

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Offering by Selling Securityholders

All references herein to our shares of Common Stock give effect to a 2.02898 for 1 forward split of our shares of Common Stock, which we completed on October 22, 2010.

We are registering the following securities issued in connection with the Offering and Bridge Financing:

For resale by the selling securityholders, 12,848,600 shares of Common Stock purchased in the Offering;

For resale by the selling securityholders, 12,848,600 shares of Common Stock issuable upon exercise of the Investor Warrants that were acquired in the Offering; and

For resale by the selling securityholders, 350,000 shares of Common Stock issuable upon exercise of the New Bridge Warrants.

As of the date of this prospectus, each Investor Warrant and New Bridge Warrant is exercisable to purchase one share of Common Stock. The exercise price and number of shares of Common Stock issuable upon exercise of the Investor Warrants and the New Bridge Warrants are subject to further adjustment in certain circumstances.

The exercise price of each Investor Warrant is $1.40. The Investor Warrants expire on varying dates up to December 3, 2015. There is a possibility that the warrants will never be exercised when in-the-money or otherwise, and that warrant holders will never receive shares or payment of cash in settlement of the warrants.

The Investor Warrants may be redeemed by us at any time our Common Stock trades above $2.80 for twenty consecutive days following the effectiveness of the registration statement covering the resale of the underlying Investor Warrant shares. The Investor Warrants can only be redeemed if this registration statement is effective at the time of the redemption notice.

The exercise price of each New Bridge Warrant is $1.00. The New Bridge Warrants expire on October 26, 2015. There is a possibility that the warrants will never be exercised when in-the-money or otherwise, and that warrant holders will never receive shares or payment of cash in settlement of the warrants. We do not have the right to redeem the New Bridge Warrants.

Common stock outstanding	51,674,712 shares as of May 18, 2011
Use of proceeds	We will not receive any of the proceeds from the sale of the securities being registered on behalf of the Selling Securityholders hereunder. We will receive the exercise price upon the exercise of any Investor Warrant or New Bridge Warrant.
OTC Bulletin Board symbol	NVIV
Risk factors	Investing in our Common Stock involves a high degree of risk. As an investor you should be able to bear a complete loss of your investment. You should carefully consider the information set forth in the Risk Factors section of this prospectus.

Our principal business office is located at One Broadway, 14th Floor, Cambridge, Massachusetts 02142, and our telephone number is (617) 475-1520. Our website address is www.invivotherapeutics.com. Information contained on our website or any other website does not constitute part of this prospectus.

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We will bear the expenses of registering these securities. The Selling Securityholders will pay the cost of any brokerage commissions and discounts, and all expenses incurred by them in connection with the resale of the securities. See Plan of Distribution.

We had 51,674,712 shares of Common Stock issued and outstanding as of May 18, 2011. Unless the context indicates otherwise, all share and per-share Common Stock information in this prospectus:

- assumes no additional exercises of the Investor Warrants and New Bridge Warrants;
- assumes no additional exercises of the Placement Agent s warrants;
- excludes 5,888,016 shares underlying outstanding options under our 2007 Stock Incentive Plan; and
- excludes 535,000 shares underlying outstanding options under our 2010 Equity Incentive Plan.

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RISK FACTORS

If you purchase our securities, you will assume a high degree of risk. In deciding whether to invest, you should carefully consider the following risk factors, as well as the other information contained elsewhere in this prospectus. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations or prospects and cause the value of our securities to decline, which could cause you to lose all or part of your investment.

Risks Relating to Our Business and Our Industry

We have a limited operating history and it is difficult to predict our future growth and operating results.

We have a limited operating history and limited operations and assets. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties encountered by companies in the early stage of development. As a development stage company, our development timelines have been and may continue to be subject to adjustments that could negatively affect our cash flow and ability to develop or bring products to market, if at all. Predicting our future operating and other results is extremely difficult, if not impossible.

Our prospects must be considered in light of inherent risks, expenses and difficulties encountered by all early stage companies, particularly companies in new and evolving markets. These risks include, by way of example and not limitation, unforeseen capital requirements, unforeseen technical problems, delays in obtaining regulatory approvals, failure of market acceptance and competition from foreseen and unforeseen sources.

We have not generated any revenues to date and have a history of losses since inception.

We have not generated any revenue to date and, through March 31, 2011, have incurred net losses of approximately $15,513,000 since inception. It can be expected that we will continue to incur significant operating expenses and continue to experience losses in the foreseeable future. As a result, we cannot predict when, if ever, we might achieve profitability and cannot be certain that we will be able to sustain profitability, if achieved.

We will need substantial additional funding to develop our products and for our future operations. If we are unable to obtain the funds necessary to do so, we may be required to delay, scale back or eliminate our product development or may be unable to continue our business.

The development and approval to market and sell our product candidates will require a commitment of substantial funds, in excess of our current capital resources. Before we can market or sell any of our products, we will need to conduct costly and time-consuming research, which will include preclinical and clinical testing and regulatory approvals. We anticipate the amount of operating funds that we use will continue to increase along with our operating expenses over at least the next several years as we plan to bring our products to market. While we believe our current capital resources will satisfy our planned capital needs for at least 12 months, our future capital requirements will depend on many factors, including:

- the progress and costs of our research and development programs, including our ability to develop our current portfolio of therapeutic products, or discover and develop new ones;
- our ability, or our partners ability and willingness, to advance partnered products or programs;
- the cost of prosecuting, defending and enforcing patent claims and other intellectual property rights;
- the progress, scope, costs, and results of our preclinical and clinical testing of any current or future products;
- the time and cost involved in obtaining regulatory approvals;

the cost of manufacturing our product candidates;

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expenses related to complying with Good Manufacturing Practice manufacturing of product candidates;

costs of financing the purchases of additional capital equipment and development technologies;

competing technological and market developments;

our ability to establish and maintain collaborative and other arrangements with third parties to assist in bringing our products to market and the cost of such arrangements.

the amount and timing of payments or equity investments that we receive from collaborators and the timing and amount of expenses we incur;

costs associated with the integration of any new operation, including costs relating to future mergers and acquisitions with companies that have complementary capabilities;

expenses related to the establishment of sales and marketing capabilities for products awaiting approval or products that have been approved;

the level of our sales and marketing expenses; and

our ability to introduce and sell new products.

We cannot assure you that we will not need additional capital sooner than currently anticipated. We will need to raise substantial additional capital to fund our future operations. We cannot be certain that additional financing will be available on acceptable terms, or at all. In recent years, it has been difficult for companies to raise capital due to a variety of factors, which may or may not continue. To the extent we raise additional capital through the sale of equity securities, the ownership position of our existing stockholders could be substantially diluted. If additional funds are raised through the issuance of preferred stock or debt securities, these securities are likely to have rights, preferences and privileges senior to our Common Stock. Fluctuating interest rates could also increase the costs of any debt financing we may obtain.

Our products will represent new and rapidly evolving technologies.

Our proprietary spinal cord injury treatment technology depends on new, rapidly evolving technologies and on the marketability and profitability of our products. Approval by applicable regulatory agencies and commercialization of our spinal cord injury treatment technology could fail for a variety of reasons, both within and outside of our control. Furthermore, because there are no approved treatments for spinal cord injuries, the regulatory requirements governing this type of product may be more rigorous or less clearly established than for other analogous products.

We license our core technology from Children s Medical Center Corporation (CMCC) and Massachusetts Institute of Technology (MIT), and we could lose our rights to this license if a dispute with CMCC or MIT arises or if we fail to comply with the financial and other terms of the license.

We license patents and core intellectual property from CMCC and MIT under the CMCC license. The CMCC license agreement imposes certain payment, milestone achievement, reporting, confidentiality and other obligations on us. In the event that we were to breach any of the obligations and fail to cure, CMCC would have the right to terminate the CMCC license agreement upon notice. In addition, CMCC has the right to terminate the CMCC license agreement upon the bankruptcy or receivership of the Company. The termination of the CMCC license would have a material adverse effect on our business, as all of our current product candidates are based on the patents and licensed intellectual property. If any dispute arises with respect to our arrangement with CMCC or MIT, such dispute may disrupt our operations and would likely have a material and adverse impact on us if resolved in a manner that is unfavorable to us.

We will face substantial competition.

The biotechnology industry in general is subject to intense competition and rapid and significant technological change. We have many potential competitors, including major drug companies, specialized biotechnology firms,

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academic institutions, government agencies and private and public research institutions. Many of these competitors have significantly greater financial and technical resources than us, and superior experience and expertise in research and development, preclinical testing, designing and implementing clinical trials, regulatory processes and approvals, production and manufacturing, and sales and marketing of approved products.

Principal competitive factors in our industry include the quality and breadth of an organization s technology; management of the organization and the execution of the organization s strategy; the skill and experience of an organization s employees and its ability to recruit and retain skilled and experienced employees; an organization s intellectual property portfolio; the range of capabilities, from target identification and validation to drug and device discovery and development to manufacturing and marketing; and the availability of substantial capital resources to fund discovery, development and commercialization activities.

Large and established companies compete in the biotech market. In particular, these companies have greater experience and expertise in securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale and marketing approved products.

Smaller or early-stage companies and research institutions may also prove to be significant competitors, particularly through collaborative arrangements with large and established biotech or other companies. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and registering subjects for clinical trials.

In order to effectively compete, we will have to make substantial investments in development, testing, manufacturing and sales and marketing or partner with one or more established companies. There is no assurance that we will be successful in having our products approved or gaining significant market share for any of our products. Our technologies and products also may be rendered obsolete or noncompetitive as a result of products introduced by our competitors.

We will require FDA approval before we can sell any of our products.

The development, manufacture and marketing of our products are subject to government regulation in the United States and other countries. In the United States and most foreign countries, we must complete rigorous preclinical testing and extensive human clinical trials that demonstrate the safety and efficacy of a product in order to apply for regulatory approval to market the product.

Our biopolymer scaffolding device is expected to be regulated as a Class III medical device by the FDA. The steps required by the FDA before our proposed medical device products may be marketed in the United States include performance of preclinical (animal and laboratory) tests; submissions to the FDA of an Investigational Device Exemption (IDE) which must become effective before human clinical trials may commence; performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product in the intended target population; performance of a consistent and reproducible manufacturing process intended for commercial use; Pre-Market Approval Application (PMA); and FDA approval of the PMA before any commercial sale or shipment of the product.

The processes are expensive and can take many years to complete, and we may not be able to demonstrate the safety and efficacy of our products to the satisfaction of such regulatory authorities. The start of clinical trials can be delayed or take longer than anticipated for many and varied reasons, many of which would be outside of our control. All statutes and regulations governing the conduct of clinical trials are subject to change in the future, which could affect the cost of such clinical trials. Safety concerns may emerge that could lengthen the ongoing trials or require additional trials to be conducted. Regulatory agencies may require us or our collaborators to delay, restrict or discontinue clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Regulatory authorities may also require additional testing, and we may be required to demonstrate that our proposed products represent an improved form of treatment over

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existing therapies, which we may be unable to do without conducting further clinical studies. Delays in regulatory approval can be extremely costly in terms of lost sales opportunities, losing any potential marketing advantage of being early to market and increased trial costs. Moreover, if the FDA grants regulatory approval of a product, the approval may be limited to specific indications or limited with respect to its distribution. Expanded or additional indications for approved devices or drugs may not be approved, which could limit our potential revenues. Foreign regulatory authorities may apply similar limitations or may refuse to grant any approval. Consequently, even if we believe that preclinical and clinical data are sufficient to support regulatory approval for our product candidates, the FDA and foreign regulatory authorities may not ultimately grant approval for commercial sale in any jurisdiction. If our products are not approved, our ability to generate revenues will be limited and our business will be adversely affected.

The results seen in animal testing of our product candidates may not be replicated in humans.

Although we have obtained some results from preclinical testing of our intended products in animals, we may not see positive results when any of our product candidates undergo clinical testing in humans in the future. Our preclinical testing to date has been limited in nature and we cannot predict whether more extensive clinical testing will obtain similar results. Success in preclinical studies or completed clinical trials does not ensure that later studies or trials, including continuing preclinical studies and large-scale clinical trials, will be successful nor does it necessarily predict future results. The rate of failure is quite high, and many companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Product candidates may fail to show desired safety and efficacy in larger and more diverse patient populations in later stage clinical trials, despite having progressed through early stage trials. Negative or inconclusive results from any of our ongoing preclinical studies or clinical trials could result in delays, modifications, or abandonment of ongoing or future clinical trials and the termination of our development of a product candidate. Additionally, even if we are able to successfully complete clinical trials, the FDA still may not approve our product candidates.

Our products are in an early stage of development and we currently have no therapeutic products approved for sale. We may be unable to develop or market any of our product candidates. If our product candidates are delayed or fail, our financial condition will be negatively affected, and we may have to curtail or cease our operations.

We currently do not sell any approved therapeutic products and do not expect to have any products commercially available for at least two years, if at all. We are subject to all of the uncertainties and complexities affecting an early stage biotechnology company. Our product candidates require additional research and development. Our strategy of using our technologies for the development of therapeutic products involves new approaches, some of which are unproven. To date, no one to our knowledge has developed or commercialized any therapeutic products using our technologies and we might never commercialize any product using our technologies and strategy. There are many reasons that our product candidates may fail or not advance to commercialization, including the possibility that our product candidates may be ineffective, unsafe or associated with unacceptable side effects; our product candidates may be too expensive to develop, manufacture or market; other parties may hold or acquire proprietary rights that could prevent us or our potential collaborators from developing or marketing our product candidates; physicians, patients, third-party payers or the medical community in general may not accept or use our contemplated products; our potential collaborators may withdraw support for or otherwise impair the development and commercialization of our product candidates; or others may develop equivalent or superior products.

If our current product candidates are delayed or fail, or we fail to successfully develop and commercialize new product candidates, our financial condition will be negatively affected, and we may have to curtail or cease our operations.

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Approval to promote, manufacture and/or sell our products, if granted, will be limited and subject to continuing review.

Even if a product gains regulatory approval, such approval is likely to limit the indicated uses for which it may be marketed, and the product and the manufacturer of the product will be subject to continuing regulatory review, including adverse event reporting requirements and the FDA s general prohibition against promoting products for unapproved uses. Failure to comply with any post-approval requirements can, among other things, result in warning letters, product seizures, recalls, substantial fines, injunctions, suspensions or revocations of marketing licenses, operating restrictions and criminal prosecutions. Any of these enforcement actions, any unanticipated changes in existing regulatory requirements or the adoption of new requirements, or any safety issues that arise with any approved products, could adversely affect our ability to market products and generate revenues and thus adversely affect our ability to continue our business.

We also may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or its manufacture are subsequently discovered and we cannot provide assurance that newly discovered or developed safety issues will not arise following any regulatory approval. With the use of any treatment by a wide patient population, serious adverse events may occur from time to time that initially do not appear to relate to the treatment itself, and only if the specific event occurs with some regularity over a period of time does the treatment become suspect as having a causal relationship to the adverse event. Any safety issues could cause us to suspend or cease marketing of our approved products, possibly subject us to substantial liabilities, and adversely affect our ability to generate revenues.

We will be required to obtain international regulatory approval to market and sell our products outside of the United States.

We intend to also have our product candidates marketed outside the United States. In order to market products in the European Union and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory agencies in other foreign countries. A failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions, including approval by the FDA. The failure to obtain regulatory approval in foreign jurisdictions could harm our business.

We will depend upon strategic relationships to develop, exploit and manufacture our products.

The near and long-term viability of our products will depend in part on our ability to successfully establish new strategic collaborations with biotechnology companies, hospitals, insurance companies and government agencies. Establishing strategic collaborations is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position. If we fail to establish a sufficient number of collaborations on acceptable terms, we may not be able to commercialize our products or generate sufficient revenue to fund further research and development efforts.

Even if we establish new collaborations, these relationships may never result in the successful development or commercialization of any product candidates for several reasons both within and outside of our control.

We will require quantities of manufactured product and may require third party manufacturers to fulfill some of our inventory requirements.

Completion of our clinical trials and commercialization of our products will require access to, or development of, facilities to manufacture a sufficient supply of our product or other product candidates. If we are unable to manufacture our products in commercial quantities, then we will need to rely on third parties. These third-party manufacturers must also receive FDA approval before they can produce clinical material or commercial products. Our products may be in competition with other products for access to these facilities and may be subject to delays in manufacture if third parties give other products greater priority. In addition, we may not be

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able to enter into any necessary third-party manufacturing arrangements on acceptable terms, or on a timely basis. Failure by us to manufacture products on a timely basis for clinical trials or for commercial needs will have a material adverse affect on us.

There are a limited number of suppliers that can provide materials to us.

We may rely on third-party suppliers and vendors for some of the materials used in the manufacture of our products or other of our product candidates. Any significant problem experienced by one of our suppliers could result in a delay or interruption in the supply of materials to us until such supplier resolves the problem or an alternative source of supply is located. Any delay or interruption could negatively affect our operations.

We will rely upon third parties for laboratory testing, animal and human studies.

We have been and will continue to be dependent on third-party contract research organizations to conduct some of our laboratory testing, animal and human studies. If we are unable to obtain any necessary testing services on acceptable terms, we may not complete our product development efforts in a timely manner. If we rely on third parties for laboratory testing and/or animal and human studies, we may lose some control over these activities and become too dependent upon these parties. These third parties may not complete testing activities on schedule or when we request. We may not be able to secure and maintain suitable contract research organizations to conduct our laboratory testing and/or animal and human studies. We are responsible for confirming that each of our clinical trials is conducted in accordance with our general plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our product candidates.

