CRYOCOR INC
Form 10-Q
November 08, 2005
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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 September 30, 2005

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 an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). YES ¨ NO x

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

The number of shares of the Registrant s common stock outstanding as of October 15, 2005 was 10,639,279.

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CRYOCOR, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE PERIOD ENDED SEPTEMBER 30, 2005

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

CryoCor, Inc.

Consolidated Balance Sheets

(in thousands except share and per share amounts)

	September 30, 2005	December 31, 2004
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 21,348	$ 5,436
Short-term investments	13,107	
Accounts receivable	203	62
Interest receivable	143	
Inventories, net	474	638
Prepaid expenses and other current assets	642	218
Amount due from related party, current		58
Total current assets	35,917	6,412
Property and equipment, net	660	849
Other assets	239	227
Total assets	$ 36,816	$ 7,488
Liabilities and stockholders equity (deficit)		
Current liabilities:		
Accounts payable	$ 456	$ 454
Accrued compensation	388	495
Accrued clinical development liabilities	509	667
Accrued liabilities	329	294
Deferred revenue	245	267
Capital lease obligation, current portion	14	82
Current portion of long-term debt		1,000
Total current liabilities	1,941	3,259
Long-term debt, less current portion	6,499	1,084
Series D redeemable convertible preferred stock, 142,000,000 shares authorized, 138,975,873 and zero shares issued and outstanding at December 31, 2004 and September 30, 2005 (unaudited), respectively		33,149

Stockholders equity (deficit):		
Series A, B and C convertible preferred stock, $0.001 par value; 7,958,311 shares authorized, 6,367,834 and zero shares issued and outstanding at December 31, 2004 and September 30, 2005 (unaudited), respectively		6
Common stock, $0.001 par value, 12,903,225 shares authorized; 51,332 and 10,639,279 shares issued and outstanding at December 31, 2004, and September 30, 2005 (unaudited), respectively	11	
Additional paid in capital	99,321	24,609
Deferred stock compensation	(5,705)	(4,568)
Accumulated comprehensive income	98	151
Accumulated deficit	(65,349)	(50,202)
Total stockholders equity (deficit)	28,376	(30,004)
Total liabilities and stockholders equity	$ 36,816	$ 7,488

See accompanying notes.

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CryoCor, Inc.

Consolidated Statements of Operations

(in thousands except share and per share amounts)

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2005	**2004**	**2005**	**2004**
Product sales	$ 152	$ 141	$ 682	$ 458
Operating expenses:				
Cost of sales	650	638	2,125	1,965
Research and development[(1)]	1,831	2,056	5,885	5,494
Selling, general and administrative[(1)]	1,688	1,565	4,702	3,650
Total costs and expenses	4,169	4,259	12,712	11,109
Loss from operations	(4,017)	(4,118)	(12,030)	(10,651)
Interest income	252	35	297	73
Interest expense	(327)	(59)	(751)	(144)
Net loss	(4,092)	(4,142)	(12,484)	(10,722)
Dividends and accretion to redemption value of redeemable convertible preferred stock		(1,342)	(2,662)	(2,966)
Cumulative dividends on Series C preferred stock		(61)	(102)	(181)
Net loss attributable to common stockholders	$ (4,092)	$ (5,545)	(15,248)	(13,869)
Basic and diluted net loss per share attributable to common stockholders	$ (0.45)	$ (236.54)	(4.86)	(606.88)
Shares used to compute basic and diluted net loss per share attributable to common stockholders	9,089,158	23,442	3,135,821	22,853

(1) Includes non-cash stock-based compensation expense as follows:

Research and development	$ 338	$ 194	$ 952	$ 202
Selling, general and administrative	195	159	593	162
	$ 533	$ 353	$ 1,545	$ 364

See accompanying notes.

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CryoCor, Inc.

Consolidated Statements of Cash Flows

(in thousands)

(Unaudited)

	Nine months ended September 30,	
	2005	**2004**
Operating activities		
Net loss	$ (12,484)	$ (10,722)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	351	356
Non-cash stock based compensation	1,545	365
Amortization of warrants	155	
Amortization of premium/discount on short-term investments.	(1)	
Loss on disposition of property, plant and equipment		2
Changes in operating assets and liabilities:		
Accounts receivable	(156)	(97)
Interest receivable	(143)	
Inventories	154	(22)
Prepaid expenses and other assets	(387)	(71)
Accounts payable	6	65
Deferred revenue	(18)	217
Accrued liabilities	(216)	376
Net cash used in operating activities	(11,194)	(9,531)
Investing activities		
Purchases of property and equipment	(163)	(169)
Proceeds from sale of property and equipment		2
Purchases of investments	(13,135)	
Net cash used in investing activities	(13,298)	(167)
Financing activities		
Net proceeds from issuance of preferred stock		12,246
Net proceeds from issuance of common stock	35,426	
Proceeds from exercise of stock options	142	1
Proceeds from long-term debt	7,000	
Principal payments on capital lease	(68)	(242)
Principal payments on long term debt	(2,084)	(667)
Net cash provided by financing activities	40,416	11,338
Effect of exchange rate changes on cash	(12)	(9)
Net increase in cash and cash equivalents	15,912	1,631

Cash and cash equivalents at beginning of period	5,436	7,923
Cash and cash equivalents at end of period	$ 21,348	$ 9,554
Supplemental disclosures of cash flow information:		
Cash payments for interest	$ 746	$ 110

See accompanying notes.

