CRYOCOR INC
Form 10-Q
May 14, 2007
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2007

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)

Delaware	**33-0922667**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**

9717 Pacific Heights Boulevard

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 x NO ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨ Accelerated filer ¨ Non-accelerated filer x

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

The number of shares of the Registrant s common stock outstanding as of April 30, 2007 was 12,117,041.

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CRYOCOR, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE PERIOD ENDED MARCH 31, 2007

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PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

CryoCor, Inc.

Consolidated Balance Sheets

(in thousands except for the number of shares and par values)

	March 31, 2007 (Unaudited)	December 31, 2006
Assets		
Current assets:		
Cash and cash equivalents	$ 6,740	$ 3,025
Short-term investments	9,202	15,979
Accounts receivable, net	71	56
Inventories, net	893	820
Prepaid expenses and other current assets	422	555
Total current assets	17,328	20,435
Property and equipment, net	547	610
Other assets	297	297
Total assets	$ 18,172	$ 21,342
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 281	$ 212
Accrued compensation	821	1,002
Accrued clinical development liabilities	892	942
Accrued liabilities	309	429
Deferred revenue	69	78
Short-term debt	6,928	6,857
Total current liabilities	9,300	9,520
Stockholders equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized; zero shares outstanding at March 31, 2007 and December 31, 2006		
Common stock, $0.001 par value, 75,000,000 shares authorized; 11,055,587 and 11,030,366 shares issued and outstanding at March 31, 2007 and December 31, 2006, respectively	11	11
Additional paid in capital	97,198	96,709
Accumulated other comprehensive income	107	114
Accumulated deficit	(88,444)	(85,012)
Total stockholders equity	8,872	11,822
Total liabilities and stockholders equity	$ 18,172	$ 21,342

See accompanying notes.

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CryoCor, Inc.

Consolidated Statements of Operations

(in thousands except per share amounts)

(Unaudited)

	Three months ended March 31,	
	2007	**2006**
Product sales	$ 66	$ 113
Operating expenses:		
Cost of sales	628	763
Research and development	1,588	1,531
Selling, general and administrative	1,244	2,131
Total costs and expenses	3,460	4,425
Loss from operations	(3,394)	(4,312)
Interest income	230	311
Interest expense	(268)	(270)
Net loss	(3,432)	(4,271)
Basic and diluted net loss per common share	$ (0.31)	$ (0.40)
Shares used to compute basic and diluted net loss per common share	11,032	10,661

See accompanying notes.

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CryoCor, Inc.

Consolidated Statements of Cash Flows

(in thousands)

(Unaudited)

	Three months ended March 31,	
	2007	**2006**
Operating activities		
Net loss	$ (3,432)	$ (4,271)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	74	78
Non-cash share-based compensation	451	455
Amortization of debt discount	72	72
Amortization of premium/discount on short-term investments.	(165)	16
Changes in operating assets and liabilities:		
Accounts receivable	(16)	(88)
Inventories	(73)	(302)
Prepaid expenses and other assets	133	164
Accounts payable	68	(229)
Deferred revenue	(8)	85
Accrued liabilities	(352)	(110)
Net cash used in operating activities	(3,248)	(4,130)
Investing activities		
Purchases of property and equipment	(11)	(114)
Purchases of short-term investments	(1,712)	(4,234)
Proceeds from sales of short-term investments	8,650	4,750
Net cash provided by investing activities	6,927	402
Financing activities		
Proceeds from issuance of common stock under stock plans, net	37	66
Principal payments on capital leases		(2)
Net cash provided by financing activities	37	64
Effect of exchange rate changes on cash	(1)	(8)
Net increase (decrease) in cash and cash equivalents	3,715	(3,672)
Cash and cash equivalents at beginning of period	3,025	10,583
Cash and cash equivalents at end of period	$ 6,740	$ 6,911
Supplemental disclosures of cash flow information:		
Cash payments for interest	$ 197	$ 268

See accompanying notes.

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CRYOCOR, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

Note 1. Organization and Basis of Presentation

Organization

CryoCor, Inc. (CryoCor or the Company or we), 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. At present, the majority of the Company s revenues relate to sales to European customers. 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, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007. For further information see our financial statements and related disclosures thereto for the year ended December 31, 2006 in our Annual Report on Form 10-K filed on March 30, 2007 with the Securities and Exchange Commission (SEC).

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. Successful completion of the Company s development program and its transition to attaining profitable operations are dependent upon obtaining additional financing adequate to fulfill its research and development activities and achieving a level of revenue adequate to support its cost structure. The Company believes that it can effectively manage its working capital to fund operations until May 2008; however, the Company does not anticipate having significant commercial operations until 2008, if at all; therefore, it expects to need additional debt or equity financing until it becomes cash flow positive. There can be no assurances that there will be adequate financing available to the Company and 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, 2007 and December 31, 2006, 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 corporate bonds, which were unrestricted as to withdrawal or use.

Investment Securities

Investment securities generally consist of high-grade auction rate securities, United States government debt securities, 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.

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.

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As of March 31, 2007 and December 31, 2006, 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, 2007 and December 31, 2006 were as follows (in thousands):

	March 31, 2007				December 31, 2006			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Corporate debt securities	7,455	2		7,457	12,735	6		12,741
Asset-backed securities	1,745			1,745	3,238			3,238
	$ 9,200	$ 2	$	$ 9,202	$ 15,973	$ 6	$	$ 15,979

Inventories

Inventories consist of the following (in thousands):

	March 31, 2007	December 31, 2006
Raw materials	$ 682	$ 612
Work-in-progress	18	38
Finished goods	231	208
	931	858
Less reserves for excess and obsolete inventories	(38)	(38)
Inventory, net	$ 893	$ 820

At March 31, 2007, the Company had $597,000 in console inventory on its balance sheet, as well as outstanding purchase commitments of approximately $86,000 for console materials. This total inventory represents ten consoles in finished goods, components to build an additional eighteen complete consoles, and components that could be used in the production of additional consoles. These materials are not expected to become obsolete in the time period anticipated for commercialization in the United States. At March 31, 2007, the Company had disposables inventory totaling $296,000, of which $275,000 is raw materials. This inventory level represents approximately 1,100 finished catheters. The Company anticipates that the existing inventory levels will be needed in either 2007 or 2008 to the extent we are able to commercialize our products in the United States.

Restructuring Accrual

The Company recorded restructuring charges of $252,000 in connection with the closing of CryoCor GmbH during 2006 and $70,000 remains accrued on the balance sheet at March 31, 2007, 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.

In January 2006, the Company received a non-approvable letter from the United States Food and Drug Administration (FDA) related to its application for premarket approval (PMA) for the treatment of atrial flutter, a cardiac arrhythmia. As a result of that letter, the Company restructured its operations in early March 2006 whereby it reduced its staffing levels to reduce its monthly cash requirements. During 2006, the Company recorded severance expenses of $280,000 and sales and marketing contract termination expenses of $50,000 associated with the restructuring, all of which was paid during 2006. The Company s San Diego facilities were not impacted by the restructuring plan and all restructuring activities were substantially completed as of July 2006. In November 2006, after an analysis of the Company s clinical data and discussions with the FDA, the Company s amended its PMA, which the FDA is currently reviewing.