To date we have performed limited preclinical safety testing of our hydrogel containing methylprednisolone sodium succinate delivered locally to treat spinal cord injuries. The intended product might not be safe for human use. If we cannot demonstrate the product is safe for human use, future development will be halted and the product will never be evaluated in human clinical studies.

Methylprednisolone sodium succinate is a powerful anti-inflammatory drug that is delivered systemically to treat spinal cord injuries. The drug is a corticosteroid administered in high dosage and its use increases the risk of serious adverse effects including pneumonia, sepsis and mortality. Even though we believe that our hydrogel, designed to locally deliver the drug over a period of days will be safer than systemic delivery, to date the combination product has only been evaluated in animal testing on a limited basis. The risk exists that the intended product will have the same serious adverse effects as with systemic delivery and the introduction of the polymer could potentially introduce new side effects.

We will have to demonstrate that this intended product is safe before we can commence human clinical testing. The risk exists that the product will not be safe for human use in which case development would be halted and the product would never be evaluated in human clinical studies.

We may have product liability exposure.

We will have exposure to claims for product liability. Product liability coverage is expensive and sometimes difficult to obtain. We may not be able to obtain or maintain insurance at a reasonable cost. There can be no

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assurance that existing insurance coverage will extend to other products in the future. Any product liability insurance coverage may not be sufficient to satisfy all liabilities resulting from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable items, if at all. Even if a claim is not successful, defending such a claim would be time-consuming and expensive, may damage our reputation in the marketplace, and would likely divert management s attention.

Our products are new and will require market acceptance.

Even if we receive regulatory approvals for the commercial sale of our product candidates, the commercial success of these product candidates will depend on, among other things, their acceptance by physicians, patients, third party payers such as health insurance companies and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. If our product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. Market acceptance of, and demand for, any product that we may develop and commercialize will depend on many factors, both within and outside of our control. If our product candidates do not become widely accepted by physicians, patients, third party payers and other members of the medical community, our business, financial condition and results of operations would be materially and adversely affected.

Physicians and hospitals will require training in order to utilize our products.

Our products have not been utilized in the past for spinal cord injury treatment. As is typical in the case of a new and rapidly evolving technology or medical treatment, demand and market acceptance for recently introduced products and services are subject to a high level of uncertainty and risk. In addition, physicians and hospitals will need to establish training and procedures to utilize and implement our products. There can be no assurance that these parties will adopt our products or that they develop sufficient training and procedures to properly utilize our products.

Our success will depend upon the level of third party reimbursement for the cost of our products to users.

Our successes may depend, in part, on the extent to which reimbursement for the costs of therapeutic products and related treatments will be available from third-party payers such as government health administration authorities, private health insurers, managed care programs, and other organizations. Over the past decade, the cost of health care has risen significantly, and there have been numerous proposals by legislators, regulators, and third-party health care payers to curb these costs. Some of these proposals have involved limitations on the amount of reimbursement for certain products. Similar federal or state health care legislation may be adopted in the future and any products that we or our collaborators seek to commercialize may not be considered cost-effective. Adequate third-party insurance coverage may not be available for us to establish and maintain price levels that are sufficient for us to continue our business or for realization of an appropriate return on investment in product development.

We will be subject to environmental, health and safety laws.

We are subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and humans, emissions and wastewater discharges, and the use and disposal of hazardous or potentially hazardous substances used in connection with our research, including infectious disease agents. We also cannot accurately predict the extent of regulations that might result from any future legislative or administrative action. Any of these laws or regulations could cause us to incur additional expense or restrict our operations.

Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts.

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We must maintain the proprietary nature of our products and must operate without infringing on the proprietary rights of others.

Our success in large part depends on our ability to maintain the proprietary nature of our licensed technology. We will rely on a combination of patent, trademark, copyright and trade secret laws, as well as confidentiality agreements, license agreements and technical measures to protect our proprietary rights. We and our licensors must prosecute and maintain existing patents and obtain new patents. Some of our proprietary information may not be patentable, and there can be no assurance that others will not utilize similar or superior solutions to compete with us. We cannot guarantee that we will develop proprietary products and services or processes that are patentable, and that if issued, any patent will give a competitive advantage or that such patent will not be challenged by third parties, or that the patents of others will not have a material adverse effect on our ability to do business. We intend to register certain trademarks in, or claim certain trademark rights in, the United States and/or foreign jurisdictions. We cannot assure you that our means of protecting our proprietary rights will suffice or that our competitors will not independently develop competitive technology or duplicate processes or design around patents or other intellectual property rights issued to us.

We also must operate without infringing the proprietary rights of third parties or allowing third parties to infringe our rights. Our research, development and commercialization activities, including any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents owned by third parties and to which we do not hold licenses or other rights. There may be rights that we are not aware of, including applications that have been filed but not published that, when issued, could be asserted against us. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or biologic treatment candidate that is the subject of the suit.

In addition, competitors may infringe our patents or the patents of our collaborators or licensors. As a result, we may be required to file infringement claims to counter infringement for unauthorized use. This can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent licensed or owned by us is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our licensed or owned patents do not cover its technology. An adverse determination of any litigation or defense proceedings could put one or more of our licensed or owned patents at risk of being invalidated or interpreted narrowly and could put our licensed or owned patent applications at the risk of not issuing.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our trade secrets or other confidential information could be compromised by disclosure during this type of litigation.

Our ability to raise capital as required may be difficult given the current condition of the capital and credit markets.

We are likely in the future to seek to access the capital markets for our capital needs. Traditionally, biotech companies have funded their research and development expenditures through raising capital in the equity markets. Declines and uncertainties in these markets over the past few years have severely restricted raising new capital and have affected companies ability to continue to expand or fund existing research and development efforts. We will require significant capital beyond our current resources for research and development for our product candidates and clinical trials. The general economic and capital market conditions, both in the United States and worldwide have deteriorated significantly and will adversely affect our access to capital and may increase the cost of capital. If these economic conditions continue or become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected.

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We are dependent on our management and other key personnel.

We depend on our senior executive officers as well as key scientific and other personnel. The loss of any of these individuals could harm our business and significantly delay or prevent the achievement of research, development or business objectives. Competition for qualified employees is intense among biotechnology companies, and the loss of qualified employees, or an inability to attract, retain and motivate additional highly skilled employees could hinder our ability to successfully develop marketable products.

Our future success also depends on our ability to identify, attract, hire, train, retain and motivate other highly skilled scientific, technical, marketing, managerial and financial personnel. Although we will seek to hire and retain qualified personnel with experience and abilities commensurate with our needs, there is no assurance that we will succeed despite our collective efforts. The loss of the services of any of the principal members of our management or other key personnel could hinder our ability to fulfill our business plan and further develop and commercialize our products and services. Competition for personnel is intense, and any failure to attract and retain the necessary technical, marketing, managerial and financial personnel would have a material adverse effect on our business, prospects, financial condition and results of operations. Although we presently do not maintain key person life insurance policies on any of our personnel, we are currently in the process of obtaining key man insurance on Frank Reynolds, our Chairman, Chief Executive Officer and Chief Financial Officer.

Risks Related to Investment in Our Securities

Our securities are Penny Stock and subject to specific rules governing their sale to investors.

The SEC has adopted Rule 15g-9 which establishes the definition of a penny stock, for the purposes relevant to us, as any equity security that has a market price of less than $5.00 per share or with an exercise price of less than $5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require that a broker or dealer approve a person s account for transactions in penny stocks; and the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person s account for transactions in penny stocks, the broker or dealer must obtain financial information and investment experience objectives of the person; and make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form sets forth the basis on which the broker or dealer made the suitability determination; and that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the penny stock rules. This may make it more difficult for our shareholders to sell shares of our Common Stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on th0pt;padding:0pt .7pt 0pt 0pt;width:12.9%;">

2,356

TOTAL ASSETS

$

80,464

$

76,809

LIABILITIES AND SHAREHOLDERS EQUITY

Current Liabilities:

Accounts payable

$

3,404

$

2,239

Accrued expenses and other current liabilities	8,441	8,578
Accrued compensation	2,014	1,467
Accrued procurement fees	4,203	3,797
Notes payable	826	
Derivative liability	225	

114

Line of credit

4,504

4,530

Current maturities of capital lease obligations

232

554

Total current liabilities

23,849

21,279

Capital lease obligations, less current maturities

135

Other long-term liabilities

4,760

4,909

Deferred income taxes

248

Total liabilities

28,992

26,188

Shareholders Equity:

Preferred stock (325 issued shares in 2006 and 325 in 2005)

3

3

Common stock (25,792 issued shares in 2006 and 25,582 in 2005)

258

256

Additional paid-in capital

114,758

113,507

Retained deficit

(58,884

)

(58,569

)

Accumulated other comprehensive income

88

123

Treasury stock at cost (904 shares in 2006 and 892 in 2005)

(4,751

)

(4,699

)

Total shareholders equity

51,472

50,621

TOTAL LIABILITIES AND SHAREHOLDERS EQUITY

$

80,464

$

76,809

See accompanying notes to summary consolidated financial statements.

CRYOLIFE, INC. AND SUBSIDIARIES

SUMMARY CONSOLIDATED STATEMENTS OF CASH FLOWS

(IN THOUSANDS)

	Nine Months Ended September 30, 2006 (Unaudited)	2005
Net cash from operating activities:		
Net income (loss)	$ 415	$ (18,854)
Adjustments to reconcile net income (loss) to net cash from operating activities:		
Gain on sale of marketable equity securities		(5)
Loss on sale or disposal of assets	385	146
Depreciation and amortization	3,646	3,816
Provision for doubtful accounts	72	72
Write-down of deferred preservation costs	1,568	1,298
Other non-cash adjustments	102	(138)
Non-cash compensation	853	166
Change in valuation of derivative	111	372
Changes in operating assets and liabilities:		
Receivables	(3,997)	(754)
Income taxes	(130)	66
Deferred preservation costs and inventories	(7,522)	(5,023)
Prepaid expenses and other assets	(460)	(940)
Accounts payable, accrued expenses, and other liabilities	2,088	4,809
Net cash used in operating activities	(2,869)	(14,969)
Net cash from investing activities:		
Capital expenditures	(1,409)	(664)
Net proceeds from sale of assets	13	
Other assets	(59)	(173)
Purchases of marketable securities	(12,436)	(21,690)
Sales and maturities of marketable securities	14,562	18,847
Net cash provided by (used in) investing activities	671	(3,680)
Net cash from financing activities:		
Proceeds from debt issuance	585	3,765
Principal payments of debt	(428)	(265)
Payment of obligations under capital leases	(370)	(582)
Proceeds from financing of insurance policies	2,349	2,482
Principal payments on short-term notes payable	(1,523)	(1,613)
Proceeds from exercise of stock options and issuance of common stock	398	308
Payment of preferred stock dividends	(730)	(533)
Proceeds from equity offerings		19,098
Purchase of treasury stock	(50)	
Net cash provided by financing activities	231	22,660
(Decrease) increase in cash and cash equivalents	(1,967)	4,011
Effect of exchange rate changes on cash	(58)	(124)
Cash and cash equivalents, beginning of period	6,631	4,713
Cash and cash equivalents, end of period	$ 4,606	$ 8,600

See accompanying notes to summary consolidated financial statements.

CRYOLIFE, INC. AND SUBSIDIARIES

NOTES TO SUMMARY CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

Note 1 Basis of Presentation

The accompanying unaudited summary consolidated financial statements have been prepared in accordance with (i) accounting principles generally accepted in the United States for interim financial information and (ii) the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the United States Securities and Exchange Commission (SEC). Accordingly, the statements do not include all of the information and disclosures required by accounting principles generally accepted in the United States for a complete presentation of financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Certain prior year cash flow line items have been reclassified to conform to current year presentation. Operating results for the nine months ended September 30, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006. For further information, refer to the consolidated financial statements and notes thereto included in the CryoLife Form 10-K for the year ended December 31, 2005.

The Company expects that the following will continue to have an adverse impact on earnings and cash flows during 2006:

- The anticipated lower preservation services revenues as compared to preservation revenues prior to the August 13, 2002 U.S. Food and Drug Administration (FDA) Order, subsequent FDA activities, and related events (discussed in Note 2),

- The high cost of human tissue preservation services as a percent of revenue, as compared to the period prior to the FDA Order, as a result of lower tissue processing volumes and changes in processing methods, which have increased the cost of processing human tissue and decreased yields of implantable tissue per donor,

- An expected use of cash related to the defense and resolution of lawsuits and claims, and

- The legal and professional costs related to ongoing FDA compliance.

The Company believes the following should continue to have a favorable impact on cash flow from operations during the remainder of 2006, although there can be no assurance that these events will occur as and when currently anticipated:

- Expected increases in product revenues over levels experienced in 2005 due to increases in BioGlue® Surgical Adhesive (BioGlue) list prices implemented in January and July 2006,

- Expected increases in preservation service revenues over levels experienced in 2005 for cardiovascular, vascular, and orthopaedic tissues due to fee increases implemented in January and July 2006, to reflect the higher cost of processing these tissues,

- Anticipated improvements in yields of implantable tissues per donor over the levels experienced in 2005 through process changes and process directives,

- Expected increases in procurement of human tissues for processing over the levels experienced in 2005, and

- Anticipated decreases in cash payments related to the defense and resolution of lawsuits and claims from the levels seen in 2003 through 2005.

The Company believes that the Company s existing cash, cash equivalents, marketable securities, and availability under the Credit Agreement (as defined in Note 6) will enable the Company to meet its liquidity needs through at least September 30, 2007.

The Company s long term liquidity and capital requirements will depend upon numerous factors, including:

- The success of the Company s strategic plan to enhance shareholder value, resulting from the conclusion of its strategic review with the assistance of Piper Jaffray & Co.,
- The success of BioGlue and other products using related technology,
- The Company s ability to increase the level of tissue procurement and demand for its tissue preservation services,
- The Company s ability to reestablish sufficient margins on its tissue preservation services, in the face of increased processing costs, by improving yields and increasing prices,
- The Company s spending levels on its research and development activities, including research studies, to develop and support its service and product pipeline,
- The timing and cost of resolving product liability lawsuits and other claims (see Note 13), and
- To a lesser degree, the Company s success at resolving the issues with the FDA regarding processing of human tissue using the SynerGraft® technology (see Note 2).

If the Company is unable to address these issues and continues to experience negative operating cash flows, the Company anticipates that it may require additional financing or seek to raise additional funds through bank facilities, debt or equity offerings, or other sources of capital to meet liquidity and capital requirements beyond September 30, 2007. Additional funds may not be available when needed or on terms acceptable to the Company, which could have a material adverse effect on the Company s business, financial condition, results of operations, and cash flows.

Note 2 FDA Order on Human Tissue Preservation and Other FDA Correspondence and Notices

FDA Order

On August 13, 2002 the Company received an order from the Atlanta district office of the FDA regarding the non-valved cardiac, vascular, and orthopaedic tissues processed by the Company since October 3, 2001 (the FDA Order). Pursuant to the FDA Order, the Company placed non-valved cardiac, vascular, and orthopaedic tissue subject to the FDA Order (i.e. processed since October 3, 2001) on quality assurance quarantine and recalled the portion of those tissues that had been distributed but not implanted. In addition the Company ceased processing non-valved cardiac, vascular, and orthopaedic tissues.

The FDA allowed non-valved cardiac and vascular tissues covered by the recall to be distributed beginning in late September 2002, subject to specified conditions. The Company changed its processing procedures and took other actions intended to address the FDA s concerns, and now processes non-valved cardiac, vascular, and orthopaedic tissues.

Other FDA Correspondence and Notices

July 2005 483

An FDA Form 483 Notice of Observations (483) was issued in August 2005 in connection with the FDA inspections of the Company s facilities in July 2005 (July 2005 483). The Company responded to the July 2005 483 in August 2005, in September 2005, and in October 2005. In April 2006 the FDA responded on the adequacy of the Company s responses. The Company responded to the FDA in June 2006. In response to the July 2005 483 the

Company has implemented new and revised existing systems and procedures. The FDA may require the Company to implement additional corrective actions, perform additional validation testing, or supply additional information related to the inspections, and has the authority to take other actions, which may be more burdensome. The Company has cooperated and will continue to cooperate with the FDA to review process improvements and address any outstanding observations.

SynerGraft

On February 20, 2003 the Company received a letter from the FDA stating that a 510(k) premarket notification should be filed for the Company s SynerGraft processed human cardiac tissues (CryoValve® SG) and that premarket approval marketing authorization should be obtained for the Company s SynerGraft processed human vascular tissues (CryoVein® SG) when marketed or labeled as an arteriovenous (A-V) access graft. The agency s position is that use of the SynerGraft technology in the processing of allograft heart valves represents a modification to the Company s legally marketed CryoValve allograft and that vascular allografts labeled for use as A-V access grafts are medical devices that require premarket approval.

