

CRYOCOR INC  
Form 10-Q  
May 15, 2008  
Table of Contents

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

**FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended March 31, 2008

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 000-51410

**CryoCor, Inc.**

(Exact name of Registrant as specified in its Charter)

Edgar Filing: CRYOCOR INC - Form 10-Q

**Delaware**  
(State or Other Jurisdiction)

**33-0922667**  
(I.R.S. Employer)

of Incorporation or Organization) **9717 Pacific Heights Boulevard** Identification Number)

**San Diego, California 92121**

(Address of Principal Executive Offices, including Zip Code)

**(858) 909-2200**

(Registrant's Telephone Number, Including Area Code)

**N/A**

(Former name, former address and former fiscal year if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES  NO

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 definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES  NO

The number of shares of the Registrant's common stock outstanding as of April 30, 2008 was 13,153,921.

---

**Table of Contents**

**CRYOCOR, INC.**

**QUARTERLY REPORT ON FORM 10-Q FOR THE PERIOD ENDED MARCH 31, 2008**

**TABLE OF CONTENTS**

	<b>Page No.</b>
<b>PART I. FINANCIAL INFORMATION</b>	
Item 1. <u>Financial Statements</u>	3
<u>Consolidated Balance Sheets as of March 31, 2008 (Unaudited) and December 31, 2007</u>	3
<u>Consolidated Statements of Operations for the three months ended March 31, 2008 and 2007 (Unaudited)</u>	4
<u>Consolidated Statements of Cash Flows for the three months ended March 31, 2008 and 2007 (Unaudited)</u>	5
<u>Notes to Consolidated Financial Statements (Unaudited)</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	19
Item 4. <u>Controls and Procedures</u>	20
<b><u>PART II. OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings</u>	20
Item 1A. <u>Risk Factors</u>	21
Item 6. <u>Exhibits</u>	36
<u>Signatures</u>	38

**Table of Contents****ITEM 1. FINANCIAL STATEMENTS.****CryoCor, Inc.****Consolidated Balance Sheets***(in thousands except for the number of shares and par values)*

	March 31, 2008 (Unaudited)	December 31, 2007
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 2,660	\$ 3,157
Short-term investments	4,740	9,106
Accounts receivable, net	63	41
Inventories, net	1,635	1,090
Prepaid expenses and other current assets	380	506
Total current assets	9,478	13,900
Property and equipment, net	478	517
Other assets	820	629
Total assets	\$ 10,776	\$ 15,046
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 976	\$ 878
Accrued compensation	526	800
Accrued clinical development liabilities	678	745
Accrued liabilities	384	394
Deferred revenue	61	206
Current debt	5,303	5,677
Total current liabilities	7,928	8,700
Stockholders' equity:		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized; zero shares outstanding at March 31, 2008 (unaudited) and December 31, 2007		
Common stock, \$0.001 par value, 75,000,000 shares authorized; 12,738,921 and 12,565,916 shares issued and outstanding at March 31, 2008 (unaudited) and December 31, 2007, respectively	13	13
Additional paid in capital	107,486	106,982
Accumulated other comprehensive income	126	119
Accumulated deficit	(104,777)	(100,768)
Total stockholders' equity	2,848	6,346
Total liabilities and stockholders' equity	\$ 10,776	\$ 15,046

See accompanying notes.

**Table of Contents****CryoCor, Inc.****Consolidated Statements of Operations***(in thousands except per share amounts)***(Unaudited)**

	<b>Three months ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
Revenue:		
Product revenue	\$ 100	\$ 66
Collaboration revenue	667	
Total revenue	767	66
Operating expenses:		
Cost of revenue	799	628
Research and development	1,308	1,588
Selling, general and administrative	2,540	1,244
Total costs and expenses	4,647	3,460
Loss from operations	(3,880)	(3,394)
Interest income	107	230
Interest expense	(236)	(268)
Net loss	(4,009)	(3,432)
Basic and diluted net loss per common share	\$ (0.32)	\$ (0.31)
Shares used to compute basic and diluted net loss per common share	12,572	11,032

See accompanying notes.

**Table of Contents****CryoCor, Inc.****Consolidated Statements of Cash Flows***(in thousands)***(Unaudited)**

	<b>Three months ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Operating activities</b>		
Net loss	\$ (4,009)	\$ (3,432)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	54	74
Non-cash share-based compensation	489	451
Amortization of debt discount	32	72
Amortization of premium/discount on short-term investments	(64)	(165)
Changes in operating assets and liabilities:		
Accounts receivable	(21)	(16)
Inventories	(546)	(73)
Prepaid expenses and other assets	(64)	133
Accounts payable	99	68
Deferred revenue	(145)	(8)
Accrued liabilities	(354)	(352)
<b>Net cash used in operating activities</b>	<b>(4,529)</b>	<b>(3,248)</b>
<b>Investing activities</b>		
Purchases of property and equipment	(16)	(11)
Purchases of short-term investments	(1,963)	(1,712)
Proceeds from sales of short-term investments	6,400	8,650
<b>Net cash provided by investing activities</b>	<b>4,421</b>	<b>6,927</b>
<b>Financing activities</b>		
Proceeds from issuance of common stock under stock plans, net	16	37
Principal payments on short-term debt	(406)	
<b>Net cash (used in) provided by financing activities</b>	<b>(390)</b>	<b>37</b>
Effect of exchange rate changes on cash	1	(1)
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(497)</b>	<b>3,715</b>
Cash and cash equivalents at beginning of period	3,157	3,025
<b>Cash and cash equivalents at end of period</b>	<b>\$ 2,660</b>	<b>\$ 6,740</b>
<b>Supplemental disclosures of cash flow information:</b>		
Cash payments for interest	\$ 174	\$ 197

See accompanying notes.

---

**Table of Contents**

**CRYOCOR, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**Note 1. Organization and Basis of Presentation**

***Organization***

CryoCor, Inc. ( CryoCor or the Company ) a Delaware corporation, is a medical technology company that has developed and manufactures a minimally invasive, disposable catheter system based on proprietary cryoablation technology for the treatment of cardiac arrhythmias.

In 2001, the Company established a wholly owned German subsidiary, CryoCor GmbH, in order to market and support the Company's products in the European community. In 2002, the Company received European regulatory approval for the commercial sale of the Company's products. In November 2005, the Company announced its intention to close CryoCor GmbH and sell its products in Europe solely through European distributors. See Note 2 for further details on the closure of the subsidiary.

***Basis of Presentation***

We have prepared the accompanying unaudited consolidated financial statements in accordance with United States generally accepted accounting principles ( GAAP ) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by GAAP for complete financial statements. In the opinion of our management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Intercompany accounts have been eliminated in consolidation. Operating results for the three months ended March 31, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008. For further information see our consolidated financial statements and related disclosures thereto for the year ended December 31, 2007 in our Annual Report on Form 10-K filed on March 21, 2008 with the Securities and Exchange Commission ( SEC ).

The Company does not have sufficient working capital to fund its planned operations through December 31, 2008 and is dependent upon closing a transaction with Boston Scientific Scimed, Inc. ( BSS ) that is more fully discussed in Note 9. If the Company does not complete the transaction with BSS and is unable to secure adequate additional debt or equity financing, the Company will be forced to restructure or significantly curtail its operations, file for bankruptcy, and/or cease operations. Therefore, the accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. This basis of accounting contemplates the recovery of the Company's assets and the satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

**Note 2. Balance Sheet Information**

***Cash and Cash Equivalents***

The Company considers all highly-liquid investments purchased with an original maturity of three months or less to be cash equivalents. As of March 31, 2008 and December 31, 2007, the Company's cash and cash equivalents were held in financial institutions in the United States and consist of deposits in money market funds, commercial paper, and asset-backed securities.

***Investment Securities***

Investment securities generally consist of corporate debt securities and asset-backed securities. The Company classifies all securities as available-for-sale, as the sale of such securities may be required prior to maturity to implement management strategies. These securities are carried at fair value, with the unrealized gains and losses reported as a component of other comprehensive income (loss) until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis. A decline in the market value below cost of any available-for-sale security that is determined to be other than temporary results in a revaluation of its carrying amount to fair value and an impairment charge to earnings, resulting in a new cost basis for the security. No such impairment charges were recorded for the periods presented. As of March 31, 2008, the Company owned no auction rate securities.

## Edgar Filing: CRYOCOR INC - Form 10-Q

Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method. The amortization and accretion, interest income and realized gains and losses are included in interest income within the Consolidated Statements of Operations. Interest income is recognized when earned.



**Table of Contents**

As of March 31, 2008 and December 31, 2007, the contractual maturity of all investment securities was less than one year. The composition of investments and gross unrealized gains and losses at March 31, 2008 and December 31, 2007 were as follows (in thousands):

	March 31, 2008			December 31, 2007				
	Unrealized			Unrealized				
	Amortized Cost	Gains	Losses	Fair Value	Amortized Cost	Gains	Losses	Fair Value
Corporate debt securities	\$ 4,213	\$ 27	\$	\$ 4,240	\$ 7,840	\$ 19	\$	\$ 7,859
Asset-backed securities	500			500	1,246	1		1,247
	\$ 4,713	\$ 27	\$	\$ 4,740	\$ 9,086	\$ 20	\$	\$ 9,106

**Inventories**

Inventories consist of the following (in thousands):

	March 31, 2008	December 31, 2007
Raw materials	\$ 1,060	\$ 656
Work-in-progress	125	52
Finished goods	488	420
	1,673	1,128
Less reserves for excess and obsolete inventories	(38)	(38)
Inventory, net	\$ 1,635	\$ 1,090

**Restructuring Accrual**

The Company recorded restructuring charges of approximately \$252,000 in connection with the closing of CryoCor GmbH during 2006 and \$16,000 remains accrued on the balance sheet at March 31, 2008, primarily due to payments owed on the remaining term of the facility lease, which will run through June 2008. The Company has not incurred any additional restructuring costs in connection with the closing of CryoCor GmbH subsequent to June 30, 2006.

**Long-Term and Short-Term Debt**

In June 2007, the Company entered into a loan and security agreement (the *Loan Agreement*) with Oxford Finance Corporation, ATEL Ventures, Inc. and Silicon Valley Bank (together, the *Lenders*) that provides the Company with a \$14.0 million credit facility (the *credit facility*), as evidenced by secured promissory notes. The credit facility is available in two draws, with the first draw of \$6.0 million received in June 2007, and the second draw of \$8.0 million available for borrowing after the occurrence of both of the following conditions: (i) approval is received from the FDA of the Company's application for pre-market approval for the treatment of right atrial flutter with the CryoCor Cardiac Cryoablation System (which occurred in August 2007), and (ii) the Company receives unrestricted net cash proceeds of at least \$20.0 million from the closing of an equity financing. Upon the applicable drawdown, the Company will make interest-only payments for the first six months following each advance, and will then make principal payments to fully amortize the advance over the subsequent 30-month term (the *Term Loan*). The Term Loan bears interest at a rate of 11.77% per annum. The Loan Agreement provides that the credit facility is secured by the Company's assets, excluding intellectual property.

In connection with entering into the Loan Agreement, the Company issued warrants to the Lenders to purchase 93,697 shares of common stock at a price of \$5.23 per share. The fair value of the warrants was \$388,000 based on the stock price on the date of grant of \$4.81 per common share, an expected life of ten years, an estimated volatility rate of 86%, and an estimated risk-free interest rate of 5.12%. The fair value of the warrants was recorded as a discount to the credit facility and is being amortized to interest expense on a straight-line basis over the 36-month

## Edgar Filing: CRYOCOR INC - Form 10-Q

term of the loan. The remaining unamortized fair value of the warrants is \$291,000 at March 31, 2008. The warrants are exercisable through June 2017.

Pursuant to the terms of the Loan Agreement, the Company is subject to a material adverse change clause, which permits the holder of the note to call the balance if a material adverse change occurs. A material adverse change is defined as, (i) a material impairment in the perfection or priority of the lenders' lien in the collateral or in the value of such collateral; (ii) a material adverse change in the business, operations, or condition (financial or otherwise) of the Company; or (iii) a material impairment of the prospect of repayment of any portion of the obligations. Due to the Company's current financial condition, it has classified the entire principal balance as current although the contractual payment structure requires the Company to make monthly payments through July 2010.

**Table of Contents**

The Company expects that if the acquisition of CryoCor by BSS that is discussed in Note 9 is not completed, the holders of the notes will believe that the prospects for repayment of the debt have been materially impaired and that a material adverse change will have occurred, which will permit the holder of the notes to call the balance of the debt principal for immediate repayment. If the holder of the notes were to call the balance of the debt principal, management believes the Company would have to cease operations.

In accordance with the Loan Agreement, the Company is subject to certain non-financial covenants. The Company was in compliance with all covenants at March 31, 2008.

**Note 3. Share-Based Payments**

Total share-based compensation expense recognized in our consolidated statement of operations related to stock options and restricted stock awards granted to employees and non-employee directors was as follows (in thousands, except per share data):

	Three months ended March 31, 2008	Three months ended March 31, 2007
Share-based compensation costs included in:		
Cost of revenue	\$ 111	\$ 101
Research and development	147	140
Selling, general, and administrative	216	173
Total share-based compensation costs	474	414
Income tax benefit recognized		
Impact on net loss	\$ 474	\$ 414
Share-based compensation expense, per common share:		
Basic and diluted	\$ 0.04	\$ 0.04

We recognized share-based employee compensation expense of \$238,000 and \$169,000 under the provisions of the Financial Accounting Standards Board ( FASB ) Statement of Financial Accounting Standard ( SFAS ) No. 123 (revised 2004), *Share-Based Payment*, during the three months ended March 31, 2008 and 2007, respectively, in addition to \$236,000 and \$245,000 in compensation expense recorded as required under Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations during the three months ended March 31, 2008 and 2007, respectively. Both of these amounts are included in the table above. Due to the Company's net operating losses, the Company did not realize any tax benefits for the tax deductions from share-based payment arrangements during the three months ended March 31, 2008 and 2007.

As of March 31, 2008, \$2.4 million of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under the CryoCor 2000 Stock Option Plan, the 2005 Equity Incentive Plan and the 2005 Non-Employee Director Plan is expected to be recognized over a weighted-average period of 1.8 years.

**Note 4. Net Loss per Common Share**

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by the Company, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.