Short-Term Debt

In March 2005, the Company entered into an agreement whereby it borrowed $7.0 million from a financial institution (the facility). The facility has restrictive covenants on the Company s operations, which preclude the Company from incurring new debt or placing liens on its assets, disposing of property, making dividend payments or distributions to stockholders, or entering into transactions that would result in a change of control. The facility bears interest at a rate of 11.25% per annum and requires monthly interest-only payments through June 2007, at which time all remaining principal is due and payable. In conjunction with the facility, the Company issued two warrants to purchase a total of 68,288 shares of common stock. The fair value of the warrants was $657,000 based upon an estimated fair value upon the date of grant of

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$13.43 per common share, an estimated life of six years, a volatility rate of 70% and a risk free interest rate of 4.34%. The fair value of the warrant was recorded as a discount to the facility and is being amortized to interest expense on a straight-line basis over the term of the loan. The remaining unamortized fair value of the warrants is $72,000 at March 31, 2007. The warrants are exercisable through 2015.

Note 3. Share-Based Payments

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

	Three months ended March 31, 2007	Three months ended March 31, 2006
Share-based compensation costs included in:		
Cost of sales	$ 101	$ 89
Research and development	140	99
Selling, general, and administrative	173	262
Total share-based compensation costs	414	450
Income tax benefit recognized		
Impact on net loss	$ 414	$ 450
Share-based compensation expense, per common share:		
Basic and diluted	$ 0.04	$ 0.04

We recognized share-based employee compensation expense of $169,000 and $34,000 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, 2007 and 2006, respectively, in addition to $245,000 and $416,000 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, 2007 and 2006, 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, 2007 and 2006.

As of March 31, 2007, $3.4 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 2.0 years.

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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, redeemable convertible preferred stock, convertible preferred stock, 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.

	Three months ended March 31,	
	2007	2006
	(in thousands, except per share amounts)	
Historical		
Numerator:		
Net loss	$ (3,432)	$ (4,271)
Denominator:		
Weighted-average common shares outstanding	11,035	10,687
Weighted-average unvested common shares subject to repurchase	(3)	(26)
Denominator for basic and diluted net loss per common share	11,032	10,661
Basic and diluted net loss per common share	$ (0.31)	$ (0.40)
Historical outstanding anti-dilutive securities not included in diluted net loss per common share:		
Options to purchase common stock	1,696	1,524
Warrants to purchase common and convertible preferred stock	83	83
	1,779	1,607

Note 5. Equity

In April 2007, the Company completed a private placement of shares 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. The investors in the transaction purchased warrants that are exercisable, in total, for 578,824 of common stock at an exercise price of $5.14 per share. The warrants were purchased by the investors at a price of $0.07 per warrant share and will be recorded as equity in accordance with the FASB s Emerging Issues Task Force Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*. The warrants will become exercisable six months after the issuance, and the warrants expire on April 24, 2012. The Company is obligated to file a registration statement on Form S-3 within 30 days of the completion of the private placement, and has up to 120 days thereafter, under certain conditions, to seek the effectiveness of the Form S-3 without penalty.

Note 6. Recent Accounting Pronouncements

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* (SFAS 159). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company s adoption of SFAS 159 is not expected to have a

material effect on its consolidated financial position or results of operations.

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In July 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109* (FIN 48). FIN 48 prescribes a recognition threshold and measurement process for recording in the financials statements uncertain tax positions taken or expected to be taken in a tax return. Additionally, FIN 48 provides guidance on the derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. The accounting provisions of FIN 48 became effective for the Company beginning January 1, 2007.

At December 31, 2006, the Company had $29.2 million in deferred tax assets. The deferred tax assets are primarily composed of federal and state tax net operating loss (NOL) carryforwards and federal and state research and development (R&D) credit carryforwards. Due to uncertainties surrounding the Company s ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset this amount. Additionally, utilization of the NOL and R&D credit carryforwards may be subject to a substantial annual limitation due to ownership changes that have occurred previously or that could occur in the future provided by Sections 382 and 383 of the Internal Revenue Code of 1986, as well as similar state provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Sections 382 and 383, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. Since the Company s formation, the Company has raised capital through the issuance of capital stock on several occasions which, combined with the purchasing shareholders subsequent disposition of those shares, may have resulted in a change of control, as defined by Sections 382 and 383, or could result in a change of control in the future upon subsequent disposition. The Company has not currently completed a study to assess whether a change in control has occurred or whether there have been multiple changes of control since the Company s formation due to the significant complexity and cost associated with such a study. If the Company experienced a change in control as defined by Section 382 and 383 at any time since the Company s formation, utilization of the NOL or R&D credit carryforwards would be subject to an annual limitation which is determined by first multiplying the value of the Company s stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in the expiration of a portion of the NOL or R&D credit carryforwards before utilization. Further, until a study is completed and any limitation determined, no amounts are being presented as an uncertain tax position under FIN 48. The Company believes that if a change of control occurred, the amount subject to limitation could be significant. Any amounts that the Company determines will expire prior to their utilization due to such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance.

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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 timing for regulatory approvals, if any, for the CryoCor Cardiac Cryoablation System, or cryoablation system, in the United States for use in treating atrial flutter, or AFL, and atrial fibrillation, or AF, the timing for when we will complete enrollment in our AF pivotal trial and submit an application for premarket approval, or PMA, for AF, statements related to our restructuring, the timing for product sales in the United States, if any, 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 and PMA filings, if any, and the period over which our existing cash reserves will be sufficient to fund our ongoing operations, 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 involved with our ability to obtain regulatory approval in the United States for our cryoablation system for use in treating AFL and AF, risks associated with our ability to complete enrollment in our AF pivotal trial and submit a PMA for AF, risks associated with our ability to receive approval from the United States Food and Drug Administration, or FDA, for the use of our cryoablation system to treat AFL, risks associated with our ability to successfully commercialize our cryoablation system in the United States and elsewhere if our cryoablation system is approved for use in the United States, 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, 2006 filed with the Securities and Exchange Commission, or SEC on March 30, 2007.

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 stroke. We have focused our initial development efforts on designing a system for treating atrial fibrillation, or AF, and 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 coexist with, AF.