On November 3, 2003 the Company filed a 510(k) premarket notification with the FDA for the CryoValve SG. On February 4, 2004 the Company received a letter from the FDA requesting additional information. On August 24, 2004 the Company submitted an amendment to its original 510(k) submission providing clarification and additional information. The FDA requested further additional information in November 2004. On June 8, 2005 CryoLife responded to some of these additional requests. CryoLife also has initiated an appeal of other requests through administrative procedures. The FDA requested further additional information in January 2006. Since March 2006 the Company has had discussions with the FDA to address the outstanding requests for additional information and seek clearance for the CryoValve SG pulmonary valve. On July 21, 2006 the Company submitted an amendment to its 510(k) application addressing information requested by the FDA. The Company is currently undertaking further clinical and preclinical evaluations in response to requests by the FDA that will be included in an additional 510(k) amendment. The FDA may still require that additional studies be undertaken. Clearance of the 510(k) premarket notification with the FDA will be required before the Company can resume distribution of SynerGraft processed CryoValve SG.

On December 8, 2003 the Company received a letter from the FDA stating that it was the agency s position that cardiovascular tissues processed with the SynerGraft technology should be regulated as medical devices. On September 14, 2004 the Company met with the FDA to discuss the data to be used to support a formal Request for Designation (RFD) filing for SynerGraft processed non-valved cardiac and vascular tissue, including the CryoVein SG. An RFD submission establishes the regulatory status of the tissue. The Company submitted the RFD on October 5, 2004. The FDA affirmed its original decision in letters received in December 2004. That decision was subject to an administrative appeal. On October 20, 2005 CryoLife was informed that the FDA had denied the appeal and that CryoLife will be unable to distribute CryoVein tissues with the SynerGraft technology until further submissions and FDA approvals are granted. The Company is evaluating whether it will file and seek approvals for CryoVein SG or discontinue the CryoVein SG.

In 2003 the Company suspended the use of the SynerGraft technology in the processing of allograft tissue and the distribution of tissues on hand previously processed with the SynerGraft technology until the regulatory issues associated with these tissues are resolved. Additionally, the Company discontinued labeling its vascular grafts for use as A-V access grafts. Until such time as the issues surrounding SynerGraft are resolved, the Company is employing its traditional processing methods on these tissues. As of September 30, 2006 the Company had no deferred preservation costs related to SynerGraft processed tissues on its Summary Consolidated Balance Sheets.

Note 3 Cash Equivalents and Marketable Securities

The Company maintains cash equivalents and investments in several large, well-capitalized financial institutions, and the Company s policy excludes investment in any securities rated less than investment-grade by national rating services. Management determines the appropriate classification of its marketable securities at the time of purchase and reevaluates such designations quarterly.

Debt securities are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Held-to-maturity securities are stated at amortized cost. Trading securities are securities that are acquired principally for the purpose of generating a profit from short-term fluctuations in price. Trading securities are stated at their fair values, with the realized and unrealized gains and losses, interest, and dividends included in investment income. Debt securities not classified as held-to-maturity or trading and marketable equity securities not classified as trading are classified as available-for-sale. Available-for-sale securities are stated at their fair values, with the unrealized gains and losses, net of applicable taxes, reported in a separate component of shareholders equity. Interest, dividends, realized gains and losses, and declines in value judged to be other than temporary are included in investment income. The cost of securities sold is based on the specific identification method.

As of September 30, 2006 $3.0 million of marketable securities were designated as available-for-sale and $565,000 were designated as held-to-maturity. As of December 31, 2005 $5.0 million of marketable securities were designated as available-for-sale and $560,000 were designated as held-to-maturity. The held-to-maturity securities were designated as such due to a contractual commitment to hold the securities as pledged collateral relating to one of the Company s product liability insurance policies, and, therefore, they are reported as restricted securities on the September 30, 2006 and December 31, 2005 Summary Consolidated Balance Sheets.

The following is a summary of cash equivalents and marketable securities (in thousands):

September 30, 2006	**Cost Basis**	**Unrealized Holding Gains (Losses)**	**Estimated Market Value**
Cash equivalents:			
Money market funds	$ 3,837	$	$ 3,837
Marketable securities:			
Government entity sponsored debt securities	$ 2,985	$ 1	$ 2,986
Total marketable securities	$ 2,985	$ 1	$ 2,986
Restricted securities:			
Government entity sponsored debt securities	$ 565	$	$ 565

December 31, 2005	**Cost Basis**	**Unrealized Holding Gains (Losses)**	**Estimated Market Value**
Cash equivalents:			
Money market funds	$ 5,595	$	$ 5,595
Marketable securities:			
Government entity sponsored debt securities	$ 2,980	$ (2)	$ 2,978
US Treasury debt securities	1,990		1,990
Total marketable securities	$ 4,970	$ (2)	$ 4,968
Restricted securities:			
Government entity sponsored debt securities	$ 560	$	$ 560

There were no gross realized gains or losses on sales of available-for-sale securities for both the three and nine months ended September 30, 2006 and 2005. Differences between cost and market listed above, consisting of a net unrealized holding gain of $1,000 less deferred taxes of zero at September 30, 2006, and a net unrealized holding loss of $2,000 less deferred taxes of zero at December 31, 2005, are included as a separate component of other comprehensive income in the shareholders equity section of the Summary Consolidated Balance Sheets.

At September 30, 2006 and December 31, 2005 all of the Company s marketable securities had a maturity date within 90 days.

Note 4 Inventories

Inventories are comprised of the following (in thousands):

	September 30, 2006 (Unaudited)	December 31, 2005
Raw materials	$ 2,935	$ 3,083
Work-in-process	374	415
Finished goods	1,704	1,111
Total inventories	$ 5,013	$ 4,609

Note 5 Income Taxes

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and tax return purposes. The Company generated deferred tax assets beginning in 2002 primarily as a result of write-downs of deferred preservation costs, accruals for product liability claims, and operating losses. These write-downs, accruals, and losses reflect reductions in revenues and additional professional fees, as a result of the FDA Order, subsequent FDA activities, and related events. The Company assesses the recoverability of its deferred tax assets, on an annual basis and on an interim basis, as necessary, when the Company experiences changes that could materially affect its determination of the recoverability of its deferred tax assets. Management provides a valuation allowance when, as a result of this analysis, management believes it is more likely than not that its deferred tax assets will not be realized. In assessing the recoverability of its deferred tax assets at December 31, 2005 the Company reviewed its historical operating results, including the reasons for its operating losses, uncertainties regarding projected future operating results, and the uncertainty of the outcome of litigation. Based on the results of this analysis, at December 31, 2005 the Company determined that it was more likely than not that the Company s deferred tax assets would not be realized. Therefore, as of December 31, 2005 the Company had a total of $26.4 million in valuation allowances against deferred tax assets and a net deferred tax asset balance of zero.

Based on the Company s results of operations for the nine months ended September 30, 2006, the Company does not expect to generate material deferred tax assets or utilize material amounts of its net operating loss carryforwards during the year ended December 31, 2006. For the nine months ended September 30, 2006 the Company did not experience any changes that would materially affect the Company s prior determination of the recoverability of its deferred tax assets. As of September 30, 2006 the Company had a total of $26.4 million in valuation allowances against deferred tax assets and a net deferred tax liability of $248,000 related to taxes in a foreign jurisdiction. The realizability of the Company s deferred tax assets could be limited in future periods as mandated by Internal Revenue Service Section 382.

As of September 30, 2006 the Company had income tax receivables related to federal income tax losses from the years ended December 31, 2005 and 2004 that can be carried back to prior years to offset income taxes paid and should result in approximately $453,000 in refunds to the Company during 2006.

Note 6 Debt

On February 8, 2005 CryoLife and its subsidiaries entered into a credit agreement with Wells Fargo Foothill, Inc. as lender (the Credit Agreement). The Credit Agreement provides for a revolving credit facility in an aggregate amount equal to the lesser of $15.0 million (including a letter of credit subfacility of up to an aggregate of $2.0 million) or a borrowing base determined in accordance with the terms of the Credit Agreement. Generally, the borrowing base is 20% of the appraised value of the business of CryoLife, reduced by specified lender reserves. The Credit Agreement places limitations on the amount that the Company may borrow, and includes various affirmative and negative covenants, including financial covenants such as a requirement that CryoLife either (i) maintain quarterly a minimum aggregate borrowing availability under the Credit Agreement, less certain payables incurred outside the Company s

historical practices, plus unrestricted cash and cash equivalents, as defined (Availability), of at least $12.5 million or (ii) achieve as of each quarter end a minimum level of earnings before extraordinary gains, interest, taxes, depreciation, and amortization (EBITDA), BioGlue gross margins of at least 70% for the preceding twelve months, as well as Availability of at least $5.0 million. While the Company currently expects that its aggregate borrowing capacity under the Credit Agreement will equal $15.0 million, there can be no assurance that the capacity will remain at this level. The Credit Agreement also includes customary conditions on incurring new indebtedness and limitations on cash dividends. Cash dividends on any class of capital stock are prohibited, provided that cash dividends on preferred stock may be paid so long as the Company maintains $7.5 million, in the aggregate, of cash, cash equivalents, and borrowing capacity, as defined. There is no restriction on the payment of stock dividends. Commitment fees are paid based on the unused portion of the facility. The Credit Agreement expires on February 7, 2008, at which time the outstanding principal balance will be due. Due to the terms of the Credit Agreement and due to the net losses and negative cash flows experienced by the Company since the FDA Order, the Company has classified amounts due under the Credit Agreement as short-term debt on the September, 2006 and December 31, 2005 Summary Consolidated Balance Sheets in accordance with the provisions of FASB Technical Bulletin No. 79-3 (As Amended).

Amounts borrowed under the Credit Agreement are secured by substantially all of the tangible and intangible assets of CryoLife and its subsidiaries and bear interest at the bank s prime rate plus 1%, which was 9.25% as of September 30, 2006. As of September 30, 2006 the outstanding balance of the Credit Agreement was $4.5 million and the remaining borrowing availability was $10.5 million.

The Company routinely enters into agreements to finance insurance premiums for periods not to exceed the terms of the related insurance policies. In the quarter ended June 30, 2005 the Company entered into two agreements to finance approximately $1.7 million and $761,000 in insurance premiums associated with the yearly renewal of certain Company insurance policies. The amounts financed accrued interest at 4.98% and 5.01%, respectively, and were payable in equal monthly payments over a nine month period and an eight month period, respectively. As of September 30, 2006 the outstanding balance under the agreements was zero.

In the second quarter of 2006 the Company entered into two agreements to finance approximately $1.6 million and $715,000 in insurance premiums associated with the yearly renewal of certain of the Company s insurance policies. The amounts financed accrue interest at 6.71% and 6.7%, respectively, and are payable in equal monthly payments over a nine month and an eight month period, respectively. As of September 30, 2006 the aggregate outstanding balance under the agreements was $826,000.

In September 2006 the Company s European subsidiary obtained a pre-approved credit facility with a bank in the United Kingdom for the financing of vehicles. This credit facility pre-approves the Company to enter into leases to finance vehicles, for which terms and interest rates are set for each individual lease agreement. The Company has accounted for the leases entered into under this credit facility as operating leases. The credit facility allows the Company to have a total exposure on outstanding leases, as defined by the bank, of £180,000 (or approximately $339,000 as of September 30, 2006). Per the bank, the Company had a total exposure of approximately £105,000 or $198,000 as of September 30, 2006, and the Company s total payment obligations related to these outstanding leases was $123,000 as of September 30, 2006.

Note 7 Convertible Preferred Stock

On December 17, 2004 the Company announced that it had filed a shelf registration statement on Form S-3 with the SEC covering the sale from time to time of up to $50 million of its common stock, preferred stock, depositary shares, or any combination of these securities for its own account in one or more offerings.

On March 18 and April 19, 2005 the Company completed a public offering of 417,000 shares of 6% convertible preferred stock (the Preferred Stock) at a price to the public of $50.00 per share. Net proceeds from the offering, after deducting underwriting discounts and offering-related expenses, totaled approximately $19.1 million.

Dividends on the Preferred Stock are cumulative from the date of original issue at the annual rate of 6% of the liquidation preference of the Preferred Stock, payable quarterly on the first day of January, April, July, and October, commencing July 1, 2005. Any dividends must be declared by the Company s board of directors and must come

from funds that are legally available for dividend payments. On September 7, 2006 the Company declared a dividend of $0.75 per share on its Preferred Stock. The dividend of approximately $243,000 was paid on October 2, 2006 to shareholders of record on September 22, 2006.

The Preferred Stock is convertible at the option of the holder at any time into the Company s common stock at a conversion rate of approximately 6.2189 shares of common stock for each share of Preferred Stock, based on an initial conversion price of $8.04 per share of common stock. The initial conversion price is subject to adjustment in certain events. The Company reserved 4,600,000 shares of common stock for issuance upon conversion. Through September 30, 2006 holders had voluntarily converted 92,000 shares of Preferred Stock into 575,000 shares of common stock.

The Company may automatically convert the Preferred Stock into common stock if the closing price of the Company s common stock has exceeded $12.06, which is 150% of the conversion price of the Preferred Stock, for at least 20 trading days during any 30-day trading period, ending within five trading days prior to notice of automatic conversion.

If the Company elects to automatically convert, or the holder elects to voluntarily convert, some or all of the Preferred Stock into common stock prior to April 1, 2008, the Company will make an additional payment on the Preferred Stock equal to the aggregate amount of dividends that would have been payable on the Preferred Stock through and including April 1, 2008, less any dividends already paid on the Preferred Stock, the Dividend Make-Whole Payment . The Dividend Make-Whole Payment is payable in cash or, at the Company s option, in shares of the Company s common stock, or a combination of cash and shares of common stock. Through September 30, 2006 the Company had issued 119,000 shares of common stock to converting holders in satisfaction of this additional payment.

The Preferred Stock has a liquidation preference of $50.00 per share, plus accrued and unpaid dividends. The liquidation preference of the Preferred Stock was approximately $16.2 million as of September 30, 2006, before the payment of the October 2006 dividend.

The Company may elect to redeem the Preferred Stock, in whole or in part, at declining redemption prices on or after April 7, 2008.

The Preferred Stock has no maturity date and no voting rights prior to conversion into common stock, except under limited circumstances and as required by law.

Note 8 Derivative

In accordance with Statement of Financial Accounting Standards (SFAS) No. 133, Accounting for Derivative Instruments and Hedging Activities (SFAS 133), the Company is required to separate and account for the Dividend Make-Whole Payment feature of its Preferred Stock as an embedded derivative, (the Derivative). As an embedded derivative instrument, the Dividend Make-Whole Payment feature must be measured at fair value and reflected as a current liability on the Company s Summary Consolidated Balance Sheets. Changes in the fair value of the Derivative are recognized in the line item change in valuation of derivative as a non-operating income/expense on the Company s Summary Consolidated Statements of Operations. The Company determined the fair value of the Derivative to be $1.0 million on March 18, 2005, the date of issuance. The Company determined the fair value of the Derivative related to the issuance of additional Preferred Stock upon exercise of the underwriter s over allotment option to be $32,000 on April 19, 2005, the date of issuance. The proceeds from the Preferred Stock as recorded on the Summary Consolidated Balance Sheets were reduced by these amounts, which were allocated to the derivative liability.

Due to the quarterly revaluation of the derivative liability, the Company recorded other expense of $44,000 and $111,000 for the three and nine months ended September 30, 2006, respectively. At September 30, 2006 the derivative liability was valued at $225,000.

Note 9 Comprehensive Income (Loss)

The following is a summary of comprehensive income (loss) (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006 (Unaudited)	2005	2006 (Unaudited)	2005
Net income (loss)	$ 1,978	$ (3,118)	$ 415	$ (18,854)
Unrealized gain (loss) on investments	1	(13)	3	(37)
Translation adjustment	(16)	20	(38)	(129)
Comprehensive income (loss)	$ 1,963	$ (3,111)	$ 380	$ (19,020)

The tax effect on the change in unrealized gain (loss) on investments is zero for both the three months ended September 30, 2006 and 2005. The tax effect on the change in unrealized gain (loss) on investments is zero and $11,000 for the nine months ended September 30, 2006 and 2005, respectively. The tax effect on the translation adjustment is zero for each period presented.

Components of accumulated other comprehensive income consist of the following, net of tax (in thousands):

	September 30, 2006 (Unaudited)	December 31, 2005
Unrealized gain (loss) on investments	$ 1	$ (2)
Translation adjustment	87	125
Total accumulated other comprehensive income	$ 88	$ 123

Note 10 Income (Loss) per Common Share

The following table sets forth the computation of basic and diluted income (loss) per common share (in thousands, except per share data). The net income (loss) for the three and nine months ended September 30, 2006 and 2005 is adjusted by the effect of the Company s cumulative, convertible Preferred Stock to arrive at net income (loss) applicable to common shares in accordance with SFAS No. 128, Earnings Per Share (SFAS 128). The Company also considers the effect of its Preferred Stock, as discussed in Note 7, the Derivative, as discussed in Note 8, and common stock options, as discussed in Note 11, in the calculation of diluted weighted-average shares below.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006 (Unaudited)	2005	2006 (Unaudited)	2005
Numerator for basic income (loss) per common share:				
Net income (loss)	$ 1,978	$ (3,118)	$ 415	$ (18,854)
Effect of preferred stock a	(243)	(243)	(730)	(533)
Net income (loss) applicable to common shares	$ 1,735	$ (3,361)	$ (315)	$ (19,387)
Denominator for basic income (loss) per common share:				
Basic weighted-average shares	24,847	24,161	24,804	23,839
Basic income (loss) per common share	$ 0.07	$ (0.14)	$ (0.01)	$ (0.81)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006 (Unaudited)	2005	2006 (Unaudited)	2005
Numerator for diluted income (loss) per common share:				
Net income (loss)	$ 1,978	$ (3,118)	$ 415	$ (18,854)
Effect of preferred stock(b)	(243)	(243)	(730)	(533)
Effect of stock options (c)				
Net income (loss) applicable to common shares	$ 1,735	$ (3,361)	$ (315)	$ (19,387)
Denominator for diluted income (loss) per common share:				
Basic weighted-average shares	24,847	24,161	24,804	23,839
Effect of dilutive convertible preferred stock (b)				
Effect of dilutive stock options (c)	271			
Adjusted weighted-average shares	25,118	24,161	24,804	23,839
Diluted income (loss) per common share	$ 0.07	$ (0.14)	$ (0.01)	$ (0.81)

(a) The amount of the accumulated dividend on Preferred Stock reduced the net income applicable to common shares by $243,000 for the three months ended September 30, 2006. The amount of the accumulated dividend on Preferred Stock offset the Company s net income and resulted in a net loss applicable to common shares with a total unfavorable effect of $730,000 for the nine months ended September 30, 2006. The amount of the accumulated dividend on Preferred Stock increased the net loss applicable to common shares by $243,000 and $533,000 for the three and nine months ended September 30, 2005, respectively.