**Table of Contents**

	<b>Three months ended March 31, 2008      2007 (in thousands, except per share amounts)</b>	
<b>Historical</b>		
Numerator:		
Net loss	\$ (4,009)	\$ (3,432)
Denominator:		
Weighted-average common shares outstanding	12,572	11,035
Weighted-average unvested common shares subject to repurchase		(3)
Denominator for basic and diluted net loss per common share	12,572	11,032
Basic and diluted net loss per common share	\$ (0.32)	\$ (0.31)
<b>Historical outstanding anti-dilutive securities not included in diluted net loss per common share:</b>		
Options to purchase common stock	1,642	1,696
Unvested restricted stock awards	160	
Warrants to purchase common and convertible preferred stock	756	83
	2,558	1,779

**Note 5. Equity**

In April 2007, the Company completed a private placement of its common stock, raising a total of \$5.5 million. The Company issued 1,052,423 shares of common stock under the private placement, at a price of \$5.14 per share, representing the closing bid price on the Nasdaq Stock Market on the date the securities purchase agreement was signed.

In June 2007, the Company entered into a series of agreements with Boston Scientific Corporation ( BSC ) and BSS, including a common stock purchase agreement with BSS pursuant to which it sold to BSS 368,188 shares of its common stock for a total of \$2.5 million. The purchase price of each share of common stock sold was \$6.79. Pursuant to the common stock purchase agreement, a second purchase of shares of the Company's common stock for an aggregate purchase price of \$2.5 million will take place within ten business days after the date, if any, that certain milestones specified in a related development and license agreement are achieved. The purchase price of each share of common stock to be sold in the second closing will be determined at the time of such closing based on the greater of (a) \$2.53 and (b) the product of (i) the average closing sales price of the Company's common stock on the Nasdaq Stock Market for the 60 consecutive trading days prior to the second closing and (ii) 1.25. As more fully discussed in Note 9, in the event the acquisition of CryoCor by BSS is completed, we do not anticipate receiving any additional milestone payments from BSC or equity investments from BSS.

**Note 6. Collaboration Agreement**

In June 2007, the Company entered into a development and license agreement with BSC pursuant to which the Company may develop certain products and license to BSC intellectual property to permit BSC to commercialize certain products. The agreement provides for payments by BSC to the Company as consideration for the Company's performance of its development obligations and also provides for possible royalty payments by each party to the other party if certain elections are made. The Company will conduct development activities under the agreement pursuant to a development plan that sets forth a description of items to be provided, including specifications and requirements. In conjunction with signing the agreement, the Company received an advance payment of \$500,000 against the development milestones which was recorded as deferred revenue when initially received. In February 2008, we received a milestone payment of \$500,000 from BSC, which was recognized as revenue as our deliverable under the collaboration had been accepted by BSC, and we had received payment from BSC. We may receive additional payments totaling \$1.0 million based upon the successful completion of the development milestones, and will receive royalty payments if either the balloon product or the console being developed under the development and license agreement are sold. As more fully discussed in Note 9, in the event the acquisition of CryoCor by BSS is completed, we do not anticipate receiving any additional milestone payments from BSC or royalty payments from BSS.

## Edgar Filing: CRYOCOR INC - Form 10-Q

Per our revenue recognition policy, revenue from a milestone achievement is recognized when earned based on several criteria. If not earned, the milestone achievement is recognized over the remaining minimum period of our performance obligations under the agreement. Therefore, advance payments the Company receives in excess of amounts earned are classified as deferred revenues until earned. At March 31, 2008, the entire advance payment received from BSC has been recognized as we believe that substantially all of our performance obligations have been completed.

---

## **Table of Contents**

### **Note 7. Recent Accounting Pronouncements**

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ( SFAS 157 ), which defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. Adoption of SFAS 157 for financial assets and liabilities is required for an entity's first fiscal year that begins after November 15, 2007. Adoption of SFAS 157 for non-financial assets and liabilities is required for an entity's first fiscal year that begins after November 15, 2008. The Company adopted SFAS 157 for financial assets and liabilities on January 1, 2008 without any material impact to the financial statements. All short-term investments held by the Company at March 31, 2008 are considered Level 1 investments under the fair value hierarchy as described in SFAS 157.

On January 1, 2008 the Company adopted the provision of SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* ( SFAS 159 ). SFAS 159 allows certain financial assets and liabilities to be recognized, at the Company's election, at fair market value, with any gains or losses for the period recorded in the statement of income. SFAS 159 includes available-for-sales securities in the assets eligible for this treatment. Currently, the Company records the gains or losses for the period in comprehensive income and in the equity section of the balance sheet. At this time, the Company has not elected to account for any available-for-sale securities using the provisions of SFAS 159.

On January 1, 2008 the Company adopted the provisions of Emerging Issue Task Force No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods and Services to Be Used in Future Research and Development Activities* ( EITF Issue 07-3 ). The consensus requires companies to defer and capitalize prepaid, nonrefundable research and development payments to third parties over the period that the research and development activities are performed or the services are provided, subject to an assessment of recoverability. The adoption of EITF Issue 07-3 did not have an impact on the Company's financial statements.

### **Note 8. Legal Proceedings**

In 2004, we requested that the United States Patent and Trademark Office ( USPTO ) institute interference proceedings between two patents owned by CryoCath Technologies, Inc. ( CryoCath ) and two of our CryoGen-licensed applications relating to certain primary and pre-cooling refrigeration system designs. In January 2008, the USPTO determined that one of our applications claimed rights to the same technology claimed by CryoCath, and declared an interference in which we were named the senior party. The purpose of the interference proceedings is to determine which company was the first to invent, and therefore has the rights to, the interfering subject matter. As the senior party, we are the presumed inventor of the technology and the burden of proof is placed on CryoCath to demonstrate an earlier date of invention. We believe we have an earlier date of invention, however, if we are not successful in these proceedings, we could fail to gain rights to certain patent claims.

In October 2007, CryoCath asserted a number of their patents covering both catheter and console technologies against us in the District Court of Delaware. We anticipate that this action will take between two and three years to resolve and that it will be costly for us to defend our position. We believe that the development and marketing of our cryoablation system for the treatment of atrial flutter and atrial fibrillation does not infringe any valid and enforceable claim of the asserted CryoCath United States patents and, in certain circumstances, we have obtained written opinions from outside patent counsel regarding the invalidity of a number of CryoCath's patents and/or their non-infringement by our cryoablation system. There can be no assurance, however, that we will successfully defend the actions initiated by CryoCath and, if we are found to infringe any of their valid patents, it would materially harm our business.

In January 2008, we brought patent infringement actions against CryoCath, asserting a number of our CryoGen-licensed patents covering both catheter and console technologies. We initially asserted our patents in district courts in Delaware and Canada, and have subsequently asked the United States International Trade Commission ( ITC ) to investigate CryoCath for illegal importation of products that infringe our intellectual property. We believe these combined actions may be an effective method of defending our intellectual property portfolio. The ITC action, in particular, is important because a successful action may block CryoCath's importation of infringing products into the United States. In 2008, in response to our action, CryoCath countersued in the District Court of Delaware, adding claims against us including infringement of an additional patent, anti-trust, and unfair competition claims. We do not believe these additional claims have merit, but we will be required to defend against this countersuit, and, if CryoCath is successful with any of these claims, it would materially harm our business.

The cost of defending and enforcing our patent rights against CryoCath has been significant, and our defensive or enforcement actions could cause us to incur significant additional costs. The time demands associated with defending or enforcing our patents rights in these actions have and will continue to interfere with our normal operations. In addition, our patents, or those licensed to us, if they are invalidated or circumvented, would not permit us to stop competitors from marketing our product, and any such invalidating or circumvention would materially harm our business.





**Table of Contents**

**Note 9. Proposed Acquisition of CryoCor**

We entered into a definitive Agreement and Plan of Merger (the *Merger Agreement*) dated April 15, 2008 with BSS and Padres Acquisition Corp., a Delaware corporation and a wholly-owned subsidiary of BSS (the *Purchaser*). Pursuant to the Merger Agreement, the Purchaser has commenced a tender offer (the *Offer*) to acquire all of CryoCor's common stock, par value \$0.001 per share, at a price of \$1.35 per share in cash without interest (the *Offer Price*). The Merger Agreement further provides that following the consummation of the Offer and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement (including, if required by applicable law, the adoption of the Merger Agreement by the holders of a majority of our outstanding shares), Purchaser will be merged with and into CryoCor, and each then-outstanding share of our common stock (other than shares held by BSS and certain BSS affiliates) will be converted into the right to receive cash in an amount equal to the Offer Price.

In addition, if the transaction contemplated under the Merger Agreement does not occur, we could be required to pay BSS a termination fee of \$700,000 if we complete an alternative merger or business combination transaction with a party other than BSS or under other circumstances described in the Merger Agreement. There are several closing conditions that are requirements for the completion of the transaction, and these closing conditions are described in greater detail in our Solicitation/Recommendation Statement on Schedule 14D-9, as filed with the SEC on April 29, 2008.

**Note 10. Subsequent Event**

On May 8, 2008, two alleged holders of our common stock (*Plaintiffs*) filed a complaint in the Superior Court of the State of California, County of San Diego, naming as defendants each member of our board of directors, CryoCor and BSC. The complaint is styled *Secondido, et al. v. CryoCor, Inc., et al.*, Case No. 37-2008-00083630-CU-MC-CTL (the *Action*). Plaintiffs purport to bring the Action on behalf of a class consisting of all holders of our common stock, except the defendants and their affiliates. Plaintiffs allege in their complaint that our board of directors, aided and abetted by BSC, breached their fiduciary duties in approving the Merger Agreement. The Action seeks, among other things, an order enjoining the transactions contemplated under the Merger Agreement, compensatory damages in the event such transactions are consummated, and the reimbursement of Plaintiffs' attorney's fees and related costs of bringing the Action. Based on our review of the complaint, we believe that the Action is without merit and intend, along with our board of directors, to defend the Action vigorously. There can be no assurance, however, that we will successfully defend the actions initiated by Plaintiffs and, if Plaintiffs are successful with any of these claims, it may prevent the transactions contemplated under the Merger Agreement from being completed and would materially harm our business.

**Table of Contents****ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The statements in this Form 10-Q that are not descriptions of historical facts may be forward-looking statements that are subject to risks and uncertainties. These include statements related to the proposed acquisition of CryoCor by BSS, the timing for regulatory review and approvals, if any, for the CryoCor Cardiac Cryoablation System, or cryoablation system, in the United States for use in treating atrial fibrillation, or AF, the timing for when we will submit an application for premarket approval, or PMA, for AF, statements related to our pivotal trial for the treatment of AF, statements related to the recent United States Food and Drug Administration Advisory Panel meeting that we participated in, statements related to our restructuring, our plans for commercializing our products, the timing for product sales in the United States, our anticipated continuing net losses, the amount and timing of future spending to develop existing and new product candidates, including in connection with related clinical trials, post-market registry studies and PMA filings, if any, our expenses in connection with our litigation with CryoCath Technologies Inc. and the outcome of that litigation, and the period over which our existing cash reserves will be sufficient to fund our ongoing operations and the consequences to us if our proposed acquisition by BSS is not completed for any reason, all of which are prospective. Such statements are only predictions and reflect our expectations and assumptions as of the date of this Form 10-Q based on currently available operating, financial, and competitive information. The actual events or results may differ materially from those projected in such forward-looking statements due to a number of factors, including risks associated with our failure to meet the requisite closing conditions in connection with the proposed acquisition of CryoCor by BSS or otherwise associated with our proposed acquisition by BSS failing to close for any reason, risks that, if we are not acquired by BSS, our lenders will consider a material adverse event or other acceleration event to have occurred under the applicable loan agreement, and will require immediate repayment in full of our outstanding debt, risks involved with our ability to obtain regulatory approval in the United States for our cryoablation system for use in treating AF, risks associated with our ability to submit a PMA for AF, risks associated with our ability to successfully commercialize our cryoablation system in the United States and elsewhere, risks associated with our dependence on patents and proprietary rights, risks associated with our protection and enforcement of our patents and proprietary rights, risks associated with the development or availability of competitive products or technologies, risks associated with our ability to obtain additional financing as necessary, and the other risks and uncertainties identified in the section of this Form 10-Q entitled "Risk Factors" and elsewhere in this Form 10-Q and in our other publicly available documents. These forward-looking statements speak only as of the date of this Form 10-Q. We expressly disclaim any intent or obligation to update any of these forward-looking statements after the filing of this Form 10-Q to reflect actual results, changes in our expectations, or otherwise. The following information should be read in conjunction with the consolidated financial statements and the notes thereto included in this Form 10-Q.*

*This Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the consolidated financial statements, including related notes, appearing in the Form 10-K for the year ended December 31, 2007 filed with the Securities and Exchange Commission, or SEC, on March 21, 2008.*

**Recent Developments**

We entered into a definitive Agreement and Plan of Merger, or Merger Agreement, dated April 15, 2008 with Boston Scientific Scimed, Inc., or BSS, and Padres Acquisition Corp., a Delaware corporation and a wholly-owned subsidiary of BSS, or Purchaser. Pursuant to the Merger Agreement, Purchaser has commenced a tender offer, or Offer, to acquire all of our common stock, par value \$0.001 per share, at a price of \$1.35 per share in cash without interest. The Merger Agreement further provides that following the consummation of the Offer and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement (including, if required by applicable law, the adoption of the Merger Agreement by the holders of a majority of our outstanding shares), Purchaser will be merged with and into CryoCor, and each then-outstanding share of our common stock (other than shares held by the BSS and certain BSS affiliates) will be converted into the right to receive cash in an amount equal to \$1.35 per share.

**Overview**

We have developed and manufacture a minimally invasive system based on our proprietary cryoablation technology for the treatment of cardiac arrhythmias. Cardiac arrhythmias are dysfunctions in the electrical activity of the heart that normally controls and maintains the highly coordinated contractions of the heart. Arrhythmias cause the heart to pump blood less efficiently, cause potentially debilitating symptoms and can result in life threatening events such as strokes. We have focused our initial development efforts on designing a system for treating atrial fibrillation, or AF, and right atrial flutter, or AFL, the two most common and difficult to treat arrhythmias. AF is the most prevalent arrhythmia and AFL is the second most prevalent arrhythmia and can lead to, and often coexists with, AF.

---

## **Table of Contents**

In August 2007, we received approval of our application for premarket approval, or PMA, from the United States Food and Drug Administration, or FDA, for the treatment of AFL with our CryoCor Cardiac Cryoablation System, or cryoablation system. In the fourth quarter of 2007, we began building our sales and marketing capabilities, including the hiring of a Vice President of Sales and Marketing and several sales representatives. However, our signing of the Merger Agreement with BSS has impacted our efforts to commercially launch our product. In April 2008, we eliminated the positions of our sales and marketing personnel, including our Vice President of Sales and Marketing, due to the need to conserve cash, which is a closing condition of the Merger Agreement. We expect that BSS will continue the commercial launch of our product if the acquisition is completed. If we do not complete the acquisition and are unable to secure additional debt or equity financing, we expect that we would have to cease operations.