We have filed an application for premarket approval, or PMA, with the United States Food and Drug Administration, or FDA, for the treatment of AFL with our CryoCor Cardiac Cryoablation System, or cryoablation system. Our PMA was filed initially in July 2005. In January 2006, we were notified by the FDA that the PMA was not approvable at that time as the data presented did not meet the FDA s chronic effectiveness criteria. Subsequent to receiving the non-approvable letter, we reevaluated the chronic effectiveness for each subject treated in the study, and after meeting with the FDA, we amended our PMA for the treatment of AFL based on this different analysis of chronic effectiveness. In this analysis, we computed our chronic effectiveness to be 81.6%. The FDA has decided to convene an Advisory Panel meeting to advise the FDA on whether our analysis of the chronic results provides a reasonable assurance of effectiveness. The Advisory Panel meeting has been scheduled for June 27, 2007, and we anticipate that the FDA will render a final decision on the approval of our PMA in August 2007. Although we believe our clinical data demonstrate adequate safety and effectiveness to support FDA approval, there can be no assurance that our product will be recommended for approval at the Advisory Panel meeting, or that our product will be approved by the FDA for the treatment of AFL.

We are currently enrolling a pivotal trial for the treatment of AF, and expect to complete enrollment in our trial in the next several months. As of May 11, 2007, we need to enroll seven to 14 additional patients to allow us to have the required population of evaluable patients. We will need to collect safety and effectiveness data on 140 evaluable patients, 70 that have been treated with cryoablation and 70 that have been treated with medical management. We anticipate needing to enroll between 166-173 patients to generate the required number of evaluable patients. In January 2007, the FDA approved our request to increase the size of our pivotal trial, as the trial was initially planned to enroll 160 patients. Some patients in our trial withdrew for various reasons, including being randomized to medical management or being denied coverage for the

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procedure by their insurance company. Based upon the anticipated timelines for completion of enrollment of our pivotal trial and the 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 the second half of 2008 and that a decision from the FDA on whether or not to approve our cryoablation system for the treatment of AF will be received in 2009.

At present, we are currently selling our products through European distributors, and our products are sold in the United Kingdom, Germany, Denmark, Belgium, the Netherlands and Italy. We do not intend to expand our current network of distributors. If we obtain marketing approval from the FDA, we plan to commercialize in the United States with a direct CryoCor sales force and/or with a marketing partner. Due to our limited cash resources, if we are approved for the treatment of AFL, we do not intend to broadly commercialize our product in the United States until our financial condition improves.

To date, we have generated minimal revenues and we have incurred net losses in each year since our inception. We expect these losses to continue as we complete our clinical trial activities and continue to develop our product candidates for potential commercial launch in the United States, and for at least some time after any commercial launch of any of our products in the United States. We have financed our operations primarily through private placements of common stock and preferred stock, convertible promissory notes, bank debt, and the proceeds of our initial public offering completed in July 2005, which raised aggregate net proceeds of $35.4 million after deducting underwriting fees, commissions and offering costs. In addition, we closed a private placement in April 2007 which raised gross proceeds of $5.5 million.

Financial Operations

Product Sales. Our product sales to date have come from a limited number of commercial sites in Europe. 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. We believe that European product revenues for companies with new medical technologies typically remain modest until United States product approval is obtained because European approvals, which are designed primarily to demonstrate product safety, are not as compelling for European physician adoption as United States approvals, which must demonstrate effectiveness as well as safety. We do not expect to generate revenues in the United States unless, and until, our cryoablation system has been approved by the FDA and we initiate the sales of our products. We expect that any revenues we generate from sales of our products will fluctuate from quarter-to-quarter.

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, including 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, 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.

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 quarterly variations in sales activities and results. Due to these uncertainties, results of future operations are difficult to predict.

Three months ended March 31, 2007 and 2006

Product Sales. Product sales decreased $47,000 to $66,000 for the three months ended March 31, 2007, compared to $113,000 for the three months ended March 31, 2006. The decrease was primarily due to the reduced sales activities in Europe associated with the restructuring and closure of our German subsidiary during 2006. Deferred revenue decreased from $78,000 at December 31, 2006 to $69,000 at March 31, 2007 due to increased cash collections and lower product shipments versus previous periods.

Cost of Sales. Cost of sales decreased $135,000 to $628,000 for the three months ended March 31, 2007, compared to $763,000 for the three months ended March 31, 2006. The decrease during the three months ended March 31, 2007 is primarily related to lower personnel costs of

$123,000 as a result of our staff restructuring in early 2006 and lower material costs related to our reduced product sales. Cost of sales is high relative to the volume of sales due to the fixed costs associated with manufacturing our product. Included in cost of sales for the three months ended March 31, 2007 and 2006 were non-cash share-based compensation of $108,000 and $89,000, respectively.

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Research and Development Expenses. Research and development expenses increased $57,000 to $1.6 million for the three months ended March 31, 2007, compared to $1.5 million for the three months ended March 31, 2006. The increase was primarily related to the costs associated with our third-party clinical research organization as well as increased non-cash share-based compensation, partially offset by lower clinical trial costs related to lower enrollment in our ongoing AF clinical trial than enrollment in the three months ended March 31, 2006. Included in research and development expenses for the three months ended March 31, 2007 and 2006 were non-cash share-based compensation of $152,000 and $100,000, respectively.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $887,000 to $1.2 million for the three months ended March 31, 2007, compared to $2.1 million for the three months ended March 31, 2006. The decrease was primarily due to lower personnel costs of $535,000 as a result of our staff restructuring in early 2006 as well as lower sales consulting costs of $99,000, lower operating costs associated with closing our foreign subsidiary of $99,000, and lower non-cash share-based compensation of $75,000. Included in general and administrative expenses for the three months ended March 31, 2007 and 2006 were non-cash share-based compensation of $191,000 and $266,000, respectively.

Liquidity and Capital Resources

We have incurred losses since our inception in August 2000. As of March 31, 2007, we had an accumulated deficit of $88.4 million. We have funded our operations to date from private placements of equity and debt securities for aggregate net cash proceeds of $51.2 million through March 31, 2007, as well as bank debt and the proceeds of our initial public offering, which was closed in July 2005 and raised aggregate net proceeds of $35.4 million after deducting underwriting fees and commissions and transaction costs. In addition, we completed a private placement of our common stock in April 2007 which raised gross proceeds of $5.5 million.

As of March 31, 2007, we had short-term debt outstanding of $7.0 million (excluding a debt discount for warrants of $72,000), working capital of $8.0 million and cash, cash equivalents and short-term investments totaling $15.9 million. Based upon our current level of expenditures, we believe that our existing funds, including the proceeds from our April 2007 private placement, will be adequate to meet our anticipated cash requirements until May 2008, and that to continue to fund our operations beyond that date, we will need to seek additional financing.

Net Cash Used in Operating Activities. Net cash used in operating activities decreased $883,000 to $3.2 million for the three months ended March 31, 2007, compared to $4.1 million for the three months ended March 31, 2006. 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. Our operating losses have been within our expectations.

Net Cash Provided by Investing Activities. Net cash provided by investing activities increased $6.5 million to $6.9 million for the three months ended March 31, 2007, compared to $402,000 for the three months ended March 31, 2006. Cash provided by investing activities relates to purchases and maturities of short-term investments as well as purchases of property and equipment. The increase in net cash provided by investing activities for the three months ended March 31, 2007 is related to purchases and maturities of short-term investments.