(b) The amount of the accumulated dividend on Preferred Stock reduced the net income applicable to common shares by $243,000 for the three months ended September 30, 2006. The amount of the accumulated dividend on Preferred Stock offset the Company s net income and resulted in a net loss applicable to common shares with a total unfavorable effect of $730,000 for the nine months ended September 30, 2006. The adjustment for the quarterly revaluation of the derivative liability, would have instead increased the net income applicable to common shareholders by $44,000 and $111,000 for the three and nine months ended September 30, 2006, respectively, and the common shares that would be issued to shareholders upon conversion of the remaining Preferred Stock and in payment of the remaining Dividend Make-Whole Payment would have increased the weighted-average shares by 2.3 million for both the three and nine months ended September 30, 2006. These adjustments were excluded from the calculation above, as they were anti-dilutive pursuant to the provisions of SFAS 128.

The amount of the accumulated dividend on the Preferred Stock increased the net loss applicable to common shares by $243,000 and $533,000 for the three and nine months ended September 30, 2005, respectively. The adjustment for the Dividend Make-Whole Payment on preferred shares converted during the period and the quarterly revaluation of the derivative liability would have increased the net loss applicable to common shareholders by $412,000 for the three months ended September 30, 2005 and decreased the net loss applicable to common shareholders by $372,000 for the nine months ended September 30, 2005, and the common shares that would be issued to shareholders upon conversion of the remaining Preferred Stock and in payment of the remaining Dividend Make-Whole Payment would have increased the weighted-average shares by 2.4 million and 1.9 million for the three and nine months ended September 30, 2005, respectively. These adjustments were excluded from the calculation above, as they were anti-dilutive pursuant to the provisions of SFAS 128.

(c) Outstanding options to purchase the Company s common stock resulted in 271,000 additional dilutive common shares for the three months ended September 30, 2006. Outstanding options to purchase the Company s common stock

that would have resulted in 211,000 additional dilutive shares for the nine months ended September 30, 2006 were excluded from the calculation, as they were anti-dilutive pursuant to the provisions of SFAS 128.

Outstanding options to purchase the Company s common stock that would have resulted in 387,000 and 382,000 additional dilutive common shares, respectively for the three and nine months ended September 30, 2005, were excluded from the calculation, as these items were anti-dilutive pursuant to the provisions of SFAS 128.

In future periods the basic and diluted earnings (loss) per common share are expected to be affected by the declaration of dividends on Preferred Stock, the conversion of Preferred Stock, fluctuations in the fair value of the Company s common stock, issuance of additional stock options, and changes in the valuation of the Derivative.

Note 11 Stock Compensation

In August 2006 the Company s Board of Directors authorized the grant of stock to its non-employee directors. The stock grants of 2,500 shares of common stock per non-employee director were valued at a total of $109,000 based on the stock price of $5.47 on the date of grant. The value of this stock grant will be recorded as director compensation over the 12-month vesting period. The Company also made cash payments totaling $38,000 to the non-employee directors to partially offset each individual s income tax liability as a result of the stock grant. The Company recorded $47,000 in expense related to these stock grants during the third quarter of 2006.

In February 2006 the Company s Board of Directors authorized the grant of stock to recognize the performance of certain Company executives. The stock grants totaled 34,000 shares of common stock, which were valued at $145,000 based on the stock price of $4.25 on the date of grant. The Company purchased $50,000 of Company stock from employees, based on the closing price on the New York Stock Exchange on the day the stock was transferred to the Company, to pay employee federal and state withholding taxes related to these stock grants. The Company recorded $145,000 in compensation expense related to these stock grants during the first quarter of 2006.

The Company has stock option and stock incentive plans that provide for grants of shares to employees and grants of options to employees and directors to purchase shares of the Company s common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. The Company maintains a shareholder approved Employee Stock Purchase Plan (the ESPP) for the benefit of its employees. The ESPP allows eligible employees the right to purchase common stock on a quarterly basis at the lower of 85% of the market price at the beginning or end of each three-month offering period. Pursuant to the adoption of SFAS 123 Revised Share-Based Payment (SFAS 123R) both the Company s 15% discount on ESPP stock purchases and the lookback portion of ESPP stock purchases are considered components of stock compensation and must be expensed in the Company s financial statements. The lookback portion of the Company s ESPP constitutes an option and, as such, the expense is determined by performing a valuation as discussed below.

The Company adopted SFAS 123R as amended by SEC Rule 2005-57 Commission Amends Compliance Dates For FASB Statement No. 123R on Employee Stock Options for the period beginning October 1, 2005. SFAS 123R requires companies to recognize the cost of all share-based payments in the financial statements using a fair-value based measurement method. SFAS 123R applies to new awards and to awards modified, repurchased, or cancelled after the implementation date, as well as to the unvested portion of awards outstanding as of the implementation date. The Company uses the Black-Scholes model to value its stock option grants under SFAS 123R and expenses the related compensation cost using the straight-line method over the vesting period. The fair value of the Company s ESPP options is also determined using the Black-Scholes model and is expensed quarterly at the end of the purchase period, as the option is fully vested at that time. The fair value of stock options is determined on the grant date using assumptions for the expected term, expected volatility, dividend yield, and the risk free interest rate. The term assumption is primarily based on the contractual term of the option and historic data related to exercise and post-vesting cancellation history experienced by the Company, adjusted based on management s expectations of future results. The expected term is determined separately for options issued to the Company s directors and to employees. The Company s anticipated volatility level is primarily based on the historic volatility of the Company s common stock, adjusted to remove the effects of certain periods of unusual volatility not expected to recur, and adjusted based on management s expectations of future volatility, for the life of the option or option group. The Company s model includes a zero dividend yield assumption, as the Company has not historically paid nor does it anticipate paying dividends on its common stock. The risk free interest rate is based on recent U.S. Treasury note

auction results with a similar life to that of the option. The Company s model does not include a discount for post-vesting restrictions, as the Company has not issued awards with such restrictions. The period expense is then determined based on the valuation of the options, and at that time an estimated forfeiture rate is used to reduce the expense recorded. The Company s estimate of pre-vesting forfeitures is primarily based on the recent historical experience of the Company, and is adjusted to reflect actual forfeitures at each vesting date.

The following weighted-average assumptions were used to determine the fair value of options under SFAS 123R:

	Three Months Ended September 30, 2006 Stock Options (Unaudited)		ESPP Options		Nine Months Ended September 30, 2006 Stock Options (Unaudited)		ESPP Options	
Expected dividend yield	0	%	0	%	0	%	0	%
Expected stock price volatility	.650		.315		.650		.441	
Risk-free interest rate	5.00	%	4.69	%	4.80	%	4.34	%
Expected life of options	4.0 Years		.24 Years		4.1 Years		.24 Years	

The Company s expense for stock options and the Company s ESPP was approximately $156,000 and $698,000, for the three and nine months ended September 30, 2006, respectively, of which approximately $19,000 and $59,000, respectively, was capitalized into the Company s deferred preservation and inventory costs. These amounts were recorded as compensation expense and were subject to the Company s normal allocation of expenses to inventory and deferred preservation costs. The Company did not recognize a tax benefit, or a related operating cash outflow and financing cash inflow, related to the additional compensation expense recorded in the three months and nine months ended September 30, 2006, as the Company is currently maintaining a full valuation allowance on its deferred tax assets. See Note 5 for additional discussions of the Company s income tax valuation.

As of September 30, 2006 there was approximately $2.3 million in total unrecognized compensation costs related to nonvested share-based compensation arrangements, before considering the effect of expected forfeitures. This expense is expected to be recognized over a weighted average period of 2.2 years.

In periods prior to October 1, 2005 the Company elected to follow Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees and related interpretations (APB 25) in accounting for its employee stock options. Under APB 25, because the exercise price of the Company s employee stock options equaled the market price of the underlying stock on the date of the grant, no compensation expense was recognized. In accordance with APB 25 the compensation recorded for employee stock grants was equal to the value of the grant on the measurement date, the date of the grant, as determined by the closing price of the Company s common stock on that date. Some employee stock grants vested in future periods based on a requirement of continued service to the Company. For these stock grants the amount of the stock grant was recorded as deferred compensation in the equity section of the Company s Summary Consolidated Balance Sheets, and was expensed on a straight-line basis over the vesting period.

Pro forma information regarding net loss and loss per share was required by SFAS 123 Accounting for Stock-Based Compensation (SFAS 123) for options accounted for under ABP 25. SFAS 123 required that option valuation information be disclosed as if the Company accounted for its employee stock options granted under the fair value method of that statement. The fair values for these options were estimated at the dates of grant using a Black-Scholes option-pricing model.

The following weighted-average assumptions were used:

	Three Months Ended September 30, 2005 (Unaudited)	Nine Months Ended September 30, 2005 (Unaudited)
Expected dividend yield	0%	0%
Expected stock price volatility	.340	.519
Risk-free interest rate	3.17 %	3.36 %
Expected life of options	0.3 Years	3.2 Years

For purposes of pro forma disclosures, the estimated fair values of the options are amortized to expense over the options vesting periods on a ratable basis. The Company s pro forma information follows (in thousands, except per share data):

	Three Months Ended September 30, 2005		Nine Months Ended September 30, 2005	
	Basic (Unaudited)	Diluted	Basic (Unaudited)	Diluted
Basic net loss applicable to commonshares as reported	$ (3,361)	$ (3,361)	$ (19,387)	$ (19,387)
Stock-based employee compensation:				
Add expense included in net loss	51	51	166	166
Deduct expense determined under the fair value based method for all awards	(1,634)	(1,634)	(3,253)	(3,253)
Basic net loss applicable to common shares pro forma	$ (4,944)	$ (4,944)	$ (22,474)	$ (22,474)
Basic weighted-average shares	24,161	24,161	23,839	23,839
Basic loss per common share:				
As reported	$ (0.14)	$ (0.14)	$ (0.81)	$ (0.81)
Pro forma	$ (0.20)	$ (0.20)	$ (0.94)	$ (0.94)

Note 12 Segment Information

The Company has two reportable segments organized according to its products and services: Implantable Medical Devices and Human Tissue Preservation Services.

The Implantable Medical Devices segment includes external revenue from product sales of BioGlue and bioprosthetic devices, including stentless porcine heart valves and SynerGraft processed bovine vascular grafts. The Human Tissue Preservation Services segment includes external services revenue from cryopreservation of cardiac, vascular, and orthopaedic allograft tissues. There are no intersegment revenues.

The primary measure of segment performance, as viewed by the Company s management, is segment gross margin, or net external revenues less cost of products and preservation services. The Company does not segregate assets by segment, therefore, asset information is excluded from the segment disclosures below.

The following table summarizes revenues, cost of products and preservation services, and gross margins for the Company s operating segments (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006 (Unaudited)	2005	2006 (Unaudited)	2005
Revenue:				
Implantable medical devices	$ 9,687	$ 9,129	$ 30,308	$ 29,102
Human tissue preservation services	10,319	7,329	29,839	22,219
All other (a)	12		74	
	20,018	16,458	60,221	51,321
Cost of Products and Preservation Services:				
Implantable medical devices	1,576	1,940	5,581	6,135
Human tissue preservation services	6,954	6,015	20,751	17,984
All other (a)				
	8,530	7,955	26,332	24,119
Gross Margin:				
Implantable medical devices	8,111	7,189	24,727	22,967
Human tissue preservation services	3,365	1,314	9,088	4,235
All other (a)	12		74	
	$ 11,488	$ 8,503	$ 33,889	$ 27,202

(a) The All other designation includes grant revenue.

The following table summarizes net revenues by product (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006 (Unaudited)	2005	2006 (Unaudited)	2005
Products:				
BioGlue	$ 9,444	$ 8,917	$ 29,534	$ 28,340
Bioprosthetic devices	243	212	774	762
Total products	9,687	9,129	30,308	29,102
Human tissue preservation services:				
Cardiovascular tissue	4,189	3,139	11,550	10,407
Vascular tissue	4,468	2,825	13,066	8,281
Orthopaedic tissue	1,662	1,365	5,223	3,531
Total preservation services	10,319	7,329	29,839	22,219
Research grants	12		74	
	$ 20,018	$ 16,458	$ 60,221	$ 51,321

Note 13 Commitments and Contingencies

Product Liability Claims

In the normal course of business as a medical device and services company, the Company has product liability complaints filed against it. As of November 1, 2006 the Company was aware of four pending product liability lawsuits. The lawsuits are currently in the pre-discovery or discovery stages. Of these lawsuits, two allege product liability claims arising out of the Company s orthopaedic tissue services and two allege product liability claims arising out of the Company s allograft heart valve tissue services.

Two of the outstanding product liability lawsuits against the Company are not covered by insurance policies, as the claimed loss date was prior to the effective coverage date for the insurance policy. Additional uninsured claims may be filed in the future. Other product liability claims have been asserted against the Company that have not resulted in lawsuits as of November 1, 2006. The Company is monitoring these claims.

The Company performed an analysis as of September 30, 2006 of the settled but unpaid claims and the four pending product liability lawsuits based on settlement negotiations to date and advice from counsel. As of September 30, 2006 the Company had accrued a total of approximately $414,000 for settled but unpaid claims and pending product liability lawsuits. The $414,000 accrual is included as a component of accrued expenses and other current liabilities on the September 30, 2006 Summary Consolidated Balance Sheet. This amount represents the Company s estimate of the probable loss related to settled but unpaid claims and one of the four pending product liability lawsuits. The Company has not recorded an accrual for the remaining three product liability claims or any asserted lawsuits that have not resulted in a lawsuit because management has concluded that either a loss is remote or that, although a loss is reasonably possible or probable, a reasonable estimate of that loss or the range of losses cannot be made at this time. As of December 31, 2005 the Company had accrued a total of approximately $1.5 million for settled but unpaid claims and pending product liability lawsuits and recorded $244,000 representing amounts to be recovered from the Company s insurance carriers. The $1.5 million accrual is included as a component of accrued expenses and other current liabilities on the December 31, 2005 Summary Consolidated Balance Sheet.

If the Company is unable to settle one or more of the product liability lawsuits in which the Company is a defendant, and if any such lawsuit should be tried with a substantial verdict rendered in favor of the plaintiff(s), there can be no assurance that such verdict(s) would not exceed the Company s available liquid assets. Additionally, the Company does not have a reasonable method for estimating the amount of compensatory or punitive damages that could be assessed by a trial jury with respect to any lawsuit that it is unable to settle prior to trial, and the Company s product liability insurance policies do not include coverage for any punitive damages. Failure by the Company to resolve the outstanding product liability claims within its ability to pay would have a material adverse effect on the financial position, results of operations, and cash flows of the Company.

On April 1, 2006 the Company bound coverage for the 2006/2007 insurance policy year. This policy is a four-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2007 and reported during the period April 1, 2006 through March 31, 2007 are covered by this policy. Claims incurred prior to April 1, 2003 that have not been reported are uninsured.

The Company maintains claims-made insurance policies to mitigate its financial exposure to 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. The Company periodically evaluates its exposure to unreported product liability claims and records accruals as necessary for the estimated cost of unreported claims related to services performed and products used. In July 2006 the Company retained an independent actuarial firm to prepare revised estimates of the unreported claims as of June 30, 2006 and December 31, 2006. The independent firm estimated the unreported product loss liability using a frequency-severity approach, whereby projected losses were calculated by multiplying the estimated number of claims by the estimated average cost per claim. The estimated claims were calculated based on the reported claim development method and the Bornhuetter-Ferguson method using a blend of the Company s historical claim experience and industry data. The estimated cost per claim was calculated using a lognormal claims model blending the Company s historical average cost per claim with industry claims data. The independent actuarial firm used a number of assumptions in order to estimate the unreported product loss liability, including:

- A ceiling of $5.0 million was selected for actuarial purposes in determining the liability per claim given the uncertainty in projecting claim losses in excess of $5.0 million,
- The future claim reporting lag time would be a blend of the Company s experiences and industry data,

- The frequency of unreported claims for accident years 2001 through 2006 would be lower than the Company s experience since the 2002/2003 policy year, but higher than the Company s historical claim frequency prior to the 2002/2003 policy year,

- The average cost per claim would be lower than the Company s experience since the 2002/2003 policy year, but higher than the Company s historical cost per claim prior to the 2002/2003 policy year,

- The average cost per BioGlue claim would be consistent with the Company s overall historical exposures until adequate historical data is available on this product line, and

- The number of BioGlue claims per million dollars of BioGlue revenue would be 35% lower than non-BioGlue claims per million dollars of revenue. The 35% factor was selected based on BioGlue claims experience to-date and consultation with the actuary.