In August 2007, we completed the enrollment of our pivotal trial for the treatment of AF and believe that we are the first company to complete the enrollment of a randomized pivotal trial for the treatment of AF. Based upon the anticipated time required to follow our patients subsequent to their cryoablation treatments, we anticipate that we will file a PMA for the treatment of AF in 2008, that this PMA will be reviewed by an Advisory Panel to the FDA and that a decision from the FDA on whether or not to approve our cryoablation system for the treatment of AF will be made in 2009. There can be no assurance that the FDA will approve our cryoablation system for the treatment of AF, and there can be no assurance that we will be the first company to file a PMA for the treatment of AF.

In June 2007, we signed a development and license agreement with Boston Scientific Corporation, or BSC, under which we agreed to modify our existing console to run a cryoablation balloon catheter developed by BSC. Under the terms of a related common stock purchase agreement, BSS made a \$2.5 million equity investment. BSC has made development milestone payments as we have achieved specified development milestones over the course of the collaboration. We have completed the first four milestones of the development agreement and will be entitled to receive additional milestone payments and a second equity investment upon the completion of the remaining milestones in the development agreement. If we are not acquired by BSS, we will seek to collect the additional \$1.0 million in milestone revenue, and the additional \$2.5 million equity investment under the original development and license agreement and common stock purchase agreement to the extent we achieve the applicable milestones.

Our product, the cryoablation system, is designed to treat cardiac arrhythmias through the use of extreme cold, or cryoenergy, to ablate, or destroy, targeted cardiac cells. Unlike radiofrequency, or RF, and other heat-based ablation technologies, which can destroy both the targeted cardiac cells and the extracellular material that binds the cells together, cryoablation leaves the material surrounding the cardiac cells fully intact. As a result, cryoablation may reduce the occurrence and severity of complications observed with heat-based ablation technologies. Our cryoablation system utilizes our proprietary technology that allows it to generate, deliver and transfer high levels of cryoenergy enabling large lesion sizes, shorter procedure times and enhanced system versatility. We believe these advantages provide better therapeutic efficacy and give us a greater ability to treat the more complex arrhythmias, such as AF and AFL, than competing cryoablation technologies. We believe our cryoablation system eliminates or reduces many of the drawbacks and risks associated with surgical and other heat-based ablation procedures.

We began selling our products in the United States in the fourth quarter of 2007, where we have received FDA approval of our cryoablation system for the treatment of AFL, and in Europe, where we have been approved for the treatment of all supraventricular tachycardias, including AF and AFL. As a result of our recent announcement to be acquired by BSS, we have discontinued our commercial launch efforts in the United States and expect that BSS will continue the commercial launch after the acquisition has been completed. Due to our limited financial resources, if the acquisition of CryoCor by BSS is not completed, we expect that we would further curtail our operations and if we are unable to raise additional equity or debt financing, we expect we would have to cease operations.

We are currently involved in a series of complex intellectual property legal actions against CryoCath Technologies Inc., or CryoCath, our only cryoablation competitor that has a cryoablation product approved for sale in the United States. These actions include offensive patent infringement actions we have brought in district courts in Delaware and Canada, an interference proceeding requested by us and declared by the United States Patent and Trademark Office, a defensive patent infringement action filed against us in the district court of Delaware, and a complaint we have brought before the United States International Trade Commission. The initial phases of these actions will take anywhere from one to three years to conclude and will be costly for us to prosecute. There can be no assurance that we will prevail in any or all of these actions.

### ***Financial Operations***

*Product Revenues.* Our product revenues to date have primarily come from a limited number of commercial sites in Europe and from our initial efforts to begin selling in the United States for the treatment of AFL. To date, we have not generated substantial revenues in Europe as our financial resources have primarily been dedicated to product development and clinical trials in the United States. This has prevented us from providing the resources necessary to broadly market our cryoablation system in Europe and from increasing the number of consoles placed in Europe. In October 2007, we began selling catheters for our cryoablation system in the United States for the treatment of AFL, and our initial commercial efforts were focused on converting the hospitals that participated



---

## **Table of Contents**

in our clinical trials to commercial accounts. As a result of the recent announcement of the potential acquisition of CryoCor by BSS, we have discontinued our direct sales efforts in the United States as a result of our need to conserve cash, which is a closing condition of the Merger Agreement.

*Research and Development Expenses.* Our research and development expenses primarily consist of costs incurred to further our research and development activities and include salaries and related employee benefits, non-cash share-based compensation, costs associated with clinical trials, pre-clinical activities, regulatory activities, research-related overhead expenses, fees paid to external service providers and fees paid under contracts with research organizations, which conduct certain research and development activities on our behalf. We expense research and development costs as they are incurred.

*Selling, General and Administrative Expenses.* Our selling, general and administrative expenses consist primarily of cash compensation and non-cash share-based compensation for executive, sales, finance and administrative personnel. Other significant costs include professional fees for accounting and legal services, including legal services associated with our efforts to obtain and maintain protection for the intellectual property related to our cryoablation system. Due to our April 2008 reduction in force, we expect to incur lower salaries and related employee benefits throughout the remainder of 2008. We anticipate that we will incur significant costs in the future related to our intellectual property litigation with CryoCath.

### ***Results of Operations***

We anticipate that our results of operations will fluctuate for the foreseeable future due to several factors, such as the progress of our research and development efforts, the timing and outcome of regulatory submissions, and our results. We also anticipate that we will continue to incur net losses for the next several years. Due to these uncertainties, results of future operations are difficult to predict.

### **Three months ended March 31, 2008 and 2007**

*Product Revenue and Collaboration Revenue.* Product revenue increased \$34,000 to \$100,000 for the three months ended March 31, 2008, compared to \$66,000 for the three months ended March 31, 2007. The increase was primarily due to our recent commercialization efforts since we received FDA approval to sell our products in the United States in August 2007. Collaboration revenue increased to \$667,000 for the three months ended March 31, 2008 from \$0 for the three months ended March 31, 2007 due to the partial recognition of an advance payment received in June 2007 under our development and license agreement with BSC of \$167,000 as well as the full recognition of a \$500,000 milestone earned and received during the three months ended March 31, 2008.

Deferred revenue decreased from \$206,000 at December 31, 2007 to \$61,000 at March 31, 2008 due primarily to an advance payment of \$500,000 received in June 2007 against development milestones under our development and license agreement with BSC, of which \$167,000 was recognized as collaboration revenue during the three months ended March 31, 2008. We recognized the advance payment over the development period of the contract, late June 2007 through March 31, 2008.

*Cost of Revenue.* Cost of revenue increased \$171,000 to \$799,000 for the three months ended March 31, 2008, compared to \$628,000 for the three months ended March 31, 2007. Cost of sales primarily consists of materials, labor and overhead costs associated with the manufacturing and warranty of our products. The increase during the three months ended March 31, 2008 is primarily related to increased personnel costs of \$83,000 and materials cost of \$47,000. Included in cost of revenue for the three months ended March 31, 2008 and 2007 were non-cash share-based compensation of \$111,000 and \$108,000, respectively.

*Research and Development Expenses.* Research and development expenses decreased \$280,000 to \$1.3 million for the three months ended March 31, 2008, compared to \$1.6 million for the three months ended March 31, 2007. The decrease was primarily related to lower trial costs of \$268,000 associated with our pivotal trial for the treatment of atrial fibrillation which completed enrollment in August 2007. Included in research and development expenses for the three months ended March 31, 2008 and 2007 were non-cash share-based compensation of \$160,000 and \$152,000, respectively.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses increased \$1.3 million to \$2.5 million for the three months ended March 31, 2008, compared to \$1.2 million for the three months ended March 31, 2007. The increase was primarily due to increased personnel costs and travel costs of \$308,000 and \$115,000, respectively, related to our recent commercialization efforts. In addition, we have incurred increased legal costs of \$815,000 associated with our litigation with CryoCath. Included in selling, general and administrative expenses for the three months ended March 31, 2008 and 2007 were non-cash share-based compensation of \$218,000 and \$191,000, respectively.



---

**Table of Contents****Liquidity and Capital Resources**

In April 2008, we executed a definitive merger agreement with BSS whereby BSS will seek to acquire all outstanding common shares of stock of CryoCor for \$1.35 per share. BSS initiated a tender offer directly to the stockholders of CryoCor, and the tender offer period is expected to close on May 27, 2008 or, if extended, in June 2008. CryoCor filed a Solicitation/Recommendation Statement on Schedule 14D-9 on April 29, 2008 with the SEC related to this transaction. In addition, BSS filed a Tender Offer Statement on Schedule TO on April 29, 2008 with the SEC. If the tender offer is completed and CryoCor is acquired by BSS, then all liabilities including our current debt outstanding will be assumed by BSS.

We have incurred losses since our inception in August 2000. As of March 31, 2008, we had an accumulated deficit of \$104.8 million. We have funded our operations to date from public and private placements of equity and debt securities, as well as bank debt, for aggregate net cash proceeds of \$105.0 million through March 31, 2008.

As of March 31, 2008, we had current debt outstanding of \$5.6 million (excluding debt discount for warrants of \$291,000), working capital of \$1.6 million and cash, cash equivalents and short-term investments totaling \$7.4 million. We currently invest our cash in money market funds, corporate bond securities and asset-backed securities.

In June 2007, we entered into a loan and security agreement that provided us with a \$14.0 million credit facility, as evidenced by secured promissory notes. The credit facility is available in two draws, with the first draw of \$6.0 million received in June 2007, and the second draw of \$8.0 million available for borrowing after the occurrence of both of the following conditions: (i) approval is received from the FDA of our application for pre-market approval for the treatment of right atrial flutter with the CryoCor Cardiac Cryoablation System (which occurred in August 2007), and (ii) we receive unrestricted net cash proceeds of at least \$20.0 million from the closing of an equity financing. Upon the applicable drawdown, we will make interest-only payments for the first six months following each advance, and will then make principal payments to fully amortize the advance over the subsequent 30-month term. The loan bears interest at a rate of 11.77% per annum. The loan provides that the credit facility is secured by our assets, excluding intellectual property. Pursuant to the terms of the loan and security agreement, we are subject to a material adverse change clause, which permits the holder of the note to call the balance for immediate repayment if a material adverse change occurs. A material adverse change is defined as, (i) a material impairment in the perfection or priority of lenders' lien in the collateral or in the value of such collateral; (ii) a material adverse change in our business, operations, or condition (financial or otherwise); or (iii) a material impairment of the prospect of repayment of any portion of the obligations. Due to our current financial condition, we have classified the entire principal balance as current although the contractual payment structure requires us to make monthly payments through July 2010.

The Company expects that if the acquisition of CryoCor by BSS that is discussed in Note 9 to the consolidated financial statements is not completed, the holders of the notes will believe that the prospects for repayment of the debt have been materially impaired and that a material adverse change will have occurred, which will permit the holder of the notes to call the balance of the debt principal for immediate repayment. If the holder of the notes were to call the balance of the debt principal, we believe we would have to cease operations.

*Net Cash Used in Operating Activities.* Net cash used in operating activities increased \$1.3 million to \$4.5 million for the three months ended March 31, 2008, compared to \$3.2 million for the three months ended March 31, 2007. The net cash used in both of these periods primarily reflects the net loss for each period, offset in part by depreciation and amortization, non-cash share-based compensation, amortization of debt discount and changes in operating assets and liabilities, including deferred revenue. Our operating losses have been within our expectations.

*Net Cash Provided by Investing Activities.* Net cash provided by investing activities decreased \$2.5 million to \$4.4 million for the three months ended March 31, 2008, compared to \$6.9 million for the three months ended March 31, 2007. Cash provided by investing activities relates to purchases and maturities of short-term investments as well as purchases of property and equipment. The decrease in net cash provided by investing activities for the three months ended March 31, 2008 is primarily related to a lower level of maturities of short-term investments compared to the three months ended March 31, 2007.

*Net Cash Provided by Financing Activities.* Net cash used in financing activities increased \$427,000 to \$390,000 for the three months ended March 31, 2008, compared to \$37,000 provided by financing activities for the three months ended March 31, 2007. Net cash used in financing activities during the three months ended March 31, 2008 was primarily related to principal payments made on short-term debt while the cash provided by financing activities in the three months ended March 31, 2007 was primarily attributable to proceeds from the issuance of common stock related to awards granted under our equity incentive plans.





---

## **Table of Contents**

### **Operating Capital and Capital Expenditure Requirements**

To date, we have had limited commercial sales in both Europe and the United States and we have not yet achieved profitability. If we do not complete the acquisition transaction with BSS and if we are in fact able to secure adequate additional debt or equity financing that will permit us to continue operations, we anticipate that we will continue to incur net losses for the next several years as we continue to engage in our litigation with CryoCath, develop our products, continue our clinical programs, expand our corporate infrastructure and commercially launch our cryoablation system in the United States for the treatment of AF, if approved. We expect that we will need to generate significant product revenues to achieve profitability.

We do not expect to generate significant product revenues until we obtain FDA marketing approval of our cryoablation system for the treatment of AF. Even though the FDA recently approved our PMA for the treatment of AFL, we have not attempted to broadly commercialize our cryoablation system, initially because we lacked adequate funding to do so and now because, in light of our proposed acquisition by BSS, we have eliminated our sales and marketing personnel. Prior to our agreeing to be acquired by BSS, our ability to build and install our planned base of cryoablation consoles and to hire the additional sales and support personnel necessary to support this installed base was impacted by our available financial resources, and we did not have the financial resources to hire additional sales and support personnel or make the capital expenditures necessary to achieve these objectives. In April 2008, we eliminated the positions of our sales and marketing personnel, including our Vice President of Sales and Marketing. If we do not complete the acquisition of CryoCor by BSS, we would need to sell additional equity or debt securities or obtain an additional credit facility, or to access the additional funds available under our existing credit facility, to increase our financial resources. The sale of additional equity and convertible debt securities will result in additional dilution to our stockholders. If we raise additional funds through the issuance of convertible debt securities, these securities would have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If the acquisition of CryoCor by BSS is not completed and we are unable to obtain additional financing, we expect that we will cease operations.

As a condition to the FDA approving our PMA for AFL, we agreed to sponsor a post-market registry study of our cryoablation system. In this registry study, we will collect safety and effectiveness data over a one-year follow-up period on our cryoablation system for the treatment of AFL in 325 patients. We will also collect safety and effectiveness data over a one-year period on competing RF ablation systems for the treatment of AFL in 325 patients. The compliance requirements for a company sponsoring a registry study are less complex than a pre-market clinical study, and we believe that we will be able to collect the required safety and effectiveness data without significant difficulty. We anticipate that the external cost of conducting the post-market registry study will be between \$1.0 million and \$1.5 million and will be incurred over a multi-year period. We intend to begin the registry study in the second half of 2008.