Net Cash Provided by Financing Activities. Net cash provided by financing activities decreased $27,000 to $37,000 for the three months ended March 31, 2007, compared to $64,000 for the three months ended March 31, 2006. Net cash provided by financing activities during the three months ended March 31, 2007 and 2006 was primarily attributable to proceeds from the issuance of common stock related to awards granted under our equity incentive plans.

Operating Capital and Capital Expenditure Requirements

To date, we have had limited commercial sales in Europe, no commercial sales in the United States, and we have not yet achieved profitability. We do not currently have any products approved for sale in the United States. We anticipate that we will continue to incur net losses for the next several years as we continue to develop our products, continue our clinical programs, expand our corporate infrastructure and prepare for the potential commercial launch of our cryoablation system in the United States. 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 marketing approval for and begin selling our cryoablation system in the United States. Based upon our current level of expenditures, we believe the proceeds from our initial public offering and our April 2007 private placement, together with cash flows from operating activities will be

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adequate to permit us to repay our outstanding debt facility in June 2007 and to meet our anticipated cash requirements for working capital until May 2008. We will need to seek additional financing and we expect to sell additional equity or debt securities or obtain an additional 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 we are unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned clinical and commercial activities, and research and development efforts, or to cease operations.

On February 21, 2006, we issued a press release announcing that we implemented a restructuring plan intended to reduce our burn rate and to permit us to finance ourselves with our then existing cash, cash equivalents and short-term investments until December 2007. The decision to implement a restructuring plan was in response to the communication that we received from the FDA informing us that our PMA for the treatment of AFL using our cryoablation system was not approvable at that time based on the data we submitted. Our Board of Directors approved the restructuring plan on February 14, 2006.

The restructuring plan included:

- a reduction in our workforce by approximately one-third; and
- postponement of some R&D programs, with possible elimination of others.

The reduction in our workforce resulted in severance-related costs of $280,000, including benefits. We also incurred $50,000 in restructuring expense associated with terminating various sales and marketing associated contracts. In total, we incurred $330,000 in costs associated with the restructuring plan, which was completed during July 2006.

In August 2006, we created an incentive compensation program for our non-executive full-time employees. Under the terms of the program, employees that remain with the Company through August 31, 2007 will receive a payment of 20% of their 2006 annual salary. The incentive payments will be paid in September 2007 and could total approximately $538,000, if all employees eligible for the program remain through August 31, 2007. Additionally, at the end of August 2006, we did not extend our employment agreement with our former Chief Executive Officer, Gregory Ayers. Under the terms of his employment agreement, he will receive separation compensation of one year s salary, or $450,000, over the 12 months subsequent to his departure. As of March 31, 2007, $193,000 of the severance amount remains accrued on the balance sheet, all of which will be paid by August 31, 2007.

At present, we have a wholly owned subsidiary in Cologne, 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 $70,000 remains accrued at March 31, 2007. 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. At present, we do not currently expect to sign additional distribution agreements in Europe. If we obtain marketing approval from the FDA, we plan to commercialize in the United States with our own sales force or in combination with a marketing partner.

We anticipate spending at least $3.9 million in external costs during the remainder of 2007 and 2008 for clinical trials and regulatory activities related to using our cryoablation system to treat AFL and AF, and an anticipated clinical trial for our next generation catheter, Quantum. We believe the total costs for our clinical trials for AFL and AF and the development of our existing product candidates will require approximately $10.5 million during the remainder of 2007 and 2008, with our remaining cash and cash equivalents being used to prosecute and maintain our intellectual property portfolio, to fund our facility, manufacturing and quality system operations and to fund our working capital and general corporate requirements during this same period.

We have filed requests with the United States Patent and Trademark Office, or USPTO, seeking to invoke interference proceedings involving two patents owned by CryoCath Technologies, Inc. and two of our patent applications to determine who first invented certain primary and pre-cooling refrigeration system designs and certain heat exchanger designs. During 2006, the USPTO agreed to reissue a patent licensed from CryoGen that we consider to be important to our efforts to invoke interference proceedings. To date, the USPTO has not invoked interference proceedings. If interference proceedings are invoked and we are not successful in these proceedings, we could fail to get rights to certain patent claims. Although we do not believe this finding would be material to our ability to operate, we believe an award of these rights to us may have a

material effect on CryoCath s ability to compete with us in the United States. We may incur substantial costs in pursuit of these proceedings.

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Our forecasts of the period of time through which our financial resources will be adequate to support our operations and the costs to complete clinical trials and development of products 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:

- our ability to obtain FDA approval 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;
- clinical trial results;
- acceptance by the FDA of our clinical trial design and data to support applications for marketing approval of the desired indications;
- 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;
- the costs of establishing sales, marketing and distribution capabilities;
- the extent and level of reimbursement for cryoablation;
- the commercial acceptance of our product following the initiation, if any, of our sales efforts in the United States;
- 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 we currently have no commitments or agreements relating to any of these types of transactions.

At March 31, 2007, the Company had $597,000 in console inventory on its balance sheet, as well as outstanding purchase commitments of approximately $86,000 for console materials. This total inventory represents ten consoles in finished goods, components to build an additional eighteen complete consoles, and components that could be used in the production of additional consoles. These materials are not expected to become obsolete in the time period anticipated for commercialization. At March 31, 2007, the Company had disposables inventory totaling $296,000, of which $275,000 is raw materials. This inventory level represents approximately 1,100 finished catheters. The Company anticipates that the existing inventory levels will be needed in either 2007 or 2008 to the extent we are able to commercialize our products in the United States.

We also 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 $767,000 in fees and expenses through March 31, 2007 payable 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. 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 $3.1 million during the remainder of 2007 and 2008. However, due to the variability associated with these agreements and the timing of patient enrollment, we are unable to estimate with certainty the future patient enrollment costs we will incur. We expect to incur additional expenses in connection with the preparation of our regulatory filings, including costs associated with employees and consultants and 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, 2007, we have agreed to cover the treatment costs for five patients at an estimated cost of approximately $77,000, which is included in the accrued clinical development liabilities on our balance sheet at March 31, 2007. We anticipate that there may be additional patients for whom we agree to pay the treatment costs, and project that the total number of patients for which we could cover the cost of the treatment could be up to an additional five patients, at an estimated cost of $15,000 $35,000 each. The total estimated costs for covering the costs of these treatments are included in our estimated $3.1 million above.

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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 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 products until one month following the expiration date of the product, which had been six months after its production. Effective October 1, 2006, our products now expire one year after production and we modified our return policy such that we will no longer grant a right to return products upon expiration of their one year product life. 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.

If our products are approved by the FDA for sale in the United States and if they gain market acceptance and our sales volumes increase, we will continue to monitor our shipments, returns, maintenance costs and bad debts. Eventually, we anticipate recording revenues upon shipment, accruing estimated warranty costs and estimated returns as a reduction of revenue upon shipment and accruing bad debts as a selling, general and administrative cost.