The Company believes that these assumptions provide a reasonable basis for the calculation of the unreported product liability loss, but the accuracy of the actuarial firm s estimates is limited by the general uncertainty that exists for any estimate of future activity due to uncertainties surrounding the assumptions used and due to Company specific conditions, including the FDA Order, the Company s recent levels of litigation activity, the Company s low volume of pre-FDA Order historical claims, and the scarcity of industry data directly relevant to the Company s business activities. Due to these factors, actual results may differ significantly from the assumptions used and amounts accrued.

Based on the actuarial valuation performed in July 2006 as of June 30, 2006 and December 31, 2006, the Company estimated that its liability for unreported product liability claims was $6.7 million and would be $7.5 million as of December 31, 2006. In accordance with Emerging Issues Task Force Issue 03-8, the Company has accrued a prorated amount of $7.1 million, representing the Company s best estimate of the total liability for unreported product liability claims related to services performed and products sold prior to September 30, 2006. The $7.1 million balance is included as a component of accrued expenses and other current liabilities of $3.6 million and other long-term liabilities of $3.5 million on the September 30, 2006 Summary Consolidated Balance Sheet. Further analysis indicated that the liability could be estimated to be as high as $13.0 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. Based on the actuarial valuation, the Company estimated that as of September 30, 2006, $2.5 million of the accrual for unreported liability claims would be recoverable under the Company s insurance policies. The $2.5 million insurance recoverable is included as a component of other receivables of $1.2 million and other long-term assets of $1.3 million on the September 30, 2006 Summary Consolidated Balance Sheet. These amounts represent management s estimate of the probable losses and anticipated recoveries for unreported product liability claims related to services performed and products sold prior to September 30, 2006. Actual results may differ from this estimate.

As of December 31, 2005 the Company accrued $7.5 million for unreported product liability claims and recorded a receivable of $2.5 million for unreported liability claims estimated to be recoverable under the Company s insurance policies. The $7.5 million balance is included as a component of accrued expenses and other current liabilities of $3.8 million and other long-term liabilities of $3.7 million on the December 31, 2005 Summary Consolidated Balance Sheet. The $2.5 million insurance recoverable is included as a component of other receivables of $1.1 million and other long-term assets of $1.4 million on the December 31, 2005 Summary Consolidated Balance Sheet.

Insurance Coverage Dispute

In September 2006 the Company settled an insurance coverage dispute with a former insurance carrier for $2.0 million, net of associated legal fees. The dispute involved losses stemming from approximately $11.25 million paid in 2005 by the Company. No party admitted any liability as part of the September settlement. The $2.0 million is included as a component of general, administrative, and marketing expenses on the Summary Consolidated Statements of Operations and other receivables on the Summary Consolidated Balance Sheet as of September 30, 2006. The net proceeds of $2.0 million were received in October 2006.

SEC Investigation

On August 19, 2002 the Company issued a press release announcing that on August 17, 2002, the Company received a letter from the Atlanta District Office of the SEC inquiring about certain matters relating to the Company s August 14, 2002 announcement of the FDA Order. The SEC notified the Company in July 2003 that the inquiry became a formal investigation in June 2003. CryoLife cooperated with this investigation both before and after the issuance of the formal order of investigation in June 2003 and intends to continue doing so. CryoLife voluntarily reported the names of six employees and former employees to the SEC in December 2002 after discovering they had apparently sold CryoLife shares on August 14, 2002, before trading was halted pending CryoLife s press release reporting the FDA Order. These individuals were not and are not executive officers of CryoLife. The formal order of investigation indicates that the SEC s scope includes whether, during 2002, among other things, CryoLife or others may have traded while in possession of material nonpublic information, made (or caused to be made) false or misleading statements or omissions in press releases and SEC filings, and failed to maintain accurate records and adequate controls. The investigation could also encompass matters not specifically identified in the formal order. On September 15, 2005 the SEC announced that it had commenced proceedings in federal district court against certain of the above-referenced former and current employees (and certain of their spouses) for alleged illegal insider trading arising out of their August 14, 2002 trading activities. Those proceedings resulted in settlements with the SEC. As of the date hereof, the SEC has had no discussions with CryoLife as to whether the SEC will seek relief against CryoLife, or the nature of any relief that may be sought. At present, CryoLife is unable to predict the ultimate focus or outcome of the investigation, or when it will be completed. An unfavorable outcome could have a material adverse effect on CryoLife s reputation, business, financial position, results of operations, and cash flows.

Note 14 New Accounting Pronouncements

The Company will be required to adopt Financial Accounting Standards Board (FASB) Interpretation No. 48 Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109 (Interpretation 48) for the fiscal year beginning January 1, 2007. Interpretation 48 establishes a threshold for recognizing tax benefits if they are more-likely-than-not to be upheld upon review by the appropriate taxing authority and the requirement that companies recognize the maximum amount of tax benefit that has a greater than 50 percent likelihood of ultimately being realized. The cumulative effect of adoption of this interpretation will be reported as an adjustment to the opening balance of retained earnings. The Company is in the process of evaluating the impact of Interpretation 48 on its results of operations and financial position.

The Company will be required to adopt FASB Statement of Financial Accounting Standards (SFAS) No. 157 Fair Value Measurements (SFAS 157) for the fiscal year beginning January 1, 2008. SFAS 157 provides a single definition of fair value and a hierarchical framework for measuring it, as well as establishing additional disclosure requirements about the use of fair value to measure assets and liabilities. The Company is in the process of evaluating the impact of SFAS 157 on its results of operations and financial position.

The Company will be required to adopt Staff Accounting Bulletin (SAB) No. 108, codified as SAB Topic 1.N, Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements (SAB 108) for the year ended December 31, 2006. SAB 108 requires the use of both a balance sheet approach and an income statement approach when quantifying and evaluating the materiality of a misstatement. Adjustment to the financial statements is required if either approach results in quantifying a misstatement that is material. The adoption of SAB 108 will not have an impact on the Company s results of operations and financial position.

Note 15 Subsequent Events

In October 2006 CryoLife announced that it had signed a licensing and distribution agreement with BioForm Medical, Inc. (BioForm), for the development and commercialization of BioGlue for use in cosmetic and plastic surgery indications. The agreement calls for BioForm to fund the development and regulatory approval process for commercializing BioGlue for use in cosmetic and plastic surgery indications in the United States, Canada, and the

European Community. Under the terms of the agreement, CryoLife will receive an initial fee from BioForm, as well as a milestone payment upon achievement of FDA approval.

PART I - FINANCIAL INFORMATION

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

Overview

During the three months ended September 30, 2006 CryoLife, Inc. (CryoLife or the Company) experienced its second consecutive quarter of profitability and also achieved profitability on a year-to-date basis. CryoLife s net income of $2.0 million during this quarter was largely impacted by the net gain of $2.0 million recorded during the quarter for the net settlement of an insurance coverage dispute. The net cash proceeds were received during October, following the close of the third quarter. The quarter ended September 30, 2006 was also a period of strong cardiovascular revenues, with a double-digit increase in cardiovascular revenues over the second quarter of 2006.

On November 1, 2006 the Company announced the successful conclusion of its strategic review begun in January 2006 at the request of the Company s Board of Directors and with the assistance of Piper Jaffray & Co. As a result of this review, the Board of Directors has directed management to actively pursue three key strategies in addition to continuing to focus on growing its business and leveraging its strengths and expertise in its core marketplaces. These strategies are designed to generate revenue and earnings growth: identify and evaluate acquisition opportunities of complimentary product lines and companies; license Company technology to third parties for non-competing uses; and analyze and identify underperforming assets for potential sale or disposal. Management s actions related to this Board directive are ongoing.

FDA Order and Subsequent FDA Activity

Pursuant to an FDA Order received on August 13, 2002, the Company quarantined tissue subject to that order, recalled the portion of the covered tissues that had been distributed but not implanted, and ceased processing them. The Company changed its processing and testing procedures and took other actions intended to address the FDA s concerns, and now processes and distributes those tissues. The FDA has inspected the Company s facilities several times since the FDA Order and issued Form 483 Notices of Observations, to which the Company has submitted responses. The process is ongoing.

In 2003 the Company received two letters from the FDA regarding its SynerGraft processed human tissues. The first letter stated that a 510(k) premarket notification was required for SynerGraft processed human cardiac tissues, known as CryoValve SG. The second stated that SynerGraft processed non-valved cardiac and vascular tissues (CryoVein SG) should be regulated as medical devices. The Company no longer processes these tissues using the SynerGraft technology. It has filed a 510(k) notification for CryoValve SG, but has not yet determined whether to file and seek approvals for CryoVein SG.

See Note 2 to the Company s summary consolidated financial statements at Part I, Item 1 to this Form 10-Q for additional details on the FDA Order and other FDA activity.

Critical Accounting Policies

A summary of the Company s significant accounting policies is included in Part II, Item 8, Note 1 of the Notes to Summary Consolidated Financial Statements, contained in the Company s Form 10-K for the fiscal year ended December 31, 2005. Management believes that the consistent application of these policies enables the Company to provide users of the financial statements with useful and reliable information about the Company s operating results and financial condition. The summary consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States for interim financial information, which require the Company to make estimates and assumptions. The following are accounting policies that management believes are most important to the portrayal of the Company s financial condition and results and may involve a higher degree of judgment and complexity.

Product Liability Claims: In the normal course of business as a medical device and services company, the Company has product liability complaints filed against it. As of November 1, 2006 the Company was aware of four pending

product liability lawsuits. The lawsuits are currently in the pre-discovery or discovery stages. Of these lawsuits, two allege product liability claims arising out of the Company s orthopaedic tissue services and two allege product liability claims arising out of the Company s allograft heart valve tissue services.

Two of the outstanding product liability lawsuits against the Company are not covered by insurance policies, as the claimed loss date was prior to the effective coverage date for the insurance policy. Additional uninsured claims may be filed in the future. Other product liability claims have been asserted against the Company that have not resulted in lawsuits as of November 1, 2006. The Company is monitoring these claims.

The Company performed an analysis as of September 30, 2006 of the settled but unpaid claims and the four pending product liability lawsuits based on settlement negotiations to date and advice from counsel. As of September 30, 2006 the Company had accrued a total of approximately $414,000 for settled but unpaid claims and pending product liability lawsuits. The $414,000 accrual is included as a component of accrued expenses and other current liabilities on the September 30, 2006 Summary Consolidated Balance Sheet. This amount represents the Company s estimate of the probable loss related to settled but unpaid claims and one of the four pending product liability lawsuits. The Company has not recorded an accrual for the remaining three product liability lawsuits or any asserted claims that have not resulted in a lawsuit because management has concluded that either a loss is remote or that, although a loss is reasonably possible or probable, a reasonable estimate of that loss or the range of losses cannot be made at this time. As of December 31, 2005 the Company had accrued a total of approximately $1.5 million for settled but unpaid claims and pending product liability lawsuits and recorded $244,000 representing amounts to be recovered from the Company s insurance carriers. The $1.5 million accrual is included as a component of accrued expenses and other current liabilities on the December 31, 2005 Summary Consolidated Balance Sheet.

If the Company is unable to settle one or more of the product liability lawsuits in which the Company is a defendant, and if any such lawsuit should be tried with a substantial verdict rendered in favor of the plaintiff(s), there can be no assurance that such verdict(s) would not exceed the Company s available liquid assets. Additionally, the Company does not have a reasonable method for estimating the amount of compensatory or punitive damages that could be assessed by a trial jury with respect to any lawsuit that it is unable to settle prior to trial, and the Company s product liability insurance policies do not include coverage for any punitive damages. Failure by the Company to resolve the outstanding product liability claims within its ability to pay would have a material adverse effect on the financial position, results of operations, and cash flows of the Company.

On April 1, 2006 the Company bound coverage for the 2006/2007 insurance policy year. This policy is a four-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2007 and reported during the period April 1, 2006 through March 31, 2007 are covered by this policy. Claims incurred prior to April 1, 2003 that have not been reported are uninsured.

The Company maintains claims-made insurance policies to mitigate its financial exposure to 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. The Company periodically evaluates its exposure to unreported product liability claims and records accruals as necessary for the estimated cost of unreported claims related to services performed and products used. In July 2006 the Company retained an independent actuarial firm to prepare revised estimates of the unreported claims as of June 30, 2006 and December 31, 2006. The independent firm estimated the unreported product loss liability using a frequency-severity approach, whereby projected losses were calculated by multiplying the estimated number of claims by the estimated average cost per claim. The estimated claims were calculated based on the reported claim development method and the Bornhuetter-Ferguson method using a blend of the Company s historical claim experience and industry data. The estimated cost per claim was calculated using a lognormal claims model blending the Company s historical average cost per claim with industry claims data. The independent actuarial firm used a number of assumptions in order to estimate the unreported product loss liability, including:

- A ceiling of $5.0 million was selected for actuarial purposes in determining the liability per claim given the uncertainty in projecting claim losses in excess of $5.0 million,
- The future claim reporting lag time would be a blend of the Company s experiences and industry data,

- The frequency of unreported claims for accident years 2001 through 2006 would be lower than the Company s experience since the 2002/2003 policy year, but higher than the Company s historical claim frequency prior to the 2002/2003 policy year,

- The average cost per claim would be lower than the Company s experience since the 2002/2003 policy year, but higher than the Company s historical cost per claim prior to the 2002/2003 policy year,

- The average cost per BioGlue claim would be consistent with the Company s overall historical exposures until adequate historical data is available on this product line, and

- The number of BioGlue claims per million dollars of BioGlue revenue would be 35% lower than non-BioGlue claims per million dollars of revenue. The 35% factor was selected based on BioGlue claims experience to-date and consultation with the actuary.

The Company believes that these assumptions provide a reasonable basis for the calculation of the unreported product liability loss, but the accuracy of the actuarial firm s estimates is limited by the general uncertainty that exists for any estimate of future activity due to uncertainties surrounding the assumptions used and due to Company specific conditions, including the FDA Order, the Company s recent levels of litigation activity, the Company s low volume of pre-FDA Order historical claims, and the scarcity of industry data directly relevant to the Company s business activities. Due to these factors, actual results may differ significantly from the assumptions used and amounts accrued.

Based on the actuarial valuation performed in July 2006 as of June 30, 2006 and December 31, 2006, the Company estimated that its liability for unreported product liability claims was $6.7 million and would be $7.5 million as of December 31, 2006. In accordance with Emerging Issues Task Force Issue 03-8, the Company has accrued a prorated amount of $7.1 million, representing the Company s best estimate of the total liability for unreported product liability claims related to services performed and products sold prior to September 30, 2006. The $7.1 million balance is included as a component of accrued expenses and other current liabilities of $3.6 million and other long-term liabilities of $3.5 million on the September 30, 2006 Summary Consolidated Balance Sheet. Further analysis indicated that the liability could be estimated to be as high as $13.0 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. Based on the actuarial valuation, the Company estimated that as of September 30, 2006, $2.5 million of the accrual for unreported liability claims would be recoverable under the Company s insurance policies. The $2.5 million insurance recoverable is included as a component of other receivables of $1.2 million and other long-term assets of $1.3 million on the September 30, 2006 Summary Consolidated Balance Sheet. These amounts represent management s estimate of the probable losses and anticipated recoveries for unreported product liability claims related to services performed and products sold prior to September 30, 2006. Actual results may differ from this estimate.

Deferred Preservation Costs: By federal law, human tissues cannot be bought or sold. Therefore, the tissues the Company preserves and further processes cannot be held as inventory. Tissue is procured from deceased human donors by organ and tissue procurement agencies, which consign the tissue to the Company for processing and preservation. Preservation costs consist primarily of direct labor and materials (including laboratory expenses, tissue procurement fees, freight-in charges, and fringe benefits) and indirect costs (including allocations of costs from departments that support processing activities and facility allocations). Although the Company cannot own human tissue, the preservation process is a manufacturing process that is accounted for in accordance with Accounting Research Bulletin #43 (ARB 43) Chapter 4, Inventory Pricing. Preservation costs are stated at the lower of cost or market on a first-in, first-out basis and are deferred until revenue is recognized upon shipment of the tissue to the implanting facilities.

The calculation of deferred preservation costs includes a high degree of judgment and complexity. The costs included in deferred preservation costs contain several estimates due to the timing differences between the occurrence of the cost and receipt of final bills for services. Costs that contain estimates include tissue procurement fees, which are estimated based on the Company s contracts with independent procurement agencies, and freight-in charges, which are estimated based on the Company s prior experiences with these charges. These costs are adjusted for differences between estimated and actual fees when invoices for these services are received. Management believes that its estimates approximate the actual costs of these services, but estimates could differ

from actual costs. Total deferred preservation costs are then allocated among the different tissues processed during the period based on specific cost drivers such as the number of donors and the number of tissues processed. At each balance sheet date a portion of the deferred preservation costs relates to tissues currently in active processing or held in quarantine pending release to implantable status. The Company applies a yield estimate to all tissues in process and in quarantine to estimate the portion of tissues that will ultimately become implantable. Management determines this estimate of quarantine yields based on its experience in prior periods and reevaluates this estimate periodically. Due to the nature of this estimate and the length of the processing times experienced by the Company, actual yields could differ from the Company s estimates. A significant change in quarantine yields could materially affect the deferred preservation costs per tissue, which could impact the amount of deferred preservation costs on the Company s Summary Consolidated Balance Sheets and the cost of preservation services, including the lower of cost or market write-down, described below, on the Company s Summary Consolidated Statements of Operations.