At present, we have a wholly owned subsidiary in Germany that previously sold our products in Germany, Belgium, and the Netherlands. We discontinued the activities of this subsidiary in 2006 and are currently pursuing the dissolution of this subsidiary. We incurred restructuring charges of \$252,000 in conjunction with the closing of our subsidiary, of which \$16,000 remains accrued at March 31, 2008. We have signed distribution agreements for the sale of our cryoablation system in the United Kingdom and Italy, and our United Kingdom distributor supports our customers in Germany, Belgium, Denmark and the Netherlands. We have discontinued our direct sales efforts in the United States as a result of our recent announcement to be acquired by BSS. We expect that BSS will continue the commercial launch efforts of our product after the acquisition has been completed.

If our acquisition by BSS is not completed for any reason and thereafter we are in fact able to secure adequate additional debt or equity financing, we anticipate spending at least a total of \$2.0 million in external costs during 2008 and 2009 for existing clinical trials and regulatory activities related to using our cryoablation system to treat AF, and an anticipated clinical trial for our next generation catheter, Quantum. In addition, under those circumstances we anticipate spending an additional \$1.0 million - \$1.5 million on the registry study required by the FDA as a condition for approval for our cryoablation system for the treatment of AFL.

In 2004, we requested that the USPTO institute interference proceedings between two patents owned by CryoCath Technologies and two of our CryoGen-licensed applications relating to certain primary and pre-cooling refrigeration system designs. In January 2008, the USPTO determined that one of our applications claimed rights to the same technology claimed by CryoCath, and declared an interference in which we were named the senior party. The purpose of the interference proceedings is to determine which company was the first to invent, and therefore has the rights to, the interfering subject matter. As the senior party, we are the presumed inventor of the technology and the burden of proof is placed on CryoCath to demonstrate and earlier date of invention. We believe we have an earlier date of invention, however, if we are not successful in these proceedings, we could fail to gain rights to certain patent claims. We believe the external cost associated with these interference proceedings will be between \$1.5 million - \$2.0 million over a two year period. In the event our acquisition by BSS does not close for any reason, we will be required to obtain adequate additional debt or equity financing to be able to continue to fund this litigation.



---

**Table of Contents**

In October 2007, CryoCath asserted a number of their patents covering both catheter and console technologies against us in the District Court of Delaware. We anticipate that this action will take between two and three years to resolve and that it will be costly for us to defend our position. We believe that the development and marketing of our cryoablation system for the treatment of AFL and AF does not infringe any valid and enforceable claim of the asserted CryoCath United States patents and, in certain circumstances, we have obtained written opinions from outside patent counsel regarding the invalidity of a number of CryoCath's patents and/or their non-infringement by our cryoablation system. There can be no assurance, however, that we will successfully defend the actions initiated by CryoCath and, if we are found to infringe any of their valid patents, it would materially harm our business. We believe the external cost associated with defending this lawsuit will be between \$2.0 million and \$2.5 million over a three year period. In the event our acquisition by BSS does not close for any reason, we will be required to obtain adequate additional debt or equity financing to be able to continue to fund this litigation.

In January 2008, we brought patent infringement actions against CryoCath, asserting a number of our CryoGen-licensed patents covering both catheter and console technologies. We initially asserted our patents in district courts in Delaware and Canada, and have subsequently asked the United States International Trade Commission, or ITC, to investigate CryoCath for illegal importation of products that infringe our intellectual property. We believe these combined actions may be an effective method of defending our intellectual property portfolio. The ITC action, in particular, is important because a successful action may block CryoCath's importation of infringing products into the United States. In 2008, in response to our action, CryoCath countersued in the District Court of Delaware, adding claims against us including infringement of an additional patent, anti-trust, and unfair competition claims. We do not believe these additional claims have merit, but we will be required to defend against this countersuit. We believe the external cost associated with pursuing these various legal actions will be between \$6.0 million - \$7.0 million over a three year period. In the event our acquisition by BSS does not close for any reason, we will be required to obtain adequate additional debt or equity financing to be able to continue to fund this litigation.

Our forecasts of the costs to complete clinical trials, post-market registry studies and development of products, as well as to engage in our litigation with CryoCath, are forward-looking statements and involve risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed in the Risk Factors section of this Form 10-Q, and in our other securities filings filed with the Securities and Exchange Commission, or SEC. We have based these estimates on assumptions that may prove to be wrong, and we may be required to utilize our available capital resources sooner than we currently expect.

Our future funding requirements will depend on many factors, including, but not limited to:

the costs of defending and enforcing our patent portfolio and other intellectual property rights, including in connection with our litigation with CryoCath;

the commercial acceptance of our product in the United States, including, to the extent we do so, after we initiate sales efforts targeting AF;

the costs of rebuilding our sales, marketing and distribution capabilities, which have recently been eliminated;

our ability to obtain FDA approval for the treatment of AF or other regulatory approval for our products;

the scope, rate of progress and cost of our clinical trials and other research and development activities;

the costs and timing of seeking regulatory approvals, including participation in FDA advisory panel meetings and performing any required additional studies or trials;

clinical trial results;

## Edgar Filing: CRYOCOR INC - Form 10-Q

acceptance by the FDA of our clinical trial design and data to support applications for marketing approval of the desired indications;

the extent and level of reimbursement for cryoablation;

the effect of competing products and technologies; and

the terms and timing of any collaborative, licensing and other arrangements that we may establish.

Future capital requirements will also depend on the extent to which we acquire or invest in other businesses, products and technologies, but, other than our development and license agreement with BSC, we currently have no commitments or agreements relating to any of these types of transactions.

---

**Table of Contents**

We have service agreements with clinical sites, individuals and institutional research organizations for the conduct of our AF pivotal trial. We make payments to these sites and organizations based upon the actual number of patients enrolled and the period of follow-up in the trials, and we have accrued approximately \$531,000 in fees and expenses through March 31, 2008 in connection with our AF pivotal trial. We do not have minimum payment obligations under these agreements and the amount to be paid to each center and the timing of those payments will vary based on the negotiated amount paid for each patient to be treated and for each patient screened who fails to or declines to participate in the clinical trial. If our acquisition by BSS is not completed for any reason and thereafter we are in fact able to secure adequate additional debt or equity financing, we anticipate that the external cash outlay of completing our AF pivotal trial and submitting a PMA for the treatment of AF with our cryoablation system will be approximately \$1.4 million during the remainder 2008. In addition to the \$1.4 million in external cash outlay, under those circumstances we expect to incur additional expenses in connection with the preparation of our regulatory filings, including costs associated with employees and consultants, as well as related legal expenses.

We have agreed to cover the treatment costs for certain patients in our AF pivotal trial who are either not insured, or who are insured but were declined coverage by their insurance company for the costs associated with our procedure. As of March 31, 2008, we have agreed to cover the treatment costs for 13 patients at an estimated cost of approximately \$276,000, of which \$108,000 is included in the accrued clinical development liabilities on our balance sheet at March 31, 2008. We anticipate that we may pay the treatment costs for up to three additional cryoablation treatments for these 13 uninsured, or underinsured, patients. We project that if we cover these costs, the additional estimated cost of these treatments would be \$12,000 to \$35,000 each. The total estimated costs for covering the costs of these treatments are included in our estimated \$1.4 million above.

**Critical Accounting Policies and Significant Judgments and Estimates**

Our Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that the following accounting policies and estimates are most critical to a full understanding and evaluation of our reported financial results.

*Revenue Recognition*

We comply with SEC Staff Accounting Bulletin No. 104, *Revenue Recognition in Financial Statements*, or SAB 104, and the Financial Accounting Standards Board, or FASB, Statement of Financial Accounting Standards No. 48, or SFAS 48, *Revenue Recognition When Right of Return Exists*. SAB 104 and SFAS 48 set forth guidelines on the timing of revenue recognition based upon factors such as passage of title, installation, payment terms and ability to return products. We recognize revenue when all of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; (iv) collectibility is reasonably assured; and (v) the ability to return the product has expired.

Historically, customers had the right to return catheter and sheath products until one month following the expiration date of the product, which had been six months after production. Effective October 1, 2006, the catheter and sheath products expire one year and two years after production, respectively. Therefore, we modified our return policy such that we will no longer grant a right to return products for other than warranty purposes. As we have had limited sales of our products, we currently recognize revenues when the customer has paid for the product and, if applicable, the right of return, if any, has expired.

Revenue from a milestone achievement is recognized when earned, as evidenced by acknowledgment from our collaborator, provided that (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement, (ii) the milestone represents the culmination of an earnings process, (iii) the milestone payment is non-refundable and (iv) our performance obligations after the milestone achievement will continue to be funded by our collaborator at a level comparable to the level before the milestone achievement. If all of these criteria are not met, the milestone achievement is recognized over the remaining minimum period of our performance obligations under the agreement. We defer non-refundable upfront fees under our collaborations and recognize them over the period in which we have significant involvement or perform services, using various factors specific to each collaboration. Amounts we receive for research funding for a specified number of full-time researchers are recognized as revenue as the services are performed. Advance payments we receive in excess of amounts earned are classified as deferred revenues until earned.



**Table of Contents**

*Clinical Trial Expenses*

Clinical trial costs are a component of research and development expenses and include fees paid to participating hospitals and other service providers which conduct clinical trial activities with patients on our behalf. The various costs of the trial are contractually based on the nature of the service and we accrue the costs as the services to the patient are provided.

*Share-Based Payments*

We have four share-based compensation plans consisting of three stock option and award programs and an employee stock purchase plan. As a result of adopting the FASB's Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123(R), on January 1, 2006, we recognized share-based employee and non-employee director compensation expense of \$238,000 and \$169,000 during the three months ended March 31, 2008 and 2007, respectively, in addition to \$236,000 and \$245,000 in compensation expense recorded as required under Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, during the three months ended March 31, 2008 and 2007, respectively. We calculated this expense based on the fair values of the share-based compensation awards as estimated using the Black-Scholes option valuation model. Use of this model requires us to make assumptions about expected future volatility of our stock price and the expected term of the stock options that we grant. Calculating share-based compensation expense under SFAS 123(R) also requires us to make assumptions about expected future forfeiture rates for our stock option awards. As of March 31, 2008, total unrecognized compensation expense related to unvested share-based compensation arrangements already granted under our various plans was \$2.4 million, which we expect will be recognized over a weighted-average period of 1.8 years. However, it is difficult to predict the actual amount of share-based compensation expense that we will recognize in future periods because that expense can be affected by changes in the amount or terms of our share-based compensation awards issued in the future, changes in the assumptions used in our model to value those future awards, changes in our stock price, and changes in interest rates, among other factors.

**Recent Accounting Pronouncements**

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements*, or SFAS 157, which defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. Adoption of SFAS 157 for financial assets and liabilities is required for an entity's first fiscal year that begins after November 15, 2007. Adoption of SFAS 157 for non-financial assets and liabilities is required for an entity's first fiscal year that begins after November 15, 2008. The Company adopted SFAS 157 for financial assets and liabilities in the current year without any material impact to the financial statements.

On January 1, 2008 the Company adopted the provision of Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, or SFAS 159. SFAS 159 allows certain financial assets and liabilities to be recognized, at the Company's election, at fair market value, with any gains or losses for the period recorded in the statement of income. SFAS 159 includes available-for-sales securities in the assets eligible for this treatment. Currently, the Company records the gains or losses for the period in comprehensive income and in the equity section of the balance sheet. At this time, the Company has not elected to account for any available-for-sale securities using the provisions of SFAS 159.

On January 1, 2008 the Company adopted the provisions of the FASB's Emerging Issue Task Force No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods and Services to Be Used in Future Research and Development Activities*, or EITF Issue 07-3. The consensus requires companies to defer and capitalize prepaid, nonrefundable research and development payments to third parties over the period that the research and development activities are performed or the services are provided, subject to an assessment of recoverability. The adoption of EITF Issue 07-3 did not have an impact on the Company's financial statements.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including commercial paper, money market funds, government and corporate debt securities and asset-backed securities. Our cash, cash equivalents and short-term investments as of March 31, 2008 included liquid money market funds, commercial paper, corporate debt securities and asset-backed securities. Due to the short-term nature of our investments, we believe that there is no material exposure to interest rate risk.





---

## **Table of Contents**

We have some activities in foreign currencies, principally our commercial efforts in Europe, which are denominated in euros and British pounds. We do not currently use derivative financial instruments to mitigate this exposure. However, we do not expect fluctuations in foreign exchange rates to have a material impact on our financial condition or results of operations.

### **ITEM 4. CONTROLS AND PROCEDURES**

#### **Evaluation of Disclosure Controls and Procedures**

Regulations under the Securities Exchange Act of 1934, or the Exchange Act, require public companies to maintain disclosure controls and procedures which are defined to mean a company's controls and other procedures that are designed to ensure that information required to be disclosed in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC's rules and forms. CryoCor's management, including our Chief Executive Officer, who is our principal executive officer, and our Chief Financial Officer, who is our principal financial officer, conducted an evaluation as of the end of the period covered by this report of the effectiveness of our disclosure controls and procedures. Based on their evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective for this purpose.

#### **Changes in Internal Control over Financial Reporting**

Our Chief Executive Officer and our Chief Financial Officer have determined that there were no changes in our internal controls over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### **Limitation on Effectiveness of Controls**

It should be noted that any system of controls, however well designed and operated, can provide only reasonable and not absolute assurance that the objectives of the system are met. The design of any control system is based, in part, upon the benefits of the control system relative to its cost. Control systems can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. In addition, over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

## **PART II OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

In 2004, we requested that the USPTO institute interference proceedings between two patents owned by CryoCath Technologies and two of our CryoGen-licensed applications relating to certain primary and pre-cooling refrigeration system designs. In January 2008, the USPTO determined that one of our applications claimed rights to the same technology claimed by CryoCath, and declared an interference in which we were named the senior party. The purpose of the interference proceedings is to determine which company was the first to invent, and therefore has the rights to, the interfering subject matter. As the senior party, we are the presumed inventor of the technology and the burden of proof is placed on CryoCath to demonstrate an earlier date of invention. We believe we have an earlier date of invention, however, if we are not successful in these proceedings, we could fail to gain rights to certain patent claims.