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 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 $169,000 and $34,000 during the three months ended March 31, 2007 and 2006, respectively, in addition to $245,000 and $416,000 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, 2007 and 2006, 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, 2007, total unrecognized compensation expense related to unvested share-based compensation arrangements already granted under our various plans was $3.4 million, which we expect will be recognized over a weighted-average period of 2.0 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.

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Inventory

At March 31, 2007, the Company had $597,000 in console inventory on its balance sheet, as well as outstanding purchase commitments of approximately $86,000 for console materials. This total inventory represents ten consoles in finished goods, components to build an additional eighteen complete consoles, and components that could be used in the production of additional consoles. These materials are not expected to become obsolete in the time period anticipated for commercialization. At March 31, 2007, the Company had disposables inventory totaling $296,000, of which $275,000 is raw materials. This inventory level represents approximately 1,100 finished catheters. We evaluated whether these levels of console and catheter inventory was excessive and concluded that they were not excessive for the following reasons:

Consoles

- completed consoles can be deployed in Europe where our product has been approved for sale;
- we expect to need between 125 to 160 consoles to effectively commercialize our product in the United States;
- we believe we will receive approval to sell our product in the United States in either 2007, 2008 or 2009; and
- the console is not subject to obsolescence in the time period contemplated for commercialization.

Disposables

- we anticipate the sale of approximately 250-550 catheters in Europe during the remainder of 2007;
- we believe we will receive approval to sell our product in the United States in either 2007, 2008 or 2009; and
- the catheter raw materials are not subject to obsolescence in the time period contemplated for commercialization.

Based on the above, we concluded that no reserves were needed at March 31, 2007 for the existing console and catheter inventory. We will continue to evaluate these inventory levels based on the progress of our trials and regulatory approvals.

Recent Accounting Pronouncements

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115,* or SFAS 159. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for fiscal years beginning after November 15, 2007. Our adoption of SFAS 159 is not expected to have a material effect on its consolidated financial position or results of operations.

In July 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes,* or FIN 48. This interpretation requires that we recognize the impact of a tax position in our financial statements, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 are effective for fiscal years beginning after December 15, 2006, with the cumulative effect of the change in accounting principle recorded as an adjustment to retained earnings. We have adopted FIN 48 as of January 1, 2007, and compliance with this guidance did not have a significant impact on our results of operations or financial position.

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 money market funds, corporate debt securities and asset-backed securities. Due to the short-term nature of our investments, we believe that we have no material exposure to interest rate risk.

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

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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 the Securities and Exchange Commission 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

From time to time, we may be involved in litigation relating to claims arising out of our operations. Other than the interference proceedings previously described under the heading Legal Proceedings in our Form 10-K for the period ending December 31, 2006, filed with the SEC on March 30, 2007 we are not currently involved in any material legal proceedings.

ITEM 1A. RISK FACTORS

The risk factors included in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2006 included disclosure regarding uncertainty as to whether or not the FDA would convene an Advisory Panel meeting to review CryoCor s PMA for AFL, or whether the FDA would conclude that an Advisory Panel meeting was not needed. The FDA has concluded that it will convene an Advisory Panel meeting on June 27, 2007 to review CryoCor s PMA for AFL. The following risk factors reflect these changes:

- The FDA has informed us that our PMA for the treatment of AFL using our cryoablation system was not approvable based on the data originally submitted, which could prevent us from obtaining FDA approval to market our cryoablation system for the treatment of AFL in the United States;

- We are dependent on the success of our cryoablation system, which has not been approved by the FDA for any indication for commercialization 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, or experience significant delays in doing so, our stock price may decline and we may be forced to cease operations; and

If the data from our clinical trials do 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.

The risk factors included in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2006 included disclosure regarding our uncertainty as to whether or not we would be able to obtain additional financing to finance our operations beyond December 2007, which was the anticipated date when our cash resources would be depleted. In April 2007, we completed a private placement of our common stock from which we obtained gross proceeds of $5.5 million. We intend to use some of these proceeds to pay off our existing debt facility of $7.0 million, and accordingly, we now believe our existing cash resources will be sufficient to fund our existing operations until May 2008. The following risk factors reflect these changes:

We will need substantial additional funding to continue our operations and may be unable to raise capital when needed, or at all, which would force us to delay, curtail or eliminate our clinical programs or product development programs

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We may not be able to continue as a going concern or fund our existing capital needs; and

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

Except as discussed above, the risk factors set forth below do not contain any other material changes from the Risk Factors set forth in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2006.

RISK FACTORS RELATED TO OUR BUSINESS

Except for the historical information contained herein, this Form 10-Q contains forward-looking statements that involve risks and uncertainties. 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.

We will need substantial additional funding to continue our operations and may be unable to raise capital when needed, or at all, 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:

fund our operations and clinical trials;

continue our research and development;

enforce our proprietary rights;

defend, in litigation or otherwise, any claims that we infringe third party patents or other intellectual property rights; and

commercialize any of our products that may be approved by the FDA.

We believe that our existing cash, cash equivalents and short-term investment balances, will be sufficient to meet our anticipated cash requirements until May 2008. However, our future funding requirements will depend on many factors, including but not limited to:

our ability to obtain FDA approval 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;

clinical trial results;

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

the costs of establishing sales, marketing and distribution capabilities;

our ability to restructure or refinance our existing debt;

the extent and level of reimbursement for cryoablation;

the commercial acceptance of our product following the initiation of our sales efforts in the United States;

the effect of competing products and technologies; and

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

Until we can generate sufficient product revenue, which may never occur, 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. Examples of such restrictive covenants, all of which we are subject to under our current loan

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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. 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. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets or delay, reduce the scope of or eliminate some or all of our clinical or product development programs or commercialization efforts, which may harm our business, financial condition, results of operations and future growth prospects.

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 included an explanatory paragraph in their report on our 2006 financial statements related to the uncertainty in our ability to continue as a going concern. Accordingly, there is considerable doubt as to whether we will be able to continue as a going concern beyond 2007 without access to additional working capital. Although we recently completed a private placement of $5.5 million, there can be no assurance that we will be able to obtain additional funds on satisfactory terms, or at all, to fund our operations beyond May 2008, which is when we anticipate our existing cash resources, including the proceeds from the private placement, will have been expended. If we cannot obtain sufficient additional financing in the short-term, we may be forced to restructure or significantly curtail our operations, file for bankruptcy or 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.

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 no products in commercial distribution in the United States. Our product candidates will require additional development, clinical trials, regulatory clearances or approvals by the FDA and additional investment before they can be commercialized in the United States. We anticipate that our cryoablation system will not be approved for commercialization in the United States by the FDA for any indication until 2007 or 2008 at the earliest, if at all.

As of March 31, 2007, we had an accumulated deficit of $88.4 million. We have incurred net losses in each year since our inception in August 2000, including net losses of $15.1 million, $17.1 million, and $15.8 million for the years ended December 31, 2006, 2005, and 2004, respectively. We expect to continue to incur significant and increasing operating losses, in the aggregate and on a per share basis, for the next several years. 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 or when we will become profitable, if at all.