The Company regularly evaluates its deferred preservation costs to determine if the costs are appropriately recorded at the lower of cost or market value. The Company recorded $277,000 and $1.0 million, respectively, in the three and nine months ended September 30, 2006 and $626,000 and $1.3 million, respectively, in the three and nine months ended September 30, 2005 as an increase to cost of preservation services to write-down the value of certain deferred tissue preservation costs that exceeded market value. The amount of these write-downs are primarily due to excess current period tissue processing costs that exceeded market value based on recent average service fees. Actual results may differ from these estimates. The Company regularly evaluates its deferred preservation costs to determine if an impairment in the value of the deferred preservation costs is required when the value of these tissues is not expected to be fully recoverable. A write-down of $538,000 was recorded for the three and nine months ended September 30, 2006 due to the impairment of certain orthopaedic tissues.

As of September 30, 2006 deferred preservation costs consisted of $4.2 million for allograft heart valve tissues, $1.1 million for non-valved cardiac tissues, $9.5 million for vascular tissues, and $4.8 million for orthopaedic tissues.

Deferred Income Taxes: Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and tax return purposes. The Company generated deferred tax assets beginning in 2002 primarily as a result of write-downs of deferred preservation costs, accruals for product liability claims, and operating losses. These write-downs, accruals, and losses reflect reductions in revenues and additional professional fees, as a result of the FDA Order, subsequent FDA activities, and related events. The Company assesses the recoverability of its deferred tax assets, on an annual basis and on an interim basis, as necessary, when the Company experiences changes that could materially affect its determination of the recoverability of its deferred tax assets. Management provides a valuation allowance when, as a result of this analysis, management believes it is more likely than not that its deferred tax assets will not be realized. In assessing the recoverability of its deferred tax assets at December 31, 2005 the Company reviewed its historical operating results, including the reasons for its operating losses, uncertainties regarding projected future operating results, and the uncertainty of the outcome of litigation. Based on the results of this analysis, at December 31, 2005 the Company determined that it was more likely than not that the Company s deferred tax assets would not be realized.

Based on the Company s results of operations for the nine months ended September 30, 2006, the Company does not expect to generate material deferred tax assets or utilize material amounts of its net operating loss carryforwards during the year ended December 31, 2006. For the nine months ended September 30, 2006 the Company did not experience any changes that would materially affect the Company s prior determination of the recoverability of its deferred tax assets. As of September 30, 2006 the Company had a total of $26.4 million in valuation allowances against deferred tax assets and a net deferred tax liability of $248,000 related to taxes in a foreign jurisdiction. The realizability of the Company s deferred tax assets could be limited in future periods as mandated by Internal Revenue Service Section 382.

Valuation of Long-lived and Intangible Assets: The Company assesses the impairment of its long-lived, identifiable intangible assets annually and whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors that management considers important that could trigger an impairment review include the following:

- Significant underperformance relative to expected historical or projected future operating results,

- Significant negative industry or economic trends,
- Significant decline in the Company s stock price for a sustained period, and
- Significant decline in the Company s market capitalization relative to net book value.

Statement of Financial Accounting Standards (SFAS) No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets (SFAS 144), requires the write-down of a long-lived asset to be held and used if the carrying value of the asset or the asset group to which the asset belongs is not recoverable. The carrying value of the asset or asset group is not recoverable if it exceeds the sum of the undiscounted future cash flows expected to result from the use and eventual disposition of the asset or asset group. In applying SFAS 144 the Company defined the specific asset groups used to perform the cash flow analysis. The Company defined the asset groups at the lowest level possible, by identifying the cash flows from groups of assets that could be segregated from the cash flows of other assets and liabilities. Using this methodology the Company determined that its asset groups consisted of the long-lived assets related to the Company s two reporting segments. As the Company does not segregate assets by segment, the Company allocated assets to the two reporting segments based on factors including facility space and revenues. The undiscounted future cash flows related to these asset groups exceeded their carrying values as of December 31, 2005 and, therefore, management concluded that there was not an impairment of the Company s long-lived intangible assets and tangible assets related to the tissue preservation business or medical device business. However, depending on the Company s ability to rebuild demand for its tissue preservation services and the future effects of events surrounding the FDA Order, these assets may become impaired. Management will continue to evaluate the recoverability of these assets in accordance with SFAS 144. For the nine months ended September 30, 2006 the Company did not experience any changes that would materially affect the Company s analysis of and recoverability of its long-lived assets.

SFAS No. 142, Goodwill and Other Intangible Assets (SFAS 142), requires that goodwill resulting from business acquisitions and other intangible assets be subject to periodic impairment testing. The Company s intangible assets consist of patent costs, which are amortized over the expected useful lives of the patents (primarily 17 years) using the straight-line method, and trademarks, which are non-amortizing. As of December 31, 2005 the Company did not believe that an impairment existed related to the other intangible assets that were assessed in accordance with SFAS 144.

Derivative Instruments: The terms of the Company s first quarter of 2005 6% convertible Preferred Stock offering included a Dividend Make-Whole Payment. If the Company elects to automatically convert, or the holder elects to voluntarily convert, some or all of the Preferred Stock into common stock prior to April 1, 2008, the Company will make an additional payment on the Preferred Stock equal to the aggregate amount of dividends that would have been payable on the Preferred Stock through and including April 1, 2008, less any dividends already paid on the Preferred Stock. The Dividend Make-Whole Payment is payable in cash or, at the Company s option, in shares of the Company s common stock, or a combination of cash and shares of common stock. In accordance with SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities (SFAS 133), the Company is required to separate and account for, as an embedded derivative, the Dividend Make-Whole Payment feature of the Preferred Stock (the Derivative). As an embedded derivative instrument, the Dividend Make-Whole Payment feature must be measured at fair value and reflected as a current liability on the Company s Summary Consolidated Balance Sheets. Changes in the fair value of the Derivative are recognized as the line item change in valuation of derivative as non-operating income/expense on the Company s Summary Consolidated Statements of Operations.

The accounting for derivatives is complex, and requires significant judgments and estimates in determining the fair value in the absence of quoted market values. These estimates are based on valuation methodologies and assumptions deemed appropriate in the circumstances. The fair value of the Dividend Make-Whole Payment feature is based on various assumptions, including the estimated market volatility and discount rates. The use of different assumptions may have a material effect on the estimated fair value amount, which is reflected in the Company s results of operations and financial position.

SFAS No. 142, Goodwill and Other Intangible Assets (SFAS 142), requires that goodwill resulting from busine

New Accounting Pronouncements

The Company will be required to adopt Financial Accounting Standards Board (FASB) Interpretation No. 48 Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109 (Interpretation 48) for the fiscal year beginning January 1, 2007. Interpretation 48 establishes a threshold for recognizing tax benefits if they are more-likely-than-not to be upheld upon review by the appropriate taxing authority and the requirement that companies recognize the maximum amount of tax benefit that has a greater than 50 percent likelihood of ultimately being realized. The cumulative effect of adoption of this interpretation will be reported as an adjustment to the opening balance of retained earnings. The Company is in the process of evaluating the impact of Interpretation 48 on its results of operations and financial position.

The Company will be required to adopt FASB Statement of Financial Accounting Standards (SFAS) No. 157 Fair Value Measurements (SFAS 157) for the fiscal year beginning January 1, 2008. SFAS 157 provides a single definition of fair value and a hierarchical framework for measuring it, as well as establishing additional disclosure requirements about the use of fair value to measure assets and liabilities. The Company is in the process of evaluating the impact of SFAS 157 on its results of operations and financial position.

The Company will be required to adopt Staff Accounting Bulletin (SAB) No. 108, codified as SAB Topic 1.N, Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements (SAB 108) for the year ended December 31, 2006. SAB 108 requires the use of both a balance sheet approach and an income statement approach when quantifying and evaluating the materiality of a misstatement. Adjustment to the financial statements is required if either approach results in quantifying a misstatement that is material. The adoption of SAB 108 will not have an impact on the Company s results of operations and financial position.

Results of Operations

Revenues
(Tables in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	**2005**	**2006**	**2005**
Total Revenues	$ 20,018	$ 16,458	$ 60,221	$ 51,321

Revenues increased 22% for the three months ended September 30, 2006 as compared to the three months ended September 30, 2005. Revenues increased 17% for the nine months ended September 30, 2006 as compared to the nine months ended September 30, 2005.

The increase in both the three and nine months ended September 30, 2006 was primarily due to an increase in tissue preservation service revenues, as well as an increase in BioGlue revenues as compared to the prior year period. A detailed discussion of the change in BioGlue revenues and in preservation service revenues for each of the three major tissue types processed by the Company is presented below.

BioGlue

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	**2005**	**2006**	**2005**
Revenues	$ 9,444	$ 8,917	$ 29,534	$ 28,340
BioGlue revenues as a percentage of total revenue	47 %	54 %	49 %	55 %

Revenues from the sale of BioGlue increased 6% for the three months ended September 30, 2006 as compared to the three months ended September 30, 2005. This increase was primarily due to an increase in average selling prices, which increased revenues by 5% and the effect of foreign currency exchange, which increased revenues by less than 1%.

Revenues from the sale of BioGlue increased 4% for the nine months ended September 30, 2006 as compared to the nine months ended September 30, 2005. This increase was primarily due to an increase in average selling prices, which increased revenues by 4%.

The increase in average selling prices for the three and nine months ended September 30, 2006 was primarily due to list price increases that went into effect in January and July 2006 domestically and in certain international markets.

Domestic revenues accounted for 76% and 75% of total BioGlue revenues for the three and nine months ended September 30, 2006, respectively, and 75% and 76% of total BioGlue revenues for the three and nine months ended September 30, 2005, respectively.

The Company anticipates that BioGlue revenues for the full year of 2006 will exceed the full year of 2005, primarily due to the domestic price increases discussed above.

Cardiovascular Preservation Services

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Revenues	$ 4,189	$ 3,139	$ 11,550	$ 10,407
Cardiovascular revenues as a percentage of total revenue	21 %	19 %	19 %	20 %

Revenues from cardiovascular preservation services increased 33% for the three months ended September 30, 2006 as compared to the three months ended September 30, 2005. This increase was primarily due to a 36% increase in unit shipments of cardiovascular tissues, which increased revenues by 17%, and an increase in average service fees, which increased revenues by 16%.

Revenues from cardiovascular preservation services increased 11% for the nine months ended September 30, 2006 as compared to the nine months ended September 30, 2005. This increase was primarily due to an increase in average service fees, which increased revenues by 8%, and a 14% increase in unit shipments of cardiovascular tissues, which increased revenues by 3%.

The increase in cardiovascular volume for the three months ended September 30, 2006 was primarily due to increased shipments of pulmonary valves and non-valved cardiac tissues. The increases in cardiac shipments were a result of increased availability of tissues due to improvements in procurement and tissue processing yields and due to strengthening demand for the Company s tissues, particularly in the pediatric cardiac market. This strong third quarter cardiovascular volume also had an affect on revenues for the nine months ended September 30, 2006, overcoming the slight volume declines experienced in the first half of 2006. The large increases in the number of tissue shipments did not result in a proportional increase in cardiovascular revenues due to a shift in product mix, as the increases were primarily experienced in products with smaller per unit revenues than the average cardiovascular tissue. The increase in average service fees for the three and nine months ended September 30, 2006 was primarily due to the fee increases that went into effect in January 2006 on all cardiac tissues and in July 2006 on certain non-valved cardiac tissues.

The Company s procurement of cardiac tissues, from which heart valves and non-valved cardiac tissues are processed, increased 9% during the three months ended September 30, 2006 as compared to the three months ended June 30, 2006. The Company s procurement of cardiac tissues increased 8% for the three months ended September 30, 2006 as compared to the three months ended September 30, 2005 and 11% for the nine months ended September 30, 2006 as compared to the nine months ended September 30, 2005.

The Company anticipates that cardiovascular service revenues for the full year of 2006 will exceed the full year of 2005 primarily due to the domestic fee increases discussed above, and due to growth in cardiovascular tissue shipments resulting from improvements in procurement, tissue processing yields, and demand for the Company s tissues.

Vascular Preservation Services

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Revenues	$ 4,468	$ 2,825	$ 13,066	$ 8,281
Vascular revenues as a percentage of total revenue	22 %	17 %	22 %	16 %

Revenues from vascular preservation services increased 58% for the three months ended September 30, 2006 as compared to the three months ended September 30, 2005. This increase was primarily due to a 37% increase in unit

shipments of vascular tissues, which increased revenues by 43%, and an increase in average service fees, which increased revenues by 15%.

Revenues from vascular preservation services increased 58% for the nine months ended September 30, 2006 as compared to the nine months ended September 30, 2005. This increase was primarily due to a 38% increase in unit shipments of vascular tissues, which increased revenues by 47%, and an increase in average service fees, which increased revenues by 11%.

The increase in vascular volume for the three and nine months ended September 30, 2006 is primarily due to increases in shipments of saphenous veins, due in part to increased availability of tissues as a result of improvements in procurement levels and tissue processing yields, coupled with a strong demand for these tissues, primarily for use in peripheral vascular reconstruction surgeries to avoid limb amputations. The increase in shipments of saphenous veins is a continuation of the favorable trend that began in the fourth quarter of 2005. The increase in average service fees for the three and nine months ended September 30, 2006 was primarily due to the fee increases that went into effect in January 2006 on all vascular tissues.

The Company s procurement of vascular tissues increased 7% during the three months ended September 30, 2006 as compared to the three months ended June 30, 2006. The Company s procurement of vascular tissues increased 18% for the three months ended September 30, 2006 as compared to the three months ended September 30, 2005 and 38% for the nine months ended September 30, 2006 as compared to the nine months ended September 30, 2005.

The Company anticipates that vascular service revenues for the full year of 2006 will exceed the full year of 2005 primarily due to the domestic fee increases discussed above, and due to growth in vascular tissue shipments resulting from improvements in procurement, tissue processing yields, and demand for the Company s tissues.

Orthopaedic Preservation Services

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Revenues	$ 1,662	$ 1,365	$ 5,223	$ 3,531
Orthopaedic revenues as a percentage of total revenue	8 %	8 %	9 %	7 %

Revenues from orthopaedic preservation services increased 22% for the three months ended September 30, 2006 as compared to the three months ended September 30, 2005. This increase was primarily due to an increase in average service fees, which increased revenues by 18%, and an 11% increase in unit shipments of orthopaedic tissues, which increased revenues by 4%.

Revenues from orthopaedic preservation services increased 48% for the nine months ended September 30, 2006 as compared to the nine months ended September 30, 2005. This increase was primarily due to a 27% increase in unit shipments of orthopaedic tissues, which increased revenues by 35% and an increase in average service fees, which increased revenues by 13%.

The increase in average service fees for the three and nine months ended September 30, 2006 was primarily due to the fee increases that went into effect in January 2006 on all orthopaedic tissues and in July 2006 for certain orthopaedic tissues. The increase in orthopaedic volume for the three months ended September 30, 2006 was primarily due to an increase in shipments of boned and non-boned tendons, primarily due to the rebuilding of the Company s supply of tissues available for shipment. The increase in orthopaedic volume for the nine months ended September 30, 2006 was primarily due to an increase in shipments of osteochondral grafts, with smaller increases in boned and non-boned tendons and menisci, primarily related to the reestablishment of the Company s presence in the orthopaedic tissue business and the rebuilding of the Company s supply of tissues available for shipment.

The Company procures orthopaedic tissues, which include knees, from which osteochondral grafts, menisci, and boned tendons are processed, and individual tendons, which are primarily non-boned. The Company s procurement

of all orthopaedic tissues increased 17% during the three months ended September 30, 2006 as compared to the three months ended June 30, 2006, 8% for the three months ended September 30, 2006 as compared to the three months ended September 30, 2005, and 19% for the nine months ended September 30, 2006 as compared to the nine months ended September 30, 2005. The Company s procurement of knees increased 23% during the three months ended September 30, 2006 as compared to the three months ended June 30, 2006, decreased 2% for the three months ended September 30, 2006 as compared to the three months ended September 30, 2005, and increased 25% for the nine months ended September 30, 2006 as compared to the nine months ended September 30, 2005.

The Company anticipates that orthopaedic service revenues for the full year of 2006 will exceed the full year of 2005 primarily due to growth in orthopaedic tissue shipments during 2006, driven by improvements in demand for the Company s tissues, procurement, and tissue processing yields. Additionally, the domestic fee increases discussed above have benefited and are expected to continue benefiting revenues for the full year of 2006 as compared to the full year of 2005.

Grant Revenues

Grant revenues were $12,000 and zero, respectively, for the three months ended September 30, 2006 and 2005 and $74,000 and zero, respectively, for the nine months ended September 30, 2006 and 2005. Grant revenues for the three and nine months ended September 30, 2006 are related to funding received under the 2005 Defense Appropriations Conference Report, the (2005 DOD Grant), which included $926,000 for the development of protein hydrogel technology for use on the battlefield. The Company applied for and was awarded the full $926,000 allocated under the 2005 DOD Grant in connection with its development of BioFoam™. The Company has received advances totaling $926,000 under this grant during 2005 and 2006, and began recognizing revenues for expenses incurred related to this grant during the fourth quarter of 2005. The Company is currently preparing for animal trials with the U.S. Army s Institute for Surgical Research.