In October 2007, CryoCath asserted a number of their patents covering both catheter and console technologies against us in the District Court of Delaware. We anticipate that this action will take between two and three years to resolve and that it will be costly for us to defend our position. We believe that the development and marketing of our cryoablation system for the treatment of AFL and AF does not infringe any valid and enforceable claim of the asserted CryoCath United States patents and, in certain circumstances, we have obtained written opinions from outside patent counsel regarding the invalidity of a number of CryoCath's patents and/or their non-infringement by our cryoablation system. There can be no assurance, however, that we will successfully defend the actions initiated by CryoCath and, if we are found to infringe any of their valid patents, it would materially harm our business.

In January 2008, we brought patent infringement actions against CryoCath, asserting a number of our CryoGen-licensed patents covering both catheter and console technologies. We initially asserted our patents in district courts in Delaware and Canada, and have subsequently asked the

## Edgar Filing: CRYOCOR INC - Form 10-Q

United States International Trade Commission, or ITC, to investigate CryoCath for illegal importation of products that infringe our intellectual property. We believe these combined actions may be an effective method of defending our intellectual property portfolio. The ITC action, in particular, is important because a successful action may block CryoCath's

**Table of Contents**

importation of infringing products into the United States. In 2008, in response to our action, CryoCath countersued in the District Court of Delaware, adding claims against us including infringement of an additional patent, anti-trust, and unfair competition claims. We do not believe these additional claims have merit, but we will be required to defend against this countersuit, and, if CryoCath is successful with any of these claims, it would materially harm our business.

The cost of defending and enforcing our patent rights against CryoCath has been significant, and our defensive or enforcement actions could cause us to incur significant additional costs. The time demands associated with defending or enforcing our patents rights in these actions have and will continue to interfere with our normal operations. In addition, our patents, or those licensed to us, if they are invalidated or circumvented, would not permit us to stop competitors from marketing our product, and any such invalidating or circumvention would materially harm our business.

On May 8, 2008, two alleged holders of our common stock ( Plaintiffs ) filed a complaint in the Superior Court of the State of California, County of San Diego, naming as defendants each member of our board of directors, CryoCor and BSC. The complaint is styled *Secondido, et al. v. CryoCor, Inc., et al.*, Case No. 37-2008-00083630-CU-MC-CTL (the Action ). Plaintiffs purport to bring the Action on behalf of a class consisting of all holders of our common stock, except the defendants and their affiliates. Plaintiffs allege in their complaint that our board of directors, aided and abetted by BSC, breached their fiduciary duties in approving the Merger Agreement. The Action seeks, among other things, an order enjoining the transactions contemplated under the Merger Agreement, compensatory damages in the event such transactions are consummated, and the reimbursement of Plaintiffs' attorney's fees and related costs of bringing the Action. Based on our review of the complaint, we believe that the Action is without merit and intend, along with our board of directors, to defend the Action vigorously. There can be no assurance, however, that we will successfully defend the actions initiated by Plaintiffs and, if Plaintiffs are successful with any of these claims, it may prevent the transactions contemplated under the Merger Agreement from being completed and would materially harm our business.

**ITEM 1A. RISK FACTORS**

*Except for the historical information contained herein, this Form 10-Q contains forward-looking statements that involve risks and uncertainties, including but not limited to risks related to the proposed acquisition of CryoCor by Boston Scientific Scimed, Inc. Our actual results may differ materially from those discussed here. Factors that could cause or contribute to differences in our actual results include those discussed in the following section, as well as those discussed in Part I, Item 2 entitled Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere throughout this Form 10-Q. You should consider carefully the following risk factors, together with all of the other information included in this Form 10-Q. Each of these risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock.*

*\*The Company has marked with an asterisk those risk factors that reflect changes from the risk factors included in the Company's Annual Report on Form 10-K filed with the SEC on March 21, 2008.*

**Going Concern** See **Going Concern** in Note 1 of Notes to Financial Statements and page 27 of this Risk Factors section, in which we discuss the need to obtain additional financing in 2008.

**Risks related to the Proposed Acquisition of CryoCor by Boston Scientific Scimed, Inc.**

*\* There are closing conditions associated with our acquisition by Boston Scientific Scimed, Inc., or BSS, and if we do not meet one or more of the closing conditions, BSS is not required to complete the acquisition of CryoCor.*

Our definitive agreement for the acquisition of CryoCor by BSS has a number of closing conditions. If we do not meet any of the closing conditions, or if BSS does not waive our requirement to meet a specific closing condition, then BSS does not have to complete the acquisition of CryoCor. There are several closing conditions, including requirements that CryoCor maintain a minimum cash balance of \$1.9 million if the tender offer is closed by May 31, 2008, or a minimum cash balance of \$720,000 if the tender offer is closed by June 15, 2008. We may encounter unforeseen expenditures that will result in our cash balance declining below these cash minimum balances, and if we do not meet this closing condition, BSS may choose not to acquire CryoCor. Additionally, BSS considers several of our employees to be key employees and if any of those employees elect not to continue employment with BSS, then BSS is not required to complete the acquisition. Finally, there are several warrants to purchase our common stock that include provisions to allow the warrant to continue beyond the time of the acquisition. BSS is requiring that we cancel these warrants and if we are unable to secure cancellation from the warrant holders, then BSS is not required to complete the acquisition. In addition to these specific closing conditions, there are customary closing conditions designed to ensure that our ongoing business has not been impaired.

## Edgar Filing: CRYOCOR INC - Form 10-Q

*\*If we are not acquired, it is possible the holders of our debt will consider that a material adverse change has occurred.*

We had debt outstanding of approximately \$5.6 million at March 31, 2008 (excluding debt discount for warrants of \$291,000), and our cash resources are declining. As a part of the acquisition of CryoCor, BSS will either assume the debt, or will pay off the debt in full. The holders of our notes consider this be a critical component to the prospects of repayment in full of their debt, and if we are not able to complete an acquisition with an acquiror that is considered creditworthy, then we believe the holders of our notes will consider a material adverse event to have occurred, and will require immediate repayment in full of our outstanding debt. It is probable that the cash and investments of CryoCor would be insufficient to meet the obligations of our creditors and we expect we would declare bankruptcy and/or cease operations.

---

## **Table of Contents**

### ***Additional Information and Where to Find It***

*This report is neither an offer to purchase nor a solicitation of an offer to sell shares of CryoCor. Stockholders of CryoCor are urged to read the relevant tender offer documents because they contain important information that stockholders should consider before making any decision regarding tendering their shares. BSS and Padres Acquisition Corp. have filed tender offer materials with the SEC and CryoCor has filed a Solicitation/Recommendation Statement with respect to the offer. The tender offer materials (including an Offer to Purchase, a related Letter of Transmittal and certain other offer documents) and the Solicitation/Recommendation Statement contain important information, which should be read carefully before any decision is made with respect to the tender offer. The Offer to Purchase, the related Letter of Transmittal and certain other offer documents, as well as the Solicitation/Recommendation Statement, are available to all stockholders of CryoCor at no expense to them. The tender offer materials and the Solicitation/Recommendation Statement are available for free at the SEC's website at <http://www.sec.gov>.*

*In addition to the Offer to Purchase, the related Letter of Transmittal and certain other offer documents, as well as the Solicitation/Recommendation Statement, CryoCor and BSC file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any reports, statements or other information filed by CryoCor or BSC at the SEC public reference room at 100 F Street, N.E., Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the public reference room. CryoCor's and BSC's filings with the SEC are also available to the public from commercial document-retrieval services and at the website maintained by the SEC at <http://www.sec.gov>.*

### ***Other Risks Related to our Business if the Acquisition of CryoCor by BSS is Not Completed***

***\* We will need substantial additional funding in a very short period of time to continue our operations. We may be unable to raise capital which would force us to delay, curtail or eliminate our clinical programs or product development programs.***

We will need to raise substantial additional capital to:

enforce our proprietary rights in connection with our litigation actions involving CryoCath, including the interference request we filed with the USPTO, the offensive legal actions in Delaware and Canada and the investigation pursued by the ITC;

restore our product commercialization activities in the United States;

fund our operations and clinical trials;

continue our research and development; and

defend, in litigation or otherwise, any claims that we infringe third party patents or other intellectual property rights or have otherwise engaged in anticompetitive behavior, including in connection with our litigation with CryoCath.

Our future funding requirements will depend on many factors, including but not limited to:

the costs of filing, prosecuting, and maintaining our owned and licensed patent applications and patents, and defending and enforcing these patents and other intellectual property rights, including in connection with our litigation with CryoCath;

the commercial acceptance of our product in the United States, including, to the extent we do so, after we initiate sales efforts targeting AF;

## Edgar Filing: CRYOCOR INC - Form 10-Q

the costs of rebuilding sales, marketing and distribution capabilities;

our ability to obtain FDA approval for AF or other regulatory approvals for our products;

the scope, rate of progress and cost of our clinical trials and other research and development activities;

the costs and timing of seeking regulatory approvals, including participation in FDA advisory panel meetings and performing any required additional studies or trials;

clinical trial results;

acceptance by the FDA of our clinical trial design and data to support marketing approval for the desired indications;

the extent and level of reimbursement for cryoablation for various indications;

the effect of competing products and technologies; and

the terms and timing of any collaborative, licensing and other arrangements that we may establish.

**Table of Contents**

Until we can generate sufficient product revenue, which may never occur, and particularly since we have ceased all sales and marketing activities, we expect to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants, and we may not meet the conditions required to access the additional funding under our existing credit facility. Examples of such restrictive covenants, all of which we are subject to under our current loan agreement, include limitations on our ability to incur additional debt or liens on any of our assets, dispose of our property, make dividend payments or distributions to our stockholders or enter into transactions that would result in a change in control of us. Additionally, pursuant to the terms of our current loan agreement, we are subject to a material adverse change clause, which permits the holder of the note to call the balance if a material adverse change occurs. A material adverse change is defined as, (i) a material impairment in the perfection or priority of lenders' lien in the collateral or in the value of such collateral; (ii) a material adverse change in our business, operations, or condition (financial or otherwise); or (iii) a material impairment of the prospect of repayment of any portion of the obligations. The Company expects that if the acquisition of CryoCor by BSS is not completed, the holders of the notes will believe that the prospects for repayment of the debt have been materially impaired and that a material adverse change has occurred, which will permit the holder of the notes to call the balance of the debt principal for immediate repayment. If the holder of the notes were to call the balance of the debt principal, we believe we would have to cease operations.

Therefore, if we become insolvent and are not able to pay our debts, our lenders have the ability to seize our remaining cash earlier than the scheduled repayment, which could force us to cease operations. The terms of any additional debt or equity financing may not be favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that are not favorable to us. The legal actions that we are undertaking with CryoCath are anticipated to be very expensive, and will take between one to three years to be resolved. If our acquisition by BSS is not completed for any reason and we are unable to raise adequate funds, we believe we would have to cease operations.

***\* We may not be able to continue as a going concern or fund our existing capital needs.***

In our Annual Report on Form 10-K, our independent registered public accounting firm has included an explanatory paragraph in their report on our 2007 financial statements related to the uncertainty of our ability to continue as a going concern. There is substantial doubt as to whether we will be able to continue as a going concern beyond 2008 without access to additional working capital. There can be no assurance that we will be able to obtain additional funds during 2008 on satisfactory terms, or at all. If we cannot obtain sufficient additional financing and our acquisition by BSS is not completed for any reason, we believe we would have to cease operations. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should we be forced to take any such actions. Based upon the foregoing, our independent registered public accounting firm has included an explanatory paragraph in their report on our 2007 financial statements related to the uncertainty in our ability to continue as a going concern.

***The litigation with CryoCath is very complex and is being pursued in several actions. It will be very expensive to prosecute and will take years to resolve. If we are not successful in our actions, it may prevent us from being able to continue our operations.***

The legal actions with CryoCath include our defense of claims by CryoCath that we infringe patents held by them. Although we do not believe we infringe any valid and enforceable claim of the CryoCath patents, we will have to spend significant time and financial resources in our defense of this lawsuit. This lawsuit will be tried before a jury in the district courts of Delaware and there can be no assurance that we will be able to obtain the financial resources necessary to defend our position, or that we will be able to convince a jury that we do not infringe the CryoCath patents. If we are not successful, it would materially harm our business and may require that we cease our operations.

Our legal actions against CryoCath also include four actions that we have initiated against CryoCath, each of which will be expensive to prosecute and that will require that we demonstrate that CryoCath infringes one or more of our valid and enforceable claims, and to establish ownership of certain claims. We will need to obtain additional financial resources to be able to prosecute these legal actions, and the financial resources that we require will be significant relative to our existing cash. If we are not able to obtain the additional financial resources needed, then we will be required to discontinue our legal actions, which may weaken the perceived or real value of our patent portfolio. Additionally, if we are not successful in any of our legal actions against CryoCath, we believe it will hinder our ability to compete with CryoCath in the commercial marketplace. Our legal actions against CryoCath have also caused, and we expect will continue to cause, a significant diversion of our management's time and attention away from our business and operations.

**Table of Contents**

***\*We have a limited operating history, have a history of operating losses, expect to continue to incur losses and may never become profitable.***

We have a limited operating history and have only recently received approval from the FDA to commercialize our product in the United States for the treatment of AFL. We began commercializing our product in the fourth quarter of 2007, however, as a result of our definitive agreement for CryoCor to be acquired by BSS, we have discontinued our commercial efforts in the United States. If our acquisition by BSS is not completed for any reason and we thereafter are in fact able to secure adequate additional debt or equity financing to restore our sales and marketing capabilities, we do not anticipate generating significant product revenues until we obtain FDA marketing approval of our cryoablation system for the treatment of AF and our product candidates may require additional development, clinical trials, regulatory clearances or approvals by the FDA if they are to be commercially accepted. There can be no assurance that, in those circumstances we will be able to raise the additional capital needed to broadly commercialize our system for the treatment of AFL, and we may never broadly commercialize our system for the treatment of AFL. We do not currently have the required approval to market our cryoablation system in the United States for the treatment of AF and we may not receive this approval.

As of March 31, 2008, we had an accumulated deficit of \$104.8 million. We have incurred net losses in each year since our inception in August 2000, including net losses of \$15.8 million, \$15.1 million and \$17.1 million for the years ended December 31, 2007, 2006, and 2005, respectively, and a net loss of \$4.0 million in the three months ending March 31, 2008. We expect to continue to incur significant operating losses, in the aggregate and on a per share basis, for the foreseeable future. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, net current assets and working capital. Because of the risks and uncertainties associated with developing medical devices, we are unable to predict the extent of any future losses.