We expect that our primary expenses for the next 24 months will be for conducting our clinical trial for AF, costs associated with preparing our PMA for AF, other costs associated with new product development and costs associated with our PMA for AFL. We expect that our general and administrative and legal costs will continue to increase due to the additional operational and regulatory burdens applicable to public companies. If we do not restructure or refinance our existing debt, we expect to pay off our existing debt of $7.0 million when due in June 2007. In addition, we anticipate that the interference we have filed with the USPTO will be declared in 2007 and substantial financial resources will be required to support this action. If we receive FDA marketing approval of our cryoablation system for either AFL or AF, we expect to incur increased sales, marketing, manufacturing, and compliance expenses. We do not currently have the required approvals to market our cryoablation system in the United States and we may not receive them. We may not become profitable even if we obtain FDA approval and succeed in commercializing our cryoablation system in the United States. As a result, we cannot be sure when we will become profitable, if at all.

The FDA has informed us that our PMA for the treatment of AFL using the cryoablation system is not approvable based on the data submitted, which could prevent us from obtaining FDA approval to market our cryoablation system for the treatment of AFL in the United States

In late January 2006, we received a letter from the FDA informing us that our PMA for the treatment of AFL using the cryoablation system was not approvable at that time. The FDA stated that its interpretation of the data presented by us from our trial did not meet the FDA s chronic effectiveness criteria. Since receiving the letter from the FDA, CryoCor retained expert physicians in the field of electrophysiology to review the clinical data for all patients treated in its pivotal trial to independently determine the success of each procedure. Additionally, CryoCor engaged external regulatory consultants to assist with its efforts to reevaluate the clinical data and advise CryoCor on a potential amendment to its PMA based on additional information. Based upon these efforts and after a meeting held with the FDA on July 26, 2006, where the process

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around and results from CryoCor s reevaluation of the AFL clinical data for purposes of determining chronic effectiveness were discussed, CryoCor announced that it would file an amendment to its PMA for the treatment of AFL, and in November 2006, the amendment was filed. The FDA has decided to convene an Advisory Panel meeting to advise the FDA on whether our analysis of chronic effectiveness is sufficient to warrant marketing approval of our PMA for AFL. The Advisory Panel meeting has been scheduled for June 27, 2007, and we anticipate that the FDA will render a final decision on the approval of our PMA by August 2007. Although we believe our clinical data demonstrate adequate safety and effectiveness to support FDA approval, there can be no assurance that our product will be recommended for approval for the treatment of AFL at the Advisory Panel meeting, or that our product will be approved by the FDA for the treatment of AFL.

The FDA s decision in January 2006 to not approve our product may, in part, be due to concerns they expressed about the design of our clinical trial, including the following:

- the OPCs against which we measured the safety and effectiveness of our cryoablation system were derived from RF ablation studies and the FDA has indicated that they may not be applicable to our AFL pivotal trial;
- selection of endpoints, including the use of acute effectiveness rather than chronic effectiveness as the primary measure of product effectiveness in the AFL pivotal trial;
- interfering effects of medication; and
- protocol deviations by our clinical investigators.

Based on these concerns, we cannot be certain that the FDA will ever agree that we have demonstrated safety and effectiveness. Additionally, the FDA may disagree with the way in which we measure and interpret the data resulting from our pivotal trials. If the FDA does not agree that our pivotal trials demonstrated safety and effectiveness, the FDA may deny marketing approval of our cryoablation system.

The evaluation of our chronic effectiveness data from our AFL pivotal trial, which was conducted by experts independent of CryoCor, resulted in chronic effectiveness that exceeds 80%, but the result did not meet the chronic effectiveness OPC established by the FDA for RF ablation, which could lead the FDA to delay or deny marketing approval for the AFL indication.

In the AFL pivotal trial, our chronic effectiveness data indicate that 81.6% of patients that had a successful initial procedure did not have a recurrence of AFL during the six month period following treatment, but did not meet the chronic effectiveness OPC established by the FDA for RF ablation. We are aware of other companies that have received PMA approval despite not meeting OPC s for RF ablation; but we cannot assure you that the FDA will agree that the data presented in our amendment to our AFL PMA has demonstrated sufficient chronic effectiveness to receive marketing approval. If the FDA does not accept our proposed approach, the FDA may conclude that we have failed to demonstrate the effectiveness of our cryoablation system and delay or deny marketing approval of our cryoablation system for the treatment of AFL.

Even if our PMA is approved for the treatment of AFL, we may not have sufficient financial resources to commercialize our cryoablation system for the treatment of AFL, and we may have difficulty obtaining additional resources to commercialize our system.

We currently have limited cash resources, and it will require significant cash resources to broadly launch our cryoablation system for the treatment of AFL. Due to our current financial condition, even if we receive approval from the FDA for the treatment of AFL, it is not our intention to broadly commercialize our cryoablation system until our financial condition has improved. There can be no assurance that we will be able to raise the additional capital needed to commercialize our system, and we may never broadly commercialize our system for the treatment of AFL.

We are dependent on the success of our cryoablation system, which has not been approved by the FDA for any indication for commercialization 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, 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 is still in clinical testing, has not yet received FDA approval for any indication and may never be commercialized in the United States. 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 enrollment of subjects in our clinical trials, 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

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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 the treatment of AFL is not approvable based on the data we submitted. In response, we analyzed our clinical data and amended our PMA for AFL in a manner that is acceptable to the FDA, and filed an amendment to our PMA in November, 2006. The FDA has decided to convene an Advisory Panel meeting to advise the FDA on whether our analysis of chronic effectiveness is sufficient to warrant marketing approval of our PMA for AFL. The Advisory Panel meeting has been scheduled for June 27, 2007, and we anticipate that the FDA will render a final decision on the approval of our PMA by August 2007. However, there can be no assurance that our amended PMA will be approved by the FDA. Additionally, our enrollment for our AF pivotal trial has progressed more slowly than we expected. We have opened new centers and have taken efforts to stimulate enrollment, which has improved the pace of our enrollment. However, it may take us longer than we anticipate to complete the enrollment of our AF pivotal trial. If we do not meet our estimated milestones as publicly disclosed for both AF and AFL, we may be unable to commercialize our products in the United States, or any commercialization of our products in the United States may be delayed and, as a result, our business may be harmed and our stock price may decline. If our cryoablation system is not approved by the FDA for any indication for commercialization in the United States, we may be forced to cease operations.

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 both AFL and AF, and will only be able to market our cryoablation system for an indication for which we receive FDA approval. If the FDA does not approve our cryoablation system for treating both AFL and AF, we intend to market our cryoablation system only for the indication for which we receive FDA approval. 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 and has approved four devices for AFL, all of which use radiofrequency, or RF, energy.