The 2006 Defense Appropriations Conference Report included approximately $2.3 million for the continued development of protein hydrogel technology for use on the battlefield. CryoLife applied for funding for BioFoam development under this bill in July 2006. The 2007 Defense Appropriations Conference Report included approximately $1.0 million for the continued development of protein hydrogel technology for use on the battlefield. CryoLife anticipates applying for funding under this bill during 2007.

The Company anticipates that grant revenues will continue to be higher in 2006 than in the corresponding periods of 2005 due to the 2005 and possibly the 2006 Department of Defense funding.

Costs and Expenses

Cost of Products

Cost of products was $1.6 million and $1.9 million for the three months ended September 30, 2006 and September 30, 2005, representing 16% and 21%, respectively, of total product revenues during such periods. Cost of products was $5.6 million and $6.1 million for the nine months ended September 30, 2006 and 2005, respectively, representing 18% and 21%, respectively, of total product revenues during such periods.

The cost of products and cost of products as a percentage of total product revenues decreased for the three and nine months ended September 30, 2006, primarily due to improvements in BioGlue margins from period to period. These margin improvements were primarily due to improvements in BioGlue average selling prices due to the price increases which went into effect in January and July 2006 and greater manufacturing throughput, which reduced the per unit cost to produce BioGlue.

Cost of Human Tissue Preservation Services

Cost of human tissue preservation services was $7.0 million and $6.0 million for the three months ended September 30, 2006 and 2005, respectively, representing 67% and 82%, respectively, of total tissue preservation service revenues during such periods. Cost of human tissue preservation services for the three months ended September 30, 2006 includes the write-down of $277,000 of certain deferred preservation costs that exceeded market value and the

write-down of $538,000 due to the impairment of certain orthopaedic tissues. Cost of human tissue preservation services for the three months ended September 30, 2005 includes the write-down of $626,000 of certain deferred preservation costs that exceeded market value.

Cost of human tissue preservation services was $20.8 million and $18.0 million for the nine months ended September 30, 2006 and 2005, respectively, representing 70% and 81%, respectively, of total tissue preservation service revenues during such periods. Cost of human tissue preservation services for the nine months ended September 30, 2006 includes the write-down of $1.0 million of certain deferred preservation costs that exceeded market value and the write-down of $538,000 due to the impairment of certain orthopaedic tissues. Cost of human tissue preservation services for the nine months ended September 30, 2005 includes the write-down of $1.3 million of certain deferred preservation costs that exceeded market value.

The write-down of deferred tissue preservation costs that exceeded market value in both years was primarily related to the Company s non-valved cardiac tissues and certain orthopaedic tissues. The Company implemented a fee increase effective July 1, 2006, in part to address these tissues, which have had costs in excess of the average service fees. The decrease of the write-down in the current year periods as compared to the prior year periods is primarily due to the effect of this fee increase on the Company s average service fees for the affected tissue types.

The increase in cost of human tissue preservation services for the three and nine months ended September 30, 2006 is primarily due to increased tissue preservation service volume as compared to the same period in 2005. The decrease in cost of tissue preservation services as a percentage of total tissue preservation service revenues is primarily due to improvements in tissue preservation margins as a result of improvements in the Company s tissue processing yields, an increase in average service fees due to fee increases in 2006, and to a lesser extent an increase in the amount of tissues processed.

The Company anticipates that aggregate cost of human tissue preservation services for the full year of 2006 will exceed the full year of 2005 due to volume increases in 2006. The Company anticipates that cost of human tissue preservation services as a percentage of tissue preservation service revenues will decrease for the full year of 2006 as compared to 2005 as a result of increases in yields of implantable tissue per donor, increases in average service fees due to fee increases implemented in 2006, and increases in the amount of tissues expected to be processed due to increased procurement.

General, Administrative, and Marketing Expenses

General, administrative, and marketing expenses decreased 23% to $8.5 million for the three months ended September 30, 2006, compared to $11.1 million for the three months ended September 30, 2005, representing 43% and 67%, respectively, of total revenues during such periods. General, administrative, and marketing expenses for the three months ended September 30, 2006 includes a favorable adjustment of $2.0 million related to the settlement of an insurance coverage dispute with an insurance company, net of associated legal fees, an unfavorable charge of $185,000 for stock based compensation expenses, and an unfavorable adjustment of $170,000 to unreported product liability accruals. General, administrative, and marketing expenses for the three months ended September 30, 2005 includes an accrual of approximately $741,000 in additional legal expenses and settlement accruals and an accrual of $701,000 for post employment benefits.

General, administrative, and marketing expenses decreased 30% to $30.1 million for the nine months ended September 30, 2006, compared to $42.7 million for the nine months ended September 30, 2005, representing 50% and 83%, respectively, of total revenues during such periods. General, administrative, and marketing expenses for the nine months ended September 30, 2006 includes a favorable adjustment of $2.0 million related to the settlement of an insurance coverage dispute with an insurance company, net of associated legal fees, an unfavorable charge of $832,000 for stock based compensation expenses, a favorable adjustment of $451,000 related to the adjustment of reserves for product liability losses, and an accrual of $448,000 for post employment benefits. General, administrative, and marketing expenses for the nine months ended September 30, 2005 includes an accrual of $11.8 million in expense related to the settlement of the shareholder class action lawsuit, an accrual of $701,000 for post employment benefits, and a favorable adjustment of approximately $403,000 to legal expenses and settlement accruals.

Excluding the items discussed above, general, administrative, and marketing expenses for the three months and nine months ended September 30, 2006 were consistent with the expenses in the respective prior year periods. General, administrative, and marketing expenses for the three and nine months ended September 30, 2006 were also impacted by lower insurance and professional fees and an increase in marketing commissions to support revenue growth.

Although several important components are difficult to estimate or control, the Company anticipates that general, administrative, and marketing expenses will be lower in the full year 2006 than in the full year 2005, due to the expense recorded in 2005 related to the resolution of the Company s class action and derivative lawsuits and the favorable adjustment to that expense that occurred in the third quarter of 2006. The Company will continue to evaluate the level of accruals for product liability claims and make adjustments as required based on periodic actuarial analyses and product liability claim status. Adjustments to these accruals may be required during the remainder of 2006, and the effect of these adjustments may be favorable or unfavorable to general, administrative, and marketing expenses.

Research and Development Expenses

Research and development expenses were $826,000 for the three months ended September 30, 2006, compared to $894,000 for the three months ended September 30, 2005, representing 4% and 5%, respectively, of total revenues during each such period. Research and development expenses were $2.6 million for the nine months ended September 30, 2006, compared to $2.7 million for the nine months ended September 30, 2005, representing 4% and 5%, respectively, of total revenues during each such period. The decrease in research and development expenses in both the three and nine month periods ended September 30, 2006 was due to timing delays for planned external research studies. Research and development spending in 2006 and 2005 was primarily focused on the Company s tissue preservation, SynerGraft, which includes allograft and xenograft heart valves, vascular grafts and surgical mesh, and Protein Hydrogel Technologies (PHT), which include BioGlue, BioFoam, BioDisc™, and related products.

Other Costs and Expenses

Interest expense increased to $169,000 for the three months ended September 30, 2006, compared to $77,000 for the three months ended September 30, 2005. Interest expense increased to $504,000 for the nine months ended September 30, 2006, compared to $220,000 for the nine months ended September 30, 2005. The increase in interest expense for the three and nine months ended September 30, 2006 is primarily due to higher borrowings under the Credit Agreement as compared to the same period in 2005 and higher interest rates on these borrowings as the bank s prime lending rate has increased since the prior year period. Interest expense for the three and nine months ended September 30, 2006 and 2005 included interest incurred related to the Credit Agreement, notes payable, and capital leases.

Interest income decreased to $94,000 for the three months ended September 30, 2006, compared to $166,000 for the three months ended September 30, 2005. Interest income decreased to $304,000 for the nine months ended September 30, 2006, compared to $408,000 for the nine months ended September 30, 2005. Interest income for the three and nine months ended September 30, 2006 and 2005 was primarily due to interest earned on the Company s cash, cash equivalents, and marketable securities.

The change in valuation of the Derivative was an expense of $44,000 for the three months ended September 30, 2006 as compared to income of $412,000 for the three months ended September 30, 2005. The change in valuation of the Derivative was an expense of $111,000 for the nine months ended September 30, 2006 as compared to $372,000 for the nine months ended September 30, 2005. The valuation of the Derivative in these periods was a function of several variables including the price and expected volatility of the Company s common stock, the number of shares of Preferred Stock outstanding, and the general level of US interest rates. The change in valuation of Derivative in the three and nine months ended September 30, 2005 also includes the amount of the Dividend Make-Whole Payment on preferred shares converted during the period.

The Company is unable to estimate the change in valuation of derivative for the remainder of 2006, as this amount is subject to several variables as discussed above. The change in valuation of derivative for the remainder of 2006 could differ significantly from the levels experienced in the corresponding period in 2005.

The Company s income tax expense of $12,000 for the three months ended September 30, 2006 was primarily due to foreign taxes on income of the Company s wholly owned European subsidiary. The Company s income tax expense of $137,000 for the nine months ended September 30, 2006 was primarily due to an expense of $248,000 to record a deferred tax liability related to a foreign jurisdiction, partially offset by the favorable effect of adjustments to estimated foreign taxes on income of the Company s wholly owned European subsidiary.

The Company s income tax expense of $106,000 and $190,000 for the three and nine months ended September 30, 2005, respectively, was related to foreign taxes on income of the Company s wholly owned European subsidiary.

Seasonality

The demand for BioGlue appears to be seasonal, with a flattening or slight decline in demand generally occurring in the third quarter followed by stronger demand in the fourth quarter. Management believes that this trend for BioGlue may be due to fewer surgeries being performed on adult patients in the summer months. The Company will continue to evaluate the seasonal nature of BioGlue sales.

The demand for the Company s cardiovascular tissue preservation services has historically been seasonal, with peak demand generally occurring in the second and third quarters. Management believes this trend for cardiovascular tissue preservation services is primarily due to the high number of surgeries scheduled during the summer months for school aged patients, who drive the demand for a large percentage of CryoLife s cardiovascular tissues. This seasonal trend has been obscured in recent years by the impact of the FDA Order and related events. The Company expects that this seasonal trend will be more apparent in future years.

The demand for the Company s orthopaedic tissue preservation services appears to be seasonal, with a flattening or slight decline in demand generally occurring in the summer months due to the scheduling of fewer elective orthopaedic surgeries during these months and due to the seasonal timing of certain sports that frequently result in the injuries treated by the Company s orthopaedic products. This seasonal trend has been obscured in recent years by the impact of the FDA Order and related events. The Company expects that this seasonal trend will be more apparent in future years.

The demand for the Company s human vascular tissue preservation services and bioprosthetic cardiovascular and vascular devices does not appear to be seasonal.

Liquidity and Capital Resources

Net Working Capital

At September 30, 2006 net working capital (current assets of $51.6 million less current liabilities of $23.9 million) was $27.7 million, with a current ratio (current assets divided by current liabilities) of 2 to 1, compared to net working capital of $23.9 million, with a current ratio of 2 to 1 at December 31, 2005.

The Company s primary capital requirements for the nine months ended September 30, 2006 arose out of general working capital needs, capital expenditures for facilities and equipment, and funding of research and development projects. In recent years the Company s operating activities have failed to generate sufficient cash to fund its business due to the increasing costs of operations, primarily costs related to the Company s tissue preservation services business, increases in general, administrative, and marketing costs over pre-FDA Order levels, and increased legal, professional, and litigation expenses. For the nine months ended September 30, 2006 the Company funded its operating cash requirements primarily through existing cash, cash equivalents, and marketable securities, and through bank credit facilities.

Overall Liquidity and Capital Resources

The Company expects that the following will continue to have an adverse impact on earnings and cash flows during the remainder or 2006:

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- The anticipated lower preservation services revenues as compared to preservation revenues prior to the August 13, 2002 FDA Order, subsequent FDA activities, and related events (discussed in Part I, Item 1, Note 2 of the Notes to Summary Consolidated Financial Statements),

- The high cost of human tissue preservation services as a percent of revenue, as compared to the period prior to the FDA Order, as a result of lower tissue processing volumes and changes in processing methods, which have increased the cost of processing human tissue and decreased yields of implantable tissue per donor,

- An expected use of cash related to the defense and resolution of lawsuits and claims, and

- The legal and professional costs related to ongoing FDA compliance.

The Company believes the following should continue to have a favorable impact on cash flow from operations during the remainder of 2006, although there can be no assurance that these events will occur as and when currently anticipated:

- Expected increases in revenues over levels experienced in 2005 due to increases in BioGlue list prices implemented in January and July 2006,

- Expected increases in total preservation service revenues over levels experienced in 2005 due to fee increases implemented in January and July 2006, to reflect the higher cost of processing these tissues,

- Anticipated improvements in yields of implantable tissues per donor over the levels experienced in 2005 through process changes and process directives, and

- Anticipated decreases in cash payments related to the defense and resolution of lawsuits and claims from the levels seen in 2003 through 2005.

The Company believes that the Company s existing cash, cash equivalents, marketable securities, and availability under the Credit Agreement will enable the Company to meet its liquidity needs through at least September 30, 2007.

The Company s long term liquidity and capital requirements will depend upon numerous factors, including:

- The success of the Company s strategic plan to enhance shareholder value, resulting from the conclusion of its strategic review with the assistance of Piper Jaffray & Co.,

- The success of BioGlue and other products using related technology,

- The Company s ability to increase the level of tissue procurement and demand for its tissue preservation services,

- The Company s ability to reestablish sufficient margins on its tissue preservation services, in the face of increased processing costs, by improving yields and increasing prices,

- The Company s spending levels on its research and development activities, including research studies, to develop and support its service and product pipeline,

- The timing and cost of resolving product liability lawsuits and other claims (as discussed in Part I, Item 1, Note 13 of the Notes to Summary Consolidated Financial Statements), and

- To a lesser degree, the Company s success at resolving the issues with the FDA regarding processing of human tissue using the SynerGraft technology (as discussed in Part I, Item 1, Note 2 of the Notes to Summary Consolidated Financial Statements).

If the Company is unable to address these issues and continues to experience negative operating cash flows, the Company anticipates that it may require additional financing or seek to raise additional funds through bank facilities, debt or equity offerings, or other sources of capital to meet liquidity and capital requirements beyond September 30, 2007. Additional funds may not be available when needed or on terms acceptable to the Company, which could have a material adverse effect on the Company s business, financial condition, results of operations, and cash flows.

On February 8, 2005 CryoLife and its subsidiaries entered into a credit agreement with Wells Fargo Foothill, Inc. as lender (the Credit Agreement) to address some of its liquidity needs. As of September 30, 2006 the outstanding balance of the Credit Agreement was $4.5 million and the remaining borrowing availability was $10.5 million.

In January 2006 the Company engaged Piper Jaffray & Co. to assist the Company s management and Board of Directors in identifying and evaluating potential strategies to enhance shareholder value. As a result of this review, the Board of Directors has directed management to actively pursue three key strategies in addition to continuing to focus on growing its business and leveraging its strengths and expertise in its core marketplaces. These strategies are designed to generate revenue and earnings growth: identify and evaluate acquisition opportunities of complimentary product lines and companies; license Company technology to third parties for non-competing uses; and analyze and identify underperforming assets for potential sale or disposal. Management s actions related to this Board directive are ongoing.

Product Liability Claims

As discussed in Part I, Item 1, Note 13 of the Notes to Summary Consolidated Financial Statements , as of September 30, 2006 the Company had accrued a total of $414,000 for settled but unpaid claims and pending product liability lawsuits. The $414,000 accrual is an estimate of the Company s portion of the costs required to resolve outstanding claims, and does not reflect actual settlement arrangements or actual judgments for all open claims, including punitive damages, which may be assessed by the courts. The $414,000 accrual is not a cash reserve. The timing and amount of actual future payments is dependent on when and if judgments are rendered, and/or settlements are reached. Should payments related to the accrual be required, the Company s portion of these monies would have to be paid from liquid assets. The Company continues to attempt to reach resolution of these outstanding claims in order to minimize the potential cash payout.

If the Company is unable to settle the outstanding claims for amounts within its ability to pay or one or more of the product liability claims in which the Company is a defendant should be tried with a substantial verdict rendered in favor of the plaintiff(s), there can be no assurance that such verdict(s) would not exceed the Company s available liquid assets. Failure by the Company to meet required future cash payments to resolve the outstanding product liability claims would have a material adverse effect on the financial position, results of operations, and cash flows of the Company.

As discussed in Part I, Item 1, Note 13 of the Notes to Summary Consolidated Financial Statements , at September 30, 2006 the Company had accrued a total $7.1 million for the estimated costs of unreported product liability claims related to services performed and products sold prior to September 30, 2006 and had recorded a receivable of $2.5 million representing amounts to be paid by the Company s insurance carriers. Further analysis indicated that the liability could be estimated to be as high as $13.0 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. The $7.1 million accrual does not represent cash set aside. The timing of future payments related to the accrual is dependent on when and if claims are asserted, judgments are rendered, and/or settlements are reached. Should payments related to the accrual be required, these monies would have to be paid from insurance proceeds and liquid assets. Since the amount accrued is based on actuarial estimates, actual amounts required could vary significantly from this estimate.