***We may need to engage in costly patent litigation against our competitors, which may harm our business, financial condition, results of operations and cash flow.***

The medical device industry is characterized by a large number of patents, patent filings and frequent litigation based on allegations of patent infringement. For example, on October 18, 2007, CryoCath initiated legal proceedings against us in the United States District Court in Delaware, seeking a declaration that our cryoablation system infringes a number of CryoCath's United States issued patents. Additionally, competitors may have filed applications for or have been issued patents and may obtain additional patents and proprietary rights related to products or processes that we compete with or are similar to ours. We may not be aware of all of the patents potentially adverse to our interests that may have been issued to others. Based on the litigious nature of the medical device industry and the fact that we may pose a competitive threat to some companies who own or control various patents, we believe that as we begin to engage in and continue on with commercialization activities in the United States, there is a significant risk that one or more third parties, in addition to CryoCath, will assert a patent infringement claim, as CryoCath already has, against the manufacture, use or sale of our cryoablation system. The CryoCath lawsuit seeks damages from CryoCor and an injunction that would prevent us from selling our cryoablation system; this will be expensive to defend. Any other similar lawsuit could also seek to prevent us from commercializing our cryoablation system or enjoin us from selling it, may seek damages from us, and would likely be expensive for us to defend against. We cannot predict if or when any third party patent holder, in addition to CryoCath, will file suit for patent infringement. We can provide no assurance as to the outcome of the CryoCath litigation.

The outcome of patent litigation is subject to substantial uncertainties, especially in medical device-related patent cases that may, for example, turn on the interpretation of claim language by the court which may not be to our advantage and also the testimony of experts as to technical facts upon which experts may reasonably disagree. Our involvement in the CryoCath patent litigation will, and our involvement in other patent litigation could, result in significant expense. Some of our competitors have considerable resources available to them and a strong economic incentive to undertake substantial efforts to stop or delay us from bringing our cryoablation system to market and achieving market acceptance. We, on the other hand, are an early stage company with comparatively few resources available to us to engage in costly and protracted litigation. Moreover, regardless of the outcome, patent litigation against or by us, including the CryoCath litigation, could significantly disrupt our development and commercialization efforts, divert our management's attention and quickly consume our financial resources.

In addition, if third parties file patent applications or are issued patents claiming technology also claimed by us in pending applications, we may be required to participate in interference proceedings with the USPTO or in other proceedings outside the United States, including oppositions, to determine priority of invention or patentability. For example, we have filed requests with the USPTO seeking to invoke an interference proceeding involving certain patents owned by CryoCath. In January 2008, the USPTO determined that one of our applications claimed rights to the same technology claimed by CryoCath, and declared an interference in which we were named the senior party. If we are not successful in this proceeding, this proceeding could result in us failing to gain rights to certain patent claims. Even if we are successful, we may incur substantial costs and the time and attention of our management and scientific personnel will be diverted in pursuit of these proceedings.



---

**Table of Contents**

In the event that we are found to infringe any valid claim in a patent held by a third party, including in connection with the CryoCath litigation, we may, among other things, be required to:

pay actual damages, plus increased damages up to triple the actual damages and the other party's attorneys' fees, which may be substantial;

obtain licenses to the infringed intellectual property, which may not be available to us on acceptable terms, or at all;

cease the development, manufacture, use and/or sale of products that infringe the patent rights of others through a court-imposed sanction called an injunction;

expend significant resources to redesign our technology so that it does not infringe others' patent rights, or to develop or acquire non-infringing technology, which may not be possible; and/or

discontinue manufacturing or other processes incorporating infringing technology.

If we need to redesign our products to avoid third party patents, we may suffer significant regulatory delays associated with conducting additional studies or submitting technical, manufacturing or other information related to any redesigned product and, ultimately, in obtaining approval. Further, any such redesigns may result in less effective and/or less commercially desirable products.

Additionally, any involvement of us in litigation in which we are accused of infringement, including the CryoCath litigation, may result in negative publicity about us or our cryoablation system, injure our relations with any then-current or prospective customers and cause delays in the commercialization of our cryoablation system.

***\* We may never receive additional milestone payments or equity investments from BSC or BSS.***

Under our development and license agreement with BSC, we are responsible for modifying our existing cryoablation console to meet certain technical specifications of BSC. Even if we are able to make the requested modifications which meet the required technical specifications, it is possible that BSC may determine, in its sole judgment, that it does not wish to continue under the development and license agreement, which would mean that we would not receive any additional milestone payments or equity investments. Additionally, even if we are successful in modifying our cryoablation console to meet BSC's technical specifications, and we receive all payments as required under the development and license agreement and common stock purchase agreement, there can be no assurance that our decision to collaborate with BSC will result in any future royalty payments, and there can be no assurance that we will receive any other benefits, commercial or financial, under our development and license agreement with BSC. In the event our acquisition by BSS is completed, we will not receive any additional payments under the development and license agreement and, in addition, if our acquisition by BSS is not completed for any reason, it may be difficult to collect the remaining payments from BSC depending on the circumstances under which the acquisition agreement is terminated.

***\*We are dependent on the success of our cryoablation system, which to date has only been approved by the FDA for the treatment of AFL in the United States. If we are unable to achieve our product development goals, gain FDA approval to commercialize our cryoablation system in the United States for the treatment of AF, or experience significant delays in doing so, our stock price may decline and we may be forced to cease operations.***

We have expended significant time, money and effort in the development of our cryoablation system, which to date has only received FDA approval for the treatment of AFL. Our cryoablation system is still in clinical evaluation for the treatment of AF, has not yet received FDA approval for the treatment of AF and may never be commercialized in the United States for the treatment of AF. In our public announcements, we have provided estimates for the timing of the accomplishment of various clinical, regulatory and other product development goals relating to our cryoablation system, which we sometimes refer to as milestones. These milestones include the submission of data from our clinical trials to the FDA, the timing of FDA approval for our cryoablation system and other clinical and regulatory events. These estimates are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control, and we may never achieve some or all of these milestones. For example, in January 2006, the FDA informed us that our PMA for

## Edgar Filing: CRYOCOR INC - Form 10-Q

the treatment of AFL was not approvable based on the data we had submitted. In response, we amended our PMA based upon a different analysis of chronic effectiveness, and the FDA has recently decided to approve our PMA for the treatment of AFL. If we do not meet our estimated milestones as publicly disclosed for AF, our business may be harmed and our stock price may decline. Our CMO recently resigned, and her resignation may impact the timing of our PMA for the treatment of AF. If our cryoablation system is not approved by the FDA for the treatment of AF, or if our cryoablation system is not commercially accepted for the treatment of AFL or AF, we may be forced to cease operations.

---

## **Table of Contents**

We will need separate FDA approval supported by a separate clinical trial for each proposed indication for our cryoablation system. We intend to seek FDA approval of our cryoablation system to treat AF, and currently can only market our cryoablation system for AFL, which is the indication for which we have received FDA approval. If the FDA does not approve our cryoablation system for treating AF, we will continue to market our cryoablation system only for AFL. For each indication, the FDA's marketing approval process is expensive and the outcome is uncertain. To obtain FDA marketing approval, we are required to submit detailed and comprehensive scientific data demonstrating safety and effectiveness of our cryoablation system to the FDA's satisfaction. The marketing approval process also requires passing FDA inspection of our manufacturing facilities and of the clinical trial records for data integrity and compliance with regulatory requirements. The FDA's PMA approval review process generally takes one to three years after filing, but may take longer. The FDA has not approved any medical device for treating AF.

We cannot assure you that we will obtain FDA approval to market our cryoablation system in the United States for AF in a timely manner or at all. In addition, even though we have received FDA approval for the treatment of AFL, we may never obtain approval for AF. If we fail to obtain FDA approval for AF, we may be forced to cease our operations.

***As a condition to the approval of our PMA for the treatment of AFL, the FDA is requiring us to conduct a registry study of patients treated for AFL with our cryoablation system, and of patients treated with radiofrequency catheters that are approved for the treatment of AFL. If we have difficulty completing the registry study, or if the FDA believes that the safety and effectiveness results for patients treated with our cryoablation system are not good, then the FDA could rescind the approval of our device for the treatment of AFL.***

As a condition of FDA approval for marketing of our cryoablation system for the treatment of AFL, we agreed to conduct a registry study of patients treated for AFL with our cryoablation system, and to include as part of the registry study patients treated for AFL with competing radiofrequency devices approved for the treatment of AFL. The FDA could determine that the results we obtain of patients treated with cryoablation do not justify continuing to make our product available for commercialization in the United States, and they could rescind our approval for the treatment of AFL. Additionally, although we intend to begin the registry study in the second half of 2008 and will seek to complete the enrollment as soon as possible, we may not be able to find patients who agree to join our registry study and it is possible that the FDA could believe that we are not actively working to complete the registry study and rescind our approval for the treatment of AFL on that basis until additional data is collected. If the FDA chooses to rescind the approval of our product for the treatment of AFL, our business would be materially harmed and our stock price would likely decline substantially, and we may not be able to reinstate our ability to commercialize our product in the United States for the treatment of AFL.

***If the data from our AF clinical trial does not demonstrate the safety and effectiveness of our cryoablation system to the FDA's satisfaction, we will not receive FDA approval to market our cryoablation system in the United States for the treatment of AF.***

To obtain FDA approval for marketing of our cryoablation system for the treatment of AF, our pivotal trial for AF must generate data demonstrating that our cryoablation system is safe and effective. The FDA's grant of permission to proceed with the AF pivotal trials does not constitute a binding commitment that the FDA will consider either trial design adequate to support approval for our cryoablation system. In addition, there can be no assurance that the data generated during the pivotal trial will meet our chosen safety and effectiveness endpoints or otherwise produce results that will lead the FDA to grant marketing approval. We may never receive PMA approval from the FDA for the treatment of AF.

***\*We may not complete our pivotal trial for AF on schedule, or at all, or it may be conducted improperly, which may delay or preclude FDA approval for marketing our cryoablation system for this indication.***

The completion of our pivotal trial for AF may be delayed or terminated for many reasons, including, but not limited to:

the recent departure of our Chief Medical Officer;

the FDA places our pivotal trial on hold;

insufficient capital to fund the pivotal trial;

lack of availability of the catheters used in the pivotal trial;

recalls of the catheters used in the pivotal trial;

subjects are not followed-up at the rate we currently expect;

subjects experience an unacceptable rate or severity of adverse side effects;

---

**Table of Contents**

third party clinical investigators do not perform our pivotal trial on our anticipated schedule or consistent with the clinical trial protocol, Good Clinical Practice and regulatory requirements, or other third party organizations do not perform data collection and analysis in a timely or accurate manner;

inspections of our clinical trial sites by the FDA or Institutional Review Boards, or IRBs, find regulatory violations that require us to undertake corrective action, suspend or terminate one or more sites, or prohibit us from using some or all of the data in support of our PMA application;

the reimbursement by governmental and other third party payers changes;

one or more of the IRBs for our clinical trial sites suspends or terminates our trial at an investigational site, precludes enrollment of additional subjects, or withdraws its approval of our trial;

one or more of our clinical investigators withdraws from our trial or deviates from our approved protocol; or

third parties, investigators and contract laboratories conducting our pivotal trial do not perform as contractually required or expected. Subject enrollment in clinical trials and successful completion of subject follow-up in clinical trials depend on many factors, including the size of the subject population, the nature of the trial protocol, the proximity of subjects to clinical sites, the eligibility criteria for the trial, and subject compliance. Subjects may be discouraged from continuing to participate in our clinical trial if the trial protocol requires them to undergo extensive pre- and post-treatment procedures to assess the safety and effectiveness of our cryoablation system. We have seen a higher withdrawal rate of patients than we originally anticipated in our AF clinical trial. Withdrawal rates may continue to increase as we conduct our AF clinical trial because the follow up period for the AF trial is 12 months as opposed to six months for the AFL trial. In addition, subjects participating in our clinical trial may die before completion of their follow-up. Moreover, it may be difficult to successfully follow our subjects for the required 12-month period. Although to date we have successfully followed all our subjects from our AF feasibility study for the required 12-month period, historical results may not be indicative of our future performance. Additionally, we have seen a higher withdrawal rate of patients than we originally anticipated which required us to request from the FDA that we be able to enroll more than the 160 patients originally planned. In January 2007, the FDA approved our request to increase the size of our pivotal trial. The FDA may require that we enroll additional patients in order to complete our dataset.

Failure of subjects to continue to participate in a trial may cause an increase in costs and delays in our clinical trial or result in the failure of the trial, which could cause us to fail to secure FDA marketing approval of our cryoablation system in a timely manner, if at all.

Our development costs will increase if we have material delays in our clinical trial or if we need to perform additional or larger clinical trials than planned. Serious or unexpected adverse events during a clinical trial could cause us to modify, suspend, repeat, or terminate a trial, or to cancel the entire program.

***We may need to enroll additional patients to be able to demonstrate safety and effectiveness of our device, if our dataset of evaluable patients for our AF pivotal trial is not deemed large enough.***

When we designed the size of our AF pivotal trial, we made certain assumptions about the number of patients to be enrolled to permit us to evaluate the results of each arm of our clinical trial. During the conduct of our pivotal trial, patients have withdrawn from our clinical study for reasons not in our control, such as, they were randomized to medical management, or drug therapy, or were not covered by insurance, and withdrew from the trial. If we do not have a sufficiently large evaluable patient population for our analysis when we have completed enrollment and patient follow-up, we may need to increase enrollment until we can generate a sufficiently large evaluable patient population. For example, the FDA has approved our request to enroll an additional 20 patients, up to 180 patients in total.

***\*In order to receive and maintain FDA approval of our product candidates, our manufacturing facilities and the manufacturing facilities of our suppliers must comply with applicable regulatory requirements. If we fail to achieve or maintain regulatory approval of these manufacturing facilities, we may be forced to cease operations.***

## Edgar Filing: CRYOCOR INC - Form 10-Q

Commercialization of our products and product candidates require access to, or the development of, manufacturing facilities that meet applicable regulatory and quality standards to manufacture a sufficient supply of our products. These facilities must be evaluated and qualified under our quality system to ensure that they meet our production and quality standards. The FDA also must inspect and approve facilities that manufacture our products for United States commercial purposes, as well as the manufacturing processes and specifications for our products prior to granting marketing approval of our cryoablation system. Suppliers of certain components of, and products used to manufacture, our products also must comply with FDA and foreign regulatory requirements, which often require significant resources and subject us and our suppliers to potential regulatory inspections and stoppages. We or our suppliers may not

---

## **Table of Contents**

satisfy these requirements. If we or our suppliers do not achieve and maintain required regulatory approval for our manufacturing operations, any commercialization efforts we undertake in the United States could be delayed, which could impair our business and financial condition and could require us to cease operations.