As discussed above, in January 2006, the FDA informed us that our PMA for the treatment of AFL using the cryoablation system was not approvable at that time. After receipt of this FDA letter, we conducted an independent evaluation of chronic effectiveness for each subject that experienced acute effectiveness, and based upon the results of this evaluation, we met with the FDA in July 2006 to discuss the process around and results from our independent review of the AFL clinical data. We filed an amendment to our PMA in November 2006, and provided additional information to the FDA in February 2007. The FDA has decided to convene an Advisory Panel meeting to advise the FDA on whether our analysis of chronic effectiveness is sufficient to warrant marketing approval of our PMA for AFL. The Advisory Panel meeting has been scheduled for June 27, 2007, and we anticipate that the FDA will render a final decision on the approval of our PMA by August 2007. Although we believe our clinical data demonstrate adequate safety and effectiveness to support FDA approval, there can be no assurance that our product will be recommended for approval for the treatment of AFL at the Advisory Panel meeting, or that our product will be approved by the FDA for the treatment of AFL.

We cannot assure you that we will obtain FDA approval to market our cryoablation system in the United States for either AFL or AF in a timely manner or at all. In addition, even if we obtain approval for one indication, we may never obtain approval for the other indication. If we fail to obtain FDA approval for at least one indication, we will not be permitted to market our cryoablation system in the United States and may be forced to cease our operations. In addition, if we do not receive FDA approval for the AF indication, we may never become profitable.

If the data from our clinical trials do 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

To obtain FDA approval for marketing, our pivotal trials must generate data demonstrating that our cryoablation system is safe and effective for each indication for which approval is sought. The FDA s grant of permission to proceed with the AFL and 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 trials will meet our chosen safety and effectiveness endpoints or otherwise produce results that will lead the FDA to grant marketing approval. For example, in January 2006, the FDA informed us that our PMA for the treatment of AFL using the cryoablation system was not approvable at that time. After receipt of this FDA letter, we conducted an independent evaluation of our chronic effectiveness data, and based upon the results of this evaluation, we met with the FDA in July 2006 to discuss the process around and results from our independent review of the AFL clinical data. We filed an amendment to our PMA in November 2006, and the FDA has decided to convene an Advisory Panel meeting to advise the FDA on whether our analysis of chronic effectiveness is sufficient to warrant marketing approval of our PMA for AFL. The Advisory Panel meeting has been scheduled for June 27, 2007, and we anticipate that the FDA will render a final decision on

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the approval of our PMA by August 2007. However, there can be no assurance that the FDA will determine that the data presented in the amended PMA meets the FDA s chronic effectiveness criteria and there can be no assurance that we will receive approval for our amended PMA. If our PMA is not approved by the FDA, we will not be able to market our cryoablation system for the treatment of AFL in the United States.

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:

subjects do not enroll in our pivotal trial at the rate we currently expect;

subjects withdraw from our pivotal trial at a higher withdrawal rate than we expected when designing the trial;

the FDA places our pivotal trial on hold;

insufficient capital to fund the pivotal trial;

supply shortages 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;

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;

changes in laws, governmental regulations or administrative actions force us to modify the conduct of our trials or otherwise create unexpected burdens;

the reimbursement by governmental and other third party payers changes;

the interim results of our clinical trials are inconclusive or negative;

one or more of our IRBs 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;

complications occur during cryoablation procedures that result in a decision by our Data Safety and Monitoring Board to delay or stop the clinical trial; 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 enrolling or 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. For example, two of the 160 patients originally enrolled in our AFL trial withdrew from the trial prior to completing the trial. In addition, 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 may experience delays in the enrollment of our pivotal trial. For example, our enrollment for our AF pivotal trial has progressed more slowly than we expected. We have opened new centers and have taken efforts to stimulate enrollment, which has improved the pace of our enrollment. However, it may take us longer than we anticipate to complete the enrollment of our AF pivotal trial. 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.

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Delays in subject enrollment or 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 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, 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. While the exact number of additional patients needed is not known at this time, we anticipate that we will need to enroll at least 166-173 patients to achieve a dataset of evaluable patients.

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.

Completion of our clinical trials and any subsequent commercialization of our 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. If we receive FDA approval for our cryoablation system for the treatment of AF or AFL, we believe we will need eventually to obtain additional commercial-scale manufacturing facilities. 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 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 satisfy these requirements. If we or our suppliers do not achieve and maintain required regulatory approval for our manufacturing operations, including for any additional commercial-scale manufacturing facilities that we may obtain in the future, our commercialization efforts in the United States, if any, 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 cardiac 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.

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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 has been associated with pulmonary vein stenosis, a narrowing of the pulmonary vein that can have serious adverse health implications. Other 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 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.

Even if we obtain regulatory approval, our future growth depends on physician adoption and market acceptance of our cryoablation system, which may not occur.

Even if we obtain regulatory approval of our cryoablation system or any other product candidate that we may develop, these products 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;
- 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, is approved by the FDA but 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 interventional cardiologists and electrophysiologists because they are often the physicians treating both AF and AFL. However, the initial point of contact for many patients may be general practitioners who commonly treat patients experiencing AF and AFL. 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 interventional cardiologists or electrophysiologists for our cryoablation system procedure, which may impair our business, financial condition and results of operations.

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Even if we obtain FDA approval to market our products, 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. In the event any of our products receives approval and is commercialized, 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 sales and earnings 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 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:

- fines, 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.

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, 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. Currently, we own or license 36 issued United States patents and a number of pending United States patent applications covering various aspects of our products and technology.

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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 Technologies, Inc., Johnson & Johnson, the Regents of the University of California and Spembly 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. Owners of these patents or their licensees may assert that the manufacture, use or sale of our cryoablation system infringes one or more claims of their patents.

The possibility of 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 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.

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. 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 proceed toward commercialization in the United States, there is a significant risk that one or more third parties will assert a patent infringement claim against the manufacture, use or sale of our cryoablation system. Such a lawsuit may have already been filed against us without our knowledge. Any lawsuit could 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, including those mentioned above, will file suit for patent infringement. Holders and prospective holders of our common stock should consider the possibility of a patent infringement suit a significant risk.

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 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 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

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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 Technologies, Inc. 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.

In the event that we are found to infringe any valid claim in a patent held by a third party, 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 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 depend on single source suppliers for our cryoablation system components and the loss of these suppliers could prevent or delay our clinical trials, possible commercialization of our cryoablation system in the United States and additional sales of our cryoablation system in Europe.

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 prevent the possible commercialization of our cryoablation system in the United States and additional sales of our cryoablation system in Europe and adversely impact our business.

If we receive FDA approval for our cryoablation system and are unable to manage our growth, our future revenue and operating results may be adversely affected.

If we receive FDA approval for the treatment of AF with our cryoablation system, we will need to rapidly expand our sales and marketing operations and grow our research and development, product development and administrative operations. This expansion would place a significant strain on our management and operational and financial resources. Our current and planned personnel, systems, procedures and controls may not be adequate to support our growth. To manage our growth and to commercialize our cryoablation system in the United States, we would be required to improve existing, and implement new, operational and financial systems, procedures and controls and expand, train and

manage our growing employee base. If we were unable to manage our growth effectively, our business and operating results could be harmed.