Net Cash from Operating Activities

Net cash used in operating activities was $2.9 million for the nine months ended September 30, 2006 as compared to $15.0 million for the nine months ended September 30, 2005. The $2.9 million in current year cash used was primarily due to the Company s working capital needs, as reflected in the increases in deferred preservation costs, inventory, and accounts receivable on the Company s Summary Consolidated Balance Sheet.

The Company uses the indirect method to prepare its cash flow statement, and as such the operating cash flows are based on the Company s net income, which is then adjusted to remove non-cash items included that generated a book gain or loss during the period and for changes in operating assets and liabilities. For the nine months ended September 30, 2006 the Company s $415,000 net income included significant recurring non-cash items that generated favorable and unfavorable adjustments to net income. For the nine months ended September 30, 2006 these adjustments included a favorable $3.6 million in depreciation and amortization, a favorable $1.6 million in write-downs for impairment of deferred preservation costs, and a favorable $853,000 in non-cash compensation, primarily related to the implementation of SFAS 123R, including the expense for new and existing stock options, and the granting of annual stock awards to the board of directors during the second quarter. The Company s working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the nine months ended September 30, 2006 these changes included an unfavorable $7.5 million due to the buildup of deferred preservation costs and inventories for which vendors and employees have already been paid, an unfavorable $4.0 million due to the timing differences between the recording of receivables and the actual receipt of cash, largely a result of the gross $2.3 million legal settlement receivable ($2.0 million on a net basis) recorded in the third quarter as discussed above, and a favorable $2.1 million due to the timing differences between the recording of accounts payable and other accruals and the actual payment of cash.

Net Cash from Investing Activities

Net cash provided by investing activities was $671,000 for the nine months ended September 30, 2006, as compared to cash used of $3.7 million for the nine months ended September 30, 2005. The $671,000 in current year cash provided was primarily due to $14.6 million in sales and maturities of marketable securities partially offset by $12.4 million in purchases of marketable securities and $1.4 million in capital expenditures.

Net Cash from Financing Activities

Net cash provided by financing activities was $231,000 for the nine months ended September 30, 2006, as compared to $22.7 million for the nine months ended September 30, 2005. The $231,000 in current year cash provided was primarily due to $2.3 million in proceeds from the financing of insurance policies, $585,000 in proceeds from issuance of debt, including borrowing on the Company s line of credit and issuance of new capital leases, and $398,000 in proceeds from exercises of options and issuance of stock. These favorable effects were partially offset by $1.5 million in principal payments on notes payable, $730,000 in payments of Preferred Stock dividends, $428,000 in debt principal payments, and $370,000 in principal payments on capital leases.

Scheduled Contractual Obligations and Future Payments

Scheduled contractual obligations and the related future payments are as follows (in thousands):

	Total	Remainder of 2006	2007	2008	2009	2010	Thereafter
Operating leases	$ 19,891	$ 586	$ 2,282	$ 2,184	$ 2,066	$ 2,103	$ 10,670
Revolving line of credit	4,504			4,504			
Insurance premium obligations	953	931	22				
Capital lease obligations	393	204	53	52	53	31	
Purchase commitments	659	657	1	1			
Other obligations	733	134	420	179			
Total contractual obligations	$ 27,133	$ 2,512	$ 2,778	$ 6,920	$ 2,119	$ 2,134	$ 10,670

The Company s operating lease obligations result from the lease of land and buildings that comprise the Company s corporate headquarters and manufacturing facilities, leases related to additional office and warehouse space rented by the Company, leases on Company vehicles, leases on housing for expatriates, and leases on a variety of office equipment.

The line of credit obligation results from the Company s borrowing of funds under its Credit Agreement. The timing of the obligation in the above table is based on the February 7, 2008 Credit Agreement expiration date, at which time the outstanding principal balance will be due. Due

to the terms of the Credit Agreement, and due to the

net losses and negative cash flows experienced by the Company since the FDA Order, the Company has classified amounts due under the Credit Agreement as short-term debt on the September 30, 2006 Summary Consolidated Balance Sheet in accordance with the provisions of FASB Technical Bulletin No. 79-3 (As Amended). Assuming the Company s level of borrowings and the interest rate on the line of credit remain the same, the Company would have additional contractual obligations for interest expense and fees of $122,000, $485,000, and $56,000 for the remainder of 2006, for 2007, and for 2008, respectively, which are not included in the table above.

The Company s insurance premium obligations represent installment payments related to payment plans and notes payable from the renewal and financing of certain Company insurance policies.

The Company s capital lease obligations result from the financing of certain of the Company s equipment and leasehold improvements. The liability for the remainder of 2006 includes a lump sum payment due at the termination of certain of the Company s capital leases.

The Company s purchase commitments generally result from agreements with suppliers to stock certain custom raw materials needed for the Company s processing and production.

The Company s other obligations contain various items including minimum required royalty payments, payments to support research and development activities, litigation settlement obligations, and other items as appropriate.

Stock Repurchases

In the first quarter of 2006 the Company s Board of Directors authorized the purchase of shares of its common stock from employees to fund the payment of employee federal and state withholding taxes in association with the grant of stock to employees in February 2006. These repurchases of stock from employees totaled $50,000. No further purchases will be made related to these employee stock grants.

Capital Expenditures

Capital expenditures for the nine months ended September 30, 2006 were $1.4 million. The Company does not expect to have significant capital expenditures during the remainder of 2006. Planned capital expenditures for 2006 are primarily related to the upgrade of the Company s accounting software and related hardware purchases, largely procured in the first half of 2006, and routine purchases of tissue processing, manufacturing, computer, and office equipment needed to support the Company s business.

FORWARD-LOOKING STATEMENTS

This Form 10-Q contains forward-looking statements and information made or provided by the Company that are based on the beliefs of its management as well as estimates and assumptions made by and information currently available to management. The words could, may, will, would, should, pro forma, potential, pending, intend, believe, expect, anticipate, estimate, plan, future, and other similar identify forward-looking statements, including, in particular, statements regarding anticipated revenues, cost savings, insurance coverage, 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 Risks and Uncertainties and elsewhere in this filing.

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

- Expected improvements in 2006 revenues over 2005,
- The impact of recent accounting pronouncements,
- Adequacy and availability of product liability insurance to defend against lawsuits,
- The outcome of lawsuits filed and claims made against the Company,
- The expected continuing adverse impact of the FDA Order, subsequent FDA activity, and measures taken by the Company as a result, and the resolution of lawsuits and claims on anticipated future revenues, profits, and business operations,
- Factors impacting the Company s long-term liquidity,
- Anticipated continuing revenue increases,
- Possible 2006 and 2007 Department of Defense funding,
- The expected continuing favorable impact of price and fee increases, anticipated processing yield and procurement improvements, and anticipated decreases in the annual cost of lawsuit and claim resolution,
- Expected future impact of continuing demand, price and fee increases, added sales personnel, and costs on revenues and gross margins,
- Potential resolution of the issues raised by the FDA Order and the FDA s Form 483 Notice of Observation,
- Potential clearance of the 510(k) application for CryoValve SG,
- The estimates of the amounts accrued for product liability claims incurred but not reported and expected amounts receivable under insurance policies,
- Changes in liquidity and capital resources,
- Statements regarding the expected 2006 performance of the Company and its business segments, including increased revenues, relative to that of 2005,
- The Company s expectations regarding the adequacy of current liquidity and financing arrangements and anticipated capital expenditures,
- Product demand and market growth,

- Anticipated seasonal trends in future periods,

- The impact of future fluctuations in the value of the Dividend Make-Whole Payment feature of the Company s 6% convertible Preferred Stock, and

- Other statements regarding future plans and strategies, anticipated events, or trends.

These statements are based on certain assumptions and analyses made by the Company 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 the Company s expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially from the Company s expectations, including without limitation, in addition to those specified in the text surrounding such statements, the risk factors set forth below, the risks set forth under Risk Factors in Part I, Item 1A of the Company s Form 10-K for the year ended December 31, 2005 and other factors,

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many of which are beyond the control of the Company. Consequently, all of the forward-looking statements made in this Form 10-Q are qualified by these cautionary statements and there can be no assurance that the actual results or developments anticipated by the Company will be realized or, even if substantially realized, that they will have the expected consequences to or effects on the Company or its business or operations. The Company assumes no obligation to update publicly any such forward-looking statements, whether as a result of new information, future events, or otherwise.

RISKS AND UNCERTAINTIES

The risks and uncertainties which might impact the forward-looking statements and the Company, its ability to continue as a going concern, and the trading value of its common and Preferred Stock include concerns that:

- The Company may be unable to sufficiently reduce costs of processing tissues, to obtain increased yields of implantable tissue, and to increase fees for tissue preservation services,

- If the Company is unable to address the causes of its historical operating losses and negative cash flows, it will need to raise additional capital which may not be available or may not be available on acceptable terms,

- The ability of the Company to successfully implement its strategic plans following the conclusion of its strategic alternatives analysis is uncertain,

- The Company s revolving credit facility imposes restrictions on its ability to borrow, which could make it more difficult to borrow needed funds,

- The Company is significantly dependent on its revenues from BioGlue and is subject to a variety of risks affecting this product,

- The FDA Order and subsequent FDA activity continue to adversely impact CryoLife s business, including reducing demand for its services and increasing processing costs relative to pre-FDA Order levels,

- Revenue from orthopaedic tissue preservation services may not return to acceptable levels,

- Physicians may be reluctant to implant CryoLife s preserved tissues,

- CryoLife s products and the tissues it processes allegedly have caused and may in the future cause injury to patients using its products or tissues and the Company has been and may be exposed to product liability claims and additional regulatory scrutiny as a result,

- Adverse publicity may reduce demand for products and services not affected by the FDA recall,

- CryoLife may be unable to address the concerns raised by the FDA in its Form 483 Notices of Observations,

- The FDA has notified CryoLife of its belief that marketing of CryoValve SG and CryoVein SG require additional regulatory submissions and/or approvals, and CryoLife may be unable to obtain such approvals,

- Regulatory action outside of the U.S. has affected CryoLife s business in the past and may also affect CryoLife s business in the future,

- Violation of government regulations could result in loss of revenues and customers and additional expense to attain compliance,

- CryoLife is the subject of an ongoing SEC investigation,

- CryoLife s insurance coverage has been and in the future may be either insufficient or unavailable by its terms,

- Satisfactory levels of insurance coverage may be difficult or impossible to obtain in the future and if obtained, could be very expensive,

- Intense competition affects CryoLife s ability to recover from the FDA Order,

- CryoLife may not be successful in obtaining necessary clinical results and regulatory approvals for products and services in development, and such products and services may not achieve market acceptance,

- Investments in new technologies or distribution rights may not be successful,

- SynerGraft processed tissues may not demonstrate expected benefits,

- If CryoLife is not successful in expanding its business activities in international markets, it will not be able to pursue one of its strategies for increasing its revenues,

- CryoLife is dependent on its key personnel,

- Extensive government regulation may adversely affect the ability to develop and sell products and services,

- Uncertainties related to patents and protection of proprietary technology may adversely affect the value of CryoLife s intellectual property,

- Future health care reimbursement methods and policies may affect the availability, amount and timing of revenues,

- Future grant funding will depend on a multitude of factors outside of CryoLife s control, and there can be no guarantee that it can be obtained,

- Rapid technological change could cause services and products to become obsolete,

- Anti-takeover provisions may discourage or make more difficult an attempt to obtain control of CryoLife,

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- Efforts by existing stockholders or others to gain influence or control over CryoLife may divert management s attention from the Company s operational recovery or otherwise be detrimental to the interests of its other stockholders,

- CryoLife could be left with no choice other than to engage in costly litigation if stockholders or others make inaccurate or misleading proposals or statements that are detrimental to the interests of its other stockholders,

- Common stock dividends are not likely to be paid in the foreseeable future,

- CryoLife may not be able to pay cash dividends on its capital stock due to legal and contractual restrictions and lack of liquidity, and

- Future fluctuations in the value of the Dividend Make-Whole Payment feature of the Company s 6% convertible Preferred Stock may have a material impact on the Company s results of operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

The Company s interest income and expense are sensitive to changes in the general level of United States interest rates. In this regard, changes in United States interest rates affect the interest earned on the Company s cash and cash equivalents of $4.6 million and the interest incurred on the line of credit balance of $4.5 million as of September 30, 2006. The Company s short-term investments in marketable securities of $3.0 million as of September 30, 2006 can also be affected by changing interest rates to the extent that these items contain variable interest rates or are subject to maturity or sale during a period of changing interest rates. A 10% adverse change in interest rates affecting the Company s cash equivalents and short-term investments or borrowings under the Company s Credit Agreement would not have a material impact on the Company s financial position, results of operations, or cash flows.

Derivative Valuation Risk

The terms of the Company s March 18, 2005 6% convertible Preferred Stock offering include a Dividend Make-Whole Payment feature. This feature is considered an embedded derivative instrument. Due to the quarterly revaluation of the derivative liability, the Company recorded other expense of $44,000 and $111,000 for the three and nine months ended September 30, 2006, respectively. At September 30, 2006 the derivative liability was valued at $225,000. The fair value of this derivative is based on various factors, including the market price of the Company s common stock and discount rates used in determination of fair value. Changes in these factors could cause the fair value of this derivative to fluctuate significantly from period to period. These resulting changes in valuation may have a significant impact on the Company s results of operations.

Item 4. Controls and Procedures.

The Company s management, including the Company s President and Chief Executive Officer (CEO) and the Company s Executive Vice President, Chief Operating Officer, and Chief Financial Officer (CFO), does not expect that its disclosure controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been or will be detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdown can occur because of simple error or mistake.

Based upon the Company s most recent disclosure controls evaluation as of September 30, 2006, the CEO and CFO have concluded that the Company s disclosure controls were effective at the reasonable assurance level to satisfy their objectives and to ensure that the information required to be disclosed by the Company in its periodic reports is accumulated and communicated to management, including the CEO and CFO, as appropriate, to allow timely decisions regarding disclosure and is recorded, processed, summarized, and reported within the time periods specified in the United States Securities and Exchange Commission s rules and forms.

During the quarter ended September 30, 2006 there were no changes in the Company s internal control over financial reporting that materially affected or that are reasonably likely to materially affect the Company s internal control over financial reporting.

Part II - OTHER INFORMATION

Item 1. Legal Proceedings.

See Note 13 of Notes to Summary Consolidated Financial Statements at Part I, Item 1, Financial Statements , which is incorporated herein by reference.

Item 1A. Risk Factors.

The Company s most recent Form 10-K was filed February 23, 2006. There have been no material changes from the risk factors previously disclosed in the Company s Form 10-K in response to Part I, Item 1A of Form 10-K.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

(c) The following table provides information about purchases by the Company during the quarter ended September 30, 2006 of equity securities that are registered by the Company pursuant to Section 12 of the Exchange Act:

Issuer Purchases of Equity Securities

Common Stock

Period		Total Number of Common Shares Purchased	Average Price Paid per Common Share	Total Number of Common Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Common Shares That May Yet Be Purchased Under the Plans or Programs
07/01/06	07/31/06		$		
08/01/06	08/31/06				
09/01/06	09/30/06	343	6.40		
Total		343	$ 6.40		

The Company currently has no stock repurchase program, publicly announced or otherwise. The common shares shown were tendered to the Company in payment of the exercise price of outstanding options.

6% Convertible Preferred Stock

The Company did not repurchase any shares of its 6% convertible preferred stock in the quarter ended September 30, 2006.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Submission of Matters to a Vote of Security Holders.

None.

Item 5. Other information.

None.

Item 6. Exhibits.

The exhibit index can be found below.

Exhibit Number	Description
3.1	Restated Articles of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.1 to the Registrant s Form 10-Q for the quarter ended March 31, 2003.)
3.2	Certificate of Amendment to the Amended and Restated Articles of Incorporation of CryoLife, Inc., classifying and designating Series A Junior Participating Preferred Stock. (Incorporated herein by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K filed on November 3, 2005.)
3.3	Preferred Stock Articles of Amendment to the Articles of Incorporation of the Registrant. (Incorporated herein by reference to Exhibit 3.4 to the Registrant s Form 8-A/A filed on March 15, 2005.)
3.4	Amended and Restated By-Laws. (Incorporated herein by reference to Exhibit 3.2 to the Registrant s Current Report on Form 8-K filed December 28, 2005.)
4.1	Form of Certificate for the Company s Common Stock. (Incorporated by reference to Exhibit 4.1 to the Registrant s Registration Statement on Form S-1 (No. 33-56388).)
10.1	Settlement Agreement and Release between the Company and St. Paul Mercury Insurance Company dated September 25, 2006.
10.2	Form of Non-Employee Director Restricted Stock Agreement (Incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K Filed on August 7, 2006).
10.3	Form of Employment Agreement, dated as of May 4, 2006, entered into with Dr. Al Heacox, as Senior Vice President, Research and Development, and Mr. Dave Fronk, as Vice President, Regulatory Affairs and Quality Assurance.
31.1	Certification by Steven G. Anderson pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

SIGNATURES

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

CRYOLIFE, INC.
(Registrant)

/s/ STEVEN G. ANDERSON
STEVEN G. ANDERSON
Chairman, President, and
Chief Executive Officer
(Principal Executive Officer)

/s/ DAVID ASHLEY LEE
DAVID ASHLEY LEE
Executive Vice President,
Chief Operating Officer, and
Chief Financial Officer
(Principal Financial Officer)

/s/ AMY D. HORTON
AMY D. HORTON
Chief Accounting Officer
(Principal Accounting Officer)

November 3, 2006
DATE