***If the integrity of a catheter used as part of our cryoablation system is compromised, serious injury or death may occur, which could lead the FDA to delay or deny or withdraw marketing approval.***

Our cryoablation system works by utilizing a pressurized system that delivers nitrous oxide to chill the tip of a catheter to freeze heart tissue in contact with the catheter tip while the catheter is in contact with the patient's heart. Although our cryoablation system is designed to prevent leaks in the catheter and to prevent the flow of nitrous oxide into the catheter if the catheter has been ruptured, nitrous oxide could enter the blood stream if the catheter developed a leak, which could result in serious injury to a patient, or even death. In April 2005, during routine quality control testing of a lot of Model 1200 catheters, we identified several instances of inadequate seals in the joint where the articulation section is welded to the catheter shaft, which could have allowed a leak of nitrous oxide into a patient. We initiated an investigation which covered several weeks to identify the source of the catheter integrity breaches, but were unable to find a specific root cause. In May 2005, we initiated a voluntary recall in Europe of all eight of the outstanding lots of our Model 1200 catheter and removed the Model 1200 from clinical trial use.

If a future leak were to occur, the FDA could deny or delay or withdraw marketing approval until we modified our device and provided proof that a similar failure could not recur. Any future leak could lead to additional recalls, cause us to incur financial liability and prevent our system from gaining market acceptance among physicians, healthcare payers, patients and the medical community, any of which could harm our business, financial condition, results of operations and growth prospects.

***If the pulmonary vein isolation, or PVI, or any other ablation procedure performed in our AF pivotal trial fails to provide a significant benefit to patients, or has serious adverse effects, we may not be able to obtain FDA approval for marketing our cryoablation system.***

AF is a complex disease and its origin and progression are not well understood in the medical community. The effectiveness of ablation in moderating AF has not been demonstrated in a controlled clinical trial. The FDA could deny approval of our cryoablation system if our pivotal AF trial does not show that AF ablation performed with our cryoablation system provides a greater benefit to patients than medical management with anti-arrhythmic medications alone.

The PVI procedure when performed with radiofrequency ablation has been associated with stroke and pulmonary vein stenosis, a narrowing of the pulmonary vein that can have serious adverse health implications. Radiofrequency ablation and other heat based ablation technologies used for AF ablation have been associated with risks such as the formation of atrial esophageal fistulas, or channels, between the heart and the esophagus. Although we believe that cryoablation reduces this risk as compared to heat-based ablation, we and the medical community do not have a complete understanding of the presentation and progression of these complications. If patients have strokes, develop significant pulmonary vein stenosis, atrio-esophageal fistulas, or other unanticipated adverse effects in our pivotal AF trial, the FDA could deny approval to market our cryoablation system, which could harm our business, financial condition, results of operations and growth prospects.

***If approved by the FDA for AF, our cryoablation system will likely be limited to use as a second line therapy for patients with AF who have failed drug treatment, which could limit our sales.***

Our pivotal AF trial will study our cryoablation system only in patients who have failed drug therapy. For this reason, if the FDA approves our cryoablation system for the treatment of AF, it is likely that the FDA will require us to label and advertise our cryoablation system only for the treatment of patients who have failed drug therapy. This restriction could limit our sales. Additional clinical trials will be required to obtain approval for use in a broader population of patients.

***Our future growth depends on physician adoption and market acceptance of our cryoablation system, which may not occur.***

Our cryoablation system may not gain market acceptance among physicians, patients, healthcare payers or the medical community. The degree of market acceptance of any product that we may develop will depend on a number of factors, including:

the perceived safety and effectiveness of the product;

the prevalence and severity of any side effects;

the procedure time associated with the use of the product;



---

**Table of Contents**

potential advantages over alternative treatments;

our ability to adequately fund the commercialization of the product;

the strength of marketing and distribution support; and

sufficient third party coverage or reimbursement.

If our cryoablation system, or any other product that we may develop, does not achieve an adequate level of acceptance by physicians, patients or healthcare payers, we may not generate significant product revenue, if any, and we may not become profitable.

We believe that another factor that will impact the degree of market acceptance of any of our products is our ability to educate physicians to change their screening and referral practices in order to ensure physician acceptance of our system. For example, despite the lack of effectiveness of treating AF and AFL with drugs, many physicians routinely prescribe drugs to patients suffering from AF and AFL without offering any treatment alternatives even when drug therapy is failing. We intend to target our sales efforts to electrophysiologists because they are often the physicians treating both AF and AFL. However, the initial point of contact of patients experiencing AF and AFL may be general practitioners. If referring physicians are not properly educated about AF and AFL and the potential benefits of using our cryoablation system over drug therapy in particular in circumstances where drug therapy fails, they may not refer AF and AFL patients who have been unsuccessfully treated with drug therapy to electrophysiologists for our cryoablation system procedure, which may impair our business, financial condition and results of operations.

*\*Our product candidates could be recalled and any failure to comply with FDA regulations could subject us to enforcement action.*

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or defects in design or manufacture. A government mandated or voluntary recall by us could occur as a result of component failures, device malfunctions, adverse events, such as serious injuries or deaths, or quality-related issues such as manufacturing errors or design or labeling defects. Recalls of our cryoablation system would divert managerial and financial resources, harm our reputation with customers and have an adverse effect on our financial condition and results of operations. A recall announcement could also negatively affect our stock price.

After the FDA permits a device to enter commercial distribution, numerous additional regulatory requirements apply. We may incur significant costs to comply with such requirements. These requirements include, among others:

compliance with the Quality System Regulations, which require manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process;

the FDA's general prohibition against promoting products for unapproved or off-label uses;

the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and

the Reports of Corrections and Removals regulation, which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce the risk to health posed by the device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act, or FDCA.

Even if our products are approved, stringent FDA conditions of approval may significantly impact our results depending on the scope and complexity of such conditions. The FDA enforces these requirements with inspections and market surveillance. If the FDA finds that we have

## Edgar Filing: CRYOCOR INC - Form 10-Q

failed to comply with one of these requirements, it could institute a wide variety of enforcement actions, ranging from a Warning Letter to more severe sanctions, including the following:

finances, injunctions and civil penalties;

recall or seizure of our products;

operating restrictions, partial suspension or total shutdown of production;

refusing requests for 510(k) clearance or PMA approval of new products;

withdrawing 510(k) clearance or PMA approvals already granted; and

criminal prosecution.

---

## **Table of Contents**

Any of these enforcement actions could be costly and significantly harm our business, financial condition and results of operations.

***If we are unable to obtain and maintain protection for our intellectual property, the value of our technology and products may be adversely affected.***

Our business and competitive positions are dependent upon our ability to protect our proprietary technology. Because of the substantial length of time and expense associated with development of new products, we, along with the rest of the medical device industry, place considerable importance on obtaining and maintaining patent protection for new technologies, products and processes. The patent positions of medical device companies, including ours, are generally uncertain and involve complex legal and factual questions. Our owned and licensed patent applications may not protect our technologies and products because, among other things:

any patents issued to us, our collaborators or our licensors, may not provide a basis for a commercially viable product or provide us with any competitive advantage;

any patents issued to us, our collaborators or our licensors may be challenged, as is currently ongoing in the CryoCath litigation, circumvented or invalidated by third parties;

all pending patent applications may not result in issued patents; and

any additional proprietary technologies that we develop may not be patentable.

We attempt to protect our intellectual property position by filing United States patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also protect our intellectual property position by pursuing infringement actions against other companies that we believe infringe our valid and enforceable IP. For example, we have initiated several actions against CryoCath that we believe are necessary for us to protect our intellectual property position. These actions include a pending interference declared by the United States Patent and Trade Office, an investigation of CryoCath by the United States International Trade Commission, and litigation that we have initiated in the district courts of Delaware and in Canada. Currently, we own or license 39 issued United States patents and a number of pending United States patent applications covering various aspects of our products and technology.

We also own or license 24 patents issued outside of the United States and have a number of pending patent applications outside the United States. Limitations on patent protection in some countries outside the United States, and the differences in what constitutes patentable subject matter in these countries, may limit the protection we have under patents issued to us outside of the United States. In addition, laws of foreign countries may not protect our intellectual property to the same extent as would laws of the United States. In determining whether or not to seek a patent or to license any patent in a particular foreign country, we weigh the relevant costs and benefits, and consider, among other things, the market potential of our product candidates in the jurisdiction, and the scope and enforceability of patent protection afforded by the law of the jurisdiction. Failure to obtain adequate patent protection for our proprietary product candidates and technology would impair our ability to be commercially competitive in these markets.

***Our ability to market our products may be impaired by the intellectual property rights of third parties.***

We are aware of numerous United States patents owned or licensed by third parties in areas potentially related to the technology used in our cryoablation system. These third parties include CryoCath, Johnson & Johnson, the Regents of the University of California and Spemby Medical Ltd. These third parties or our other competitors may have issued patents that cover technologies that we use in producing our product candidates, or that we use in treating patients with our product candidates. CryoCath initiated legal proceedings against us in the United States District Court in Delaware, seeking a declaration that our cryoablation system infringes a number of CryoCath's United States issued patents. Other owners of patents or their licensees may also assert that the manufacture, use or sale of our cryoablation system infringes one or more claims of their patents.

The possibility of litigation, in addition to the CryoCath litigation, being filed against us based on one or more of these or other patents or other intellectual property is a significant risk. Because of the uncertainty inherent in any intellectual property litigation, a court may determine that current or future third party patents, including CryoCath patents, contain one or more claims that are valid, enforceable and infringed upon by

our cryoablation system.

There is also a risk that other third party patents or intellectual property rights in areas of technology related to our products of which we are not aware may materially and adversely affect our business. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications of which we are not yet aware that may result in issued patents that if successfully asserted against us, would materially and adversely affect our business, financial condition and results of operations.

**Table of Contents**

***\*We depend on single source suppliers for our cryoablation system components and the loss of these suppliers could prevent or delay our clinical trials and otherwise adversely affect our business.***

We do not have long-term contracts with our third party suppliers for any of the equipment and components that are used in our manufacturing process. Our suppliers may have difficulty supplying components that meet our required specifications or needs. None of our suppliers has agreed to maintain a guaranteed level of production capacity. Establishing additional or replacement suppliers for these components may cause us to incur substantial costs and take a considerable amount of time, may require product redesign and could result in the need for submission to the FDA of a PMA supplement or possibly a separate PMA, which would cause us to incur considerable expense. We also may have difficulty obtaining similar components from other suppliers that are acceptable to our quality requirements and specifications, the FDA or foreign regulatory authorities. Even if available, similar components from other suppliers could be significantly more expensive. Any delays, regulatory or otherwise, could delay the manufacture and delivery of our cryoablation system and any commercialization efforts we undertake in the United States and sales of our cryoablation system in Europe and adversely impact our business.

***\*We have limited manufacturing capabilities and manufacturing personnel, and if our manufacturing facilities are unable to provide an adequate supply of products, our business could be harmed.***

We currently manufacture our cryoablation system at our facilities in San Diego, California. If there was a disruption to our manufacturing operations, we would have no other means of manufacturing our cryoablation system until we have restored and re-qualified our manufacturing capability at our facilities or developed alternative manufacturing facilities. Additionally, any damage to or destruction of our San Diego facilities or our equipment, prolonged power outage or contamination at our facility would significantly impair our ability to produce our cryoablation system. If we were unable to produce sufficient quantities of our cryoablation system, any commercialization activities we undertake for AFL and AF in the United States would be delayed, as would any sales of our cryoablation systems in Europe.

We currently have limited resources, facilities and experience to commercially manufacture our products and product candidates. In the first half of 2006, we restructured our workforce, including reductions in our manufacturing staffing that has reduced our capacity to manufacture catheters and consoles. To produce our cryoablation system in the quantities that we believe will be required to meet anticipated market demand in the United States in the event that we receive regulatory approval for AF and undertake commercialization activities for AF, we will need to increase, or scale up, the production process by a significant factor over the current level of production. There are technical challenges to scaling up manufacturing capacity, and developing commercial-scale manufacturing facilities under these circumstances would require the investment of substantial additional funds and hiring and retaining additional management and technical personnel who have the necessary manufacturing experience. Under these circumstances, we may not successfully complete any required scale up in a timely manner, or at all due to such technical difficulties and/or insufficient funds. If we are unable to do so, we may not be able to produce our cryoablation system in sufficient quantities to meet the requirements for the launch of the product in the United States if we receive the required regulatory approval from the FDA for AF and we undertake commercialization activities for AF in the United States, or to meet demand, if any, for our cryoablation system in the United States for AFL or in Europe. If we obtain regulatory approval from the FDA for our cryoablation system for AF and undertake commercialization activities for AF but are unable to manufacture a sufficient supply of our cryoablation systems, our revenues, business and financial prospects would be materially adversely affected. In addition, if we obtain regulatory approval for our cryoablation system for AF and undertake commercialization activities for AF, but the scaled up production process is not efficient or produces cryoablation systems that do not meet quality and other standards, our future gross margins, if any, will be adversely affected.

***We have never manufactured our Quantum catheter in large quantities, and we may experience delays and difficulties in our manufacturing of this catheter.***

Our Quantum catheter is more complicated to manufacture than our CryoBlator catheter, and our experience in manufacturing the initial prototypes indicate that it will take longer to manufacture a single Quantum catheter than as required to manufacture a single CryoBlator catheter. This complexity may delay our ability to advance the Quantum catheter into human clinical trials. However, we believe we will develop efficiencies in manufacturing our Quantum catheter to permit us to manufacture it in a commercially viable amount of time. For example, the time required to initially manufacture the Model 1100 catheter, and time required to initially manufacture the Model 1200 catheter, were substantially longer than the time currently required to manufacture our CryoBlator catheter. In addition, after we have conducted further animal studies, we may determine that Quantum is not suitable for human use, and we may discontinue the development of the catheter.

---

**Table of Contents**

***We must be licensed to handle and use hazardous materials and may be liable for contamination or other harm caused by hazardous materials that we use.***

We use hazardous materials in our research and development and manufacturing processes. We are subject to federal, state and local regulations governing use, storage, handling and disposal of these materials and waste products. We are currently licensed to handle such materials in all states in which we operate, but there can be no assurances that we will be able to retain those licenses in the future. In addition, we must become licensed in all states in which we plan to expand. Obtaining those additional licenses is an expensive and time consuming process, and in some cases we may not be able to obtain those licenses at all.

Although we believe that our procedures for the use, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We have also incurred and may continue to incur expenses related to compliance with environmental laws. Such future expenses or liability could have a significant negative impact on our business, financial condition and results of operations. Further, we cannot assure you that the cost of complying with these laws and regulations will not materially increase in the future.