We have limited manufacturing capabilities and manufacturing personnel, and if our manufacturing facilities are unable to provide an adequate supply of products, our growth could be limited and 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

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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 for use in our current and planned clinical trials, or if our manufacturing process yields substandard cryoablation systems, completion of our AF clinical trials and commercialization efforts for AFL and AF in the United States, as well as sales of our cryoablation systems in Europe, would be delayed.

We currently have limited resources, facilities and experience to commercially manufacture our 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. Currently, we can only produce sufficient quantities of catheters to support our existing clinical trials and our expected commercial sales in Europe for 2007 and 2008. 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, 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 would require the investment of substantial additional funds and hiring and retaining additional management and technical personnel who have the necessary manufacturing experience. 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, or to meet demand for our cryoablation system in Europe. If we obtain regulatory approval from the FDA for our cryoablation system 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, 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 may 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.

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 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 efforts 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

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maintain stringent quality controls, or if contamination problems arise, our clinical development and potential commercialization efforts in the United States and our sales efforts in Europe 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 product candidates. The effectiveness, safety, performance and cost-effectiveness of our 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 currently under development and limit our ability to sell our 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.

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

If our products are approved for marketing in the United States, some of our customers will most likely 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.

If we are unable to establish sales and marketing capabilities or enter into and maintain arrangements with third parties to sell and market our cryoablation system, our business may be harmed.

We do not have a sales organization in the United States and have limited experience as a company in the sales, marketing and distribution of medical devices. If our cryoablation system is approved by the FDA, we plan to establish our own sales force to market our cryoablation system in the United States. Developing a sales force is expensive and time

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consuming and could delay or limit the success of any product launch. We may not be able to develop this capacity on a timely basis or at all. Additionally, if we are approved for the treatment of AFL, due to our limited cash resources, we do not intend to broadly commercialize our product in the United States until our financial condition improves. We may choose to contract with third parties, including distributors or agents, to perform sales, marketing and distribution services in the United States. If we enter into arrangements with third parties to perform sales, marketing and distribution services in the United States, our product revenues could be lower than if we directly sold, marketed and distributed our cryoablation system, or any other product that we may develop. Furthermore, if we enter into co-promotion or other marketing and sales arrangements with third parties, any revenues received will depend in part on the skills and efforts of these third parties, and we do not know whether these efforts will be successful. Some or all of our future distributors may have products or product candidates that compete with ours, and they may have an incentive not to devote their best efforts to marketing our products.

We have signed distribution agreements with third parties in Europe to market and sell our cryoablation system in the United Kingdom and Italy. We do not intend to sign additional distribution agreements in Europe and we may never sign additional distribution agreements. If our relationships with our distributors do not progress as anticipated, if we seek to identify alternative distributors and are unable to do so, or if their sales and marketing strategies fail to generate sales of our products in the future, our business, financial condition and results of operations would be harmed. We have closed our subsidiary in Germany through which we historically distributed our product in Belgium, the Netherlands and Germany and we may no longer sell our product in these geographic areas.

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. Any products that we commercialize 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 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.

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We do not and will not promote our cryoablation system for off-label or otherwise unapproved uses. However, if our cryoablation system is approved by the FDA, 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.

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.

Failure to obtain additional regulatory approval in foreign jurisdictions will prevent us from expanding the commercialization of our products abroad.

If we obtain approval to market our products in the United States, we may pursue marketing our products in a number of international markets. Although our cryoablation system has been approved for commercialization in the European Union, or EU, in order to market our products in other foreign jurisdictions, we will need to obtain separate regulatory approvals. The approval procedure varies among jurisdictions and can involve substantial additional testing. Approval by the FDA does not ensure approval by regulatory authorities in other jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign jurisdictions or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval in addition to other risks. In addition, the time required to obtain foreign approval may differ from that required to obtain FDA approval and we may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market other than in the EU.

Our efforts to discover, develop and commercialize 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, develop and commercialize 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 by the end of 2007. Research programs to identify new product candidates require substantial technical, financial and human 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 and commercialize 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 keyman insurance on any of our current executive officers.

In the event we need to hire additional qualified scientific, commercial, 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 any commercialization activities.

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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.

Legislative and regulatory proposals to amend the FDA regulatory and healthcare systems could impact our ability to sell our products, if any, 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.

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 auditors that both addresses management s assessments and provides for the independent auditor s assessment of the effectiveness of our internal controls. 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 auditors may not be able or willing to issue a favorable assessment of our conclusions. 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 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:

- results of our clinical trials;
- failure of any of our products to receive FDA or other regulatory approvals;

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

regulatory developments in the United States and foreign countries;

developments, disputes or litigation concerning patents or other proprietary rights;

failure of any of our product candidates, if approved for commercial sale, to achieve commercial success;

ability to manufacture our products to commercial standards;

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public concern over our products;

the departure of key personnel;

future sales of our common stock;

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;

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. In addition, stockholders may initiate securities class action lawsuits if the market price of our stock drops significantly, which may cause us to incur substantial costs and could divert the time and attention of our management. For example, on February 2, 2006, we announced that the FDA informed us that our PMA for the treatment of AFL was not approvable at that time. In response to this news, the market price of our stock dropped significantly.

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, 2007, beneficially owned approximately 76.0% 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 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Use of Proceeds

Our first Registration Statements on Form S-1 (Reg. Nos. 333-123841 and 333-126582), as amended, relating to our initial public offering was declared effective by the SEC on July 13, 2005. The offering commenced the same day and 3,709,090 shares of common stock were sold on our behalf at $11.00 per share, for an aggregate offering price of $40.8 million. Following the sale of shares, the offering was terminated. The net offering proceeds to us, after deducting underwriting discounts and commissions and estimated offering expenses, were approximately $35.4 million.

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We invested $35.4 million in proceeds from the offering, net of underwriting discounts and commissions and offering expenses, in money market funds, United States government or corporate bond securities, and asset-backed securities. Through March 31, 2007, we have used approximately $22.8 million of the proceeds from our initial public offering for research and development activities, clinical trial activities, expenses related to our facility, manufacturing and quality system operations, sales and marketing activities, and for working capital and general corporate purposes.

The foregoing payments were direct payments made to third parties who were not our directors or officers (or their associates), persons owning ten percent or more of any class of our equity securities or any other affiliate, except that a portion of the proceeds used for general corporate purposes included regular compensation for our officers and directors. We continue to invest the balance of the net proceeds of the offering in short-term, interest-bearing, investment-grade securities. We cannot predict whether the proceeds will yield a favorable return.

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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

Number	**Description of Exhibit**
3.1	Amended and Restated Certificate of Incorporation (1)
3.2	Amended and Restated Bylaws of the Company (1)
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)
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) Indicates management contract or compensatory plan.

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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 14, 2007

CryoCor, Inc.

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