***\*Quality-control difficulties in our manufacturing processes could delay our clinical development programs and any commercialization activities we undertake or prevent us from continuing the development of our product candidates.***

Our sterile products, including our catheters and our sheaths, must be produced in a highly controlled, clean environment to minimize foreign particles and other contaminants. Despite stringent quality controls, weaknesses in process control or minute impurities in materials may cause a substantial percentage of defective products in a lot. If we are unable to maintain stringent quality controls, or if contamination problems arise, our clinical development activities and any commercialization activities we undertake could be delayed or terminated, which would harm our business, financial condition and results of operations.

***If we fail to obtain an adequate level of reimbursement for our products by third party payers, there may be no commercially viable markets for our product candidates or the markets may be much smaller than expected.***

The availability and amount of reimbursement by governmental and other third party payers affect the market for our products and product candidates. The effectiveness, safety, performance and cost-effectiveness of our products and product candidates and of any competing products will determine the availability and level of reimbursement. We believe that reimbursement may be subject to increased restrictions both in the United States and in international markets in the future. New legislation, regulation or reimbursement policies of third party payers may adversely affect the demand for our products and product candidates and limit our ability to sell our products and product candidates on a profitable basis. In addition, third party payers continually attempt to minimize or reduce the costs of healthcare by challenging the prices charged for healthcare products and services.

Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government sponsored healthcare and private insurance. To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical data, which may involve one or more clinical trials, that compares the cost-effectiveness of our products to other available therapies. We may not obtain international reimbursement or pricing approvals in a timely manner, or at all. Our failure to receive international reimbursement or pricing approvals would negatively impact market acceptance of our products in the international markets in which those approvals are sought.

If reimbursement for our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, market acceptance of our products would be impaired and our business, financial condition, results of operations and future revenues, if any, would be adversely affected.

***We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and regulations and, if we are unable to fully comply with such laws, could face substantial penalties.***

Our operations may be directly or indirectly affected by various broad state and federal healthcare fraud and abuse laws, including the Federal Healthcare Programs Anti-Kickback Statute, which prohibits any person from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce or reward either the referral of an individual for an item or service, or the ordering, furnishing or arranging for an item or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. If our past or present operations, including our consulting arrangements with physicians who use our product, are found to be in violation of these laws, we or our officers may be subject to civil or criminal penalties, including large monetary penalties, damages, fines, imprisonment and exclusion from Medicare and Medicaid program participation. If enforcement action were to occur, our business and financial

condition would be harmed.

---

## **Table of Contents**

***\*We may be subject to federal and state false claims laws which impose substantial penalties.***

It is possible that some of our customers may file claims for reimbursement with government programs such as Medicare and Medicaid. As a result, we may be subject to the federal False Claims Act if we knowingly cause the filing of false claims. Violations may result in substantial civil penalties, including treble damages. The federal False Claims Act also contains whistleblower or qui tam provisions that allow private individuals to bring actions on behalf of the government alleging that the defendant has defrauded the government. In recent years, the number of suits brought in the healthcare industry by private individuals has increased dramatically. Various states have enacted laws modeled after the federal False Claims Act, including qui tam provisions, and some of these laws apply to claims filed with commercial insurers.

We are unable to predict whether we could be subject to actions under the federal False Claims Act, or the impact of such actions. However, the costs of defending claims under the False Claims Act, as well as sanctions imposed under the False Claims Act, could significantly affect our financial performance.

***The medical device industry is highly competitive and subject to rapid technological change. If our competitors are better able to develop and market products for similar indications that are safer, more effective, or gain greater acceptance in the marketplace than any products that we may develop, our commercial opportunities will be reduced or eliminated.***

The medical device industry is characterized by rapidly advancing technologies and a strong emphasis on proprietary products, designs and processes and intense competition. Our products and product candidates face and will face intense competition. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified personnel, establishing clinical trial sites and patient registration for clinical trials, as well as acquiring technology and technology licenses complementary to our programs or advantageous to our business.

Our competitors may:

develop and patent processes or products earlier than us;

obtain regulatory approvals for competing products more rapidly than us; and

develop safer, more effective and/or less expensive products or technologies that render our technology or products or product candidates obsolete or non-competitive.

If any of the foregoing occurs, our business will be harmed and our commercial opportunities will be reduced or eliminated.

***We face the risk of product liability claims and may not be able to obtain insurance on favorable terms, or at all.***

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices. We may be subject to product liability claims, including frivolous lawsuits, if our cryoablation system causes, or appears to have caused, an injury. Claims may be made by consumers, healthcare providers, third party strategic collaborators or others selling our products. Although we have product liability and clinical trial liability insurance that we believe is appropriate for our company, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, the coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations.

We may be subject to claims against us even if an alleged injury is due to the actions of others. For example, we rely on the expertise of physicians, nurses and other associated medical personnel to perform the medical procedures and related processes relating to our cryoablation system. If these medical personnel are not properly trained or are negligent in using our cryoablation system, the therapeutic effect of our cryoablation system may be diminished or the patient may suffer critical injury, which may subject us to liability. In addition, an injury resulting



from the activities of our suppliers may serve as a basis for a claim against us.

We do not and will not promote our cryoablation system for off-label or otherwise unapproved uses. However, we cannot prevent a physician from using our cryoablation system for any off-label applications. If injury to a patient results from such an inappropriate use, we may become involved in a product liability suit, which will likely be expensive to defend.

---

## **Table of Contents**

These liabilities could prevent or interfere with our clinical efforts, product development efforts and any subsequent product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, which could result in the withdrawal of, or inability to recruit, clinical trial volunteers or reduced acceptance of our products in the market.

*\*Our efforts to discover and develop new product candidates beyond our cryoablation system are at an early stage and are subject to a high risk of failure.*

We expect that a key element of our strategy will be to discover and develop new products for the treatment of AFL and AF as extensions of, or in addition to, our cryoablation system. For example, we are completing development of our next generation catheter, Quantum, which we expect to introduce into clinical testing in mid-2008. Research programs to identify new product candidates require substantial technical and human resources, and will require us to obtain additional financial resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

the research may not be successful in identifying potential product candidates;

there is a high rate of attrition for product candidates in preclinical trials;

competitors may develop alternatives that render our product candidates obsolete; and

product candidates may on further study be shown to have harmful side effects or other characteristics that indicate they are unlikely to be effective.

If we fail to develop new product candidates, our business would be harmed.

*\*We are highly dependent on our officers and other employees, and if we are not able to retain them or to recruit and retain additional qualified personnel, our business will suffer.*

We are highly dependent upon our senior management and scientific staff. The loss of services of one or more of our members of senior management could delay or prevent the successful completion of our pivotal trials or the commercialization of our cryoablation system in the United States. Although we have employment agreements with each of our executive officers, their employment with us is at will, and each executive officer can terminate his agreement with us at any time. We do not carry key-man insurance on any of our current executive officers.

In the event we need to hire additional qualified scientific, commercial, operations, regulatory, quality assurance and control and administrative personnel, we may not be able to attract and retain qualified personnel on acceptable terms given the competition for such personnel among medical device companies. Our offices are located in San Diego, where competition for personnel with healthcare industry skills is intense. If we fail to identify, attract, retain and motivate these highly skilled personnel, or if we lose current employees, we may be unable to continue our development and commercialization activities.

*We may incur increased costs as a result of recently enacted and proposed changes in laws and regulations.*

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and rules related to corporate governance and other matters subsequently adopted by the SEC and the Nasdaq Stock Market, or Nasdaq, could result in increased costs to us and may divert our management's attention from other matters that are important to our business. The new rules and any related regulations that may be proposed in the future could make it more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. We are presently evaluating and monitoring developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs.

## Edgar Filing: CRYOCOR INC - Form 10-Q

Legislative and regulatory proposals to amend the FDA regulatory and healthcare systems could impact our ability to sell our products profitably, if at all. In the United States in recent years, new legislation has been proposed at the federal and state levels that would effect major changes in the healthcare system. In addition, new regulations and interpretations of existing healthcare statutes and regulations are frequently adopted.

---

**Table of Contents**

***Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and stock price.***

As a public company, we will be required to document and test our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act, which requires, among other things, annual management assessments of the effectiveness of our internal controls over financial reporting and, for 2008, a report by our independent registered public accounting firm on our internal controls over financial reporting. During the course of our future testing, we may identify deficiencies which we may not be able to remediate in time to meet our deadline for compliance with Section 404.

Testing and maintaining internal controls also involves significant costs and could divert our management's attention from other matters that are important to our business. We may not be able to conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404, and our independent registered public accounting firm may not be able to issue an unqualified opinion on our internal controls over financial reporting. Failure to achieve and maintain an effective internal control environment could harm our operating results and could cause us to fail to meet our reporting obligations. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

***Changes in European to United States currency exchange rates may increase our expenses or reduce our revenues.***

We currently market our cryoablation system in certain foreign markets through European distributors. The related distribution agreements may provide for payments in a foreign currency. Accordingly, if the United States dollar strengthens against the euro or British pound sterling our United States dollar payments from such distributors, if any, will decrease.

We may become exposed to fluctuations in other foreign currencies in the future, and our exposure to foreign currency exchange rates may adversely affect our business, financial condition and results of operations.

***\*Our stock price has been volatile and may continue to be volatile.***

Our stock price has been and may continue to be volatile. The stock market in general and the market for small medical device companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The price for our common stock will be determined in the marketplace and may be influenced by many factors, including:

our acquisition by BSS not being completed for any reason;

developments, disputes or litigation concerning patents or other proprietary rights, including our current litigation with CryoCath;

failure of any of our products or product candidates to achieve commercial success, to the extent we restore our sales and marketing capabilities;

results of our clinical trials;

failure of any of our product candidates to receive FDA or other regulatory approvals;

success or failure to raise any additional capital on a timely basis or on acceptable terms;

future sales of our common stock;

regulatory developments in the United States and foreign countries;

ability to manufacture our products to commercial standards;

public concern over our products;

the departure of key personnel;

variations in our financial results or those of companies that are perceived to be similar to us;

changes in the structure of healthcare payment systems;

changes in reimbursement;

investors' perceptions of us; and

general economic, industry and market conditions.

A decline in the market price of our common stock could cause our stockholders to lose some or all of their investment and may adversely impact our ability to attract and retain employees and raise capital. There can be no assurance that in the future, the market price of our common stock will not be impacted by similar events.

---

**Table of Contents**

*Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and applicable Delaware law may prevent or discourage third parties or our stockholders from attempting to replace our management or influencing significant decisions.*

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may have the effect of delaying or preventing a change in control of us or our management, even if doing so would be beneficial to our stockholders. These provisions include:

dividing our board of directors into three classes serving staggered three-year terms;

authorizing our board of directors to issue preferred stock without stockholder approval;

prohibiting stockholder actions by written consent;

limiting the persons who may call special meetings of stockholders;

prohibiting our stockholders from making certain changes to our certificate of incorporation or bylaws except with 66 2/3 % stockholder approval; and

requiring advance notice for raising business matters or nominating directors at stockholders' meetings.

We are also subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for three years unless the holder's acquisition of our stock was approved in advance by our board of directors. Together, these charter and statutory provisions could make the removal of management more difficult and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our common stock.

*\*Our principal stockholders and management own a significant percentage of our outstanding common stock and will be able to exercise significant influence over our affairs.*

Our executive officers, current directors and holders of five percent or more of our common stock, as of April 30, 2008, beneficially owned approximately 54.2% of our common stock based on the SEC's rules for determining beneficial ownership. These stockholders will likely be able to determine the composition of our board of directors, retain the voting power to approve all matters requiring stockholder approval and continue to have significant influence over our operations. The interests of these stockholders may be different than the interests of other stockholders on these matters. This concentration of ownership could also have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could reduce the price of our common stock.

**ITEM 6. EXHIBITS**

The exhibits listed on the accompanying index to exhibits are filed or incorporated by reference (as stated therein) as part of this Quarterly Report on Form 10-Q.

**Exhibit**

<b>Number</b>	<b>Description of Exhibit</b>
3.1	Amended and Restated Certificate of Incorporation (1)

## Edgar Filing: CRYOCOR INC - Form 10-Q

- 3.2 Amended and Restated Bylaws of the Company (2)
- 4.1 Form of Common Stock Certificate of the Company (1)
- 4.2 Amended and Restated Investor Rights Agreement dated June 4, 2003 between the Company and certain of its stockholders (1)
- 4.3 Securities Purchase Agreement, dated April 20, 2007, by and among the Registrant and the purchasers listed on the signature pages thereto. (3)
- 4.4 Form of Warrant. (3)
- 4.5 Form of Warrant to Purchase Stock. (4)
- 4.6 Common Stock Purchase Agreement, dated June 28, 2007, by and between the Registrant and Boston Scientific Scimed, Inc. (5)
- 4.7 Registration Rights Agreement, dated June 28, 2007, by and between the Registrant and Boston Scientific Scimed, Inc. (5)

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Exhibit</b>
10.27	Second Amendment to Amended and Restated Executive Employment Agreement, dated February 12, 2008, by and between Registrant and Helen Barold.(6)*
10.28	Third Amendment to Amended and Restated Executive Employment Agreement, dated April 23, 2008, by and between Registrant and Helen Barold.(6)*
10.29	Agreement and Plan of Merger, dated as of April 15, 2008, by and among Boston Scientific Scimed, Inc., a Minnesota corporation ( Parent ), Padres Acquisition Corp., a Delaware corporation and a wholly-owned subsidiary of Parent, and CryoCor, Inc.(7)
10.30	Form of Restricted Stock Bonus Agreement.*
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities and Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities and Exchange Act of 1934, as amended
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Filed as an exhibit to the Company's Registration Statement on Form S-1 (File No. 333-123841) originally filed with the Securities and Exchange Commission on April 5, 2005, as amended, and incorporated herein by reference.

(2) Incorporated by reference to the registrant's Current Report on Form 8-K filed with the SEC on July 25, 2007.

(3) Incorporated by reference to the registrant's Current Report on Form 8-K filed with the SEC on April 25, 2007.

(4) Incorporated by reference to the registrant's Current Report on Form 8-K filed with the SEC on June 22, 2007.

(5) Incorporated by reference to the registrant's Current Report on Form 8-K filed with the SEC on June 29, 2007.

(6) Incorporated by reference to the registrant's Solicitation/Recommendation Statement on Schedule 14D-9 filed with the SEC on April 29, 2008.

(7) Incorporated by reference to the registrant's Current Report on Form 8-K filed with the SEC on April 17, 2008.

\* Indicates management contract or compensatory plan.



**Table of Contents**

**CryoCor, Inc.**

**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.

Date: May 15, 2008

CryoCor, Inc.

By: /s/ Gregory J. Tibbitts  
Gregory J. Tibbitts  
Vice President, Finance and Chief Financial Officer  
(Principal Financial and Accounting Officer)