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CRYOCOR, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

1. Organization and Basis of Presentation

Organization

CryoCor, Inc. (CryoCor or the Company or we), a Delaware corporation, has developed and manufactures a minimally invasive, disposable catheter system based on proprietary cryoablation technology for the treatment of cardiac arrhythmias. The Company has focused its initial development efforts on atrial fibrillation, or AF, and atrial flutter, or AFL, the two most common and difficult to treat arrhythmias, and currently sells its catheter product in Europe through a wholly owned German subsidiary, CryoCor GmbH. The Company has submitted its application for premarket approval, or PMA, for AFL, and is conducting its pivotal trial for treatment of atrial fibrillation in the U.S.

We have prepared the accompanying unaudited consolidated financial statements in accordance with accounting principles generally accepted in the United States of America 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 generally accepted accounting principles 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 and nine months ended September 30, 2005 are not necessarily indicative of the results that may be expected for the year ending December 31, 2005. For further information, see the financial statements and disclosures thereto for the year ended December 31, 2004 included in our prospectus filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the Securities and Exchange Commission on July 14, 2005.

Reclassifications

Certain prior period expenses have been reclassified to conform to the current period presentation.

2. Balance Sheet Details

Cash and Cash Equivalents

We consider all investments with an original maturity of three months or less when purchased to be cash equivalents. Cash equivalents primarily represent funds invested in money market funds whose cost equals fair market value.

Investment Securities

Investment securities consist of high-grade auction rate securities and U.S. government or corporate debt securities. We classify 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 of any available-for-sale security below cost that is determined to be other than temporary results in a revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method. Interest income is recognized when earned.

The composition of investments and gross unrealized losses at September 30, 2005 are as follows (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Corporate debt securities	11,641		(27)	11,614
U.S. government securities	1,494		(1)	1,493
	$ 13,135	$	$ (28)	$ 13,107

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CRYOCOR, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

Inventories

Inventories consist of the following:

	September 30, 2005	December 31, 2004
Raw materials	$ 359	$ 552
Work-in-progress	52	42
Finished goods	115	124
	526	718
Less reserves for excess and obsolete inventories	(52)	(80)
Inventory, net	$ 474	$ 638

Long-Term Debt

On March 18, 2005, the Company entered into an agreement whereby we borrowed $7.0 million from a financial institution. As part of this transaction, the Company paid off its existing term loan which had an outstanding balance of $1.8 million. This facility places 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 new debt 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 its common stock redeemable at $6.15 per share. The fair value of the warrants was $657,000 based upon an estimated fair value upon the date of grants of $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 is recorded as a discount to the new debt facility, and will be amortized to interest expense on a straight-line basis over the term of the loan. The warrants are exercisable through 2015.

3. Stockholders Equity

Redeemable convertible preferred stock

As part of our initial public offering completed in July 2005, all of our convertible preferred stock and redeemable convertible preferred stock was converted into 6,615,234 shares of our common stock. These shares include 695,210 shares of common stock issued to holders of our Series C convertible preferred stock and Series D redeemable convertible preferred stock in settlement of cumulative dividends.

Initial Public Offering

In July 2005, we completed an initial public offering whereby we sold 3,709,090 shares of our common stock at $11 per share and received net proceeds of $35.4 million (after underwriting discounts and commissions and offering costs).

2005 Equity Incentive Plan

We adopted our 2005 Equity Incentive Plan in March 2005, and reserved 193,548 shares of common stock for future issuance under the plan. This plan became effective upon the effective date of our initial public offering.

2005 Non-Employee Directors Stock Option Plan

We adopted our 2005 Non-Employee Directors Stock Option Plan in March 2005, and reserved 106,451 shares of common stock for future issuance under the plan. This plan became effective upon the effective date of our initial public offering.

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CRYOCOR, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

2005 Employee Stock Purchase Plan

We adopted our 2005 Employee Stock Purchase Plan in March 2005, and reserved 161,290 shares of common stock for future issuance under the plan. This plan became effective upon the effective date of our initial public offering.

4. Stock-Based Compensation

The Company accounts for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB Opinion No. 25) and related interpretations and has adopted the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS No. 123).

The information regarding net loss as required by SFAS No. 123, as amended, has been determined as if the Company had accounted for its employee stock options under the fair-value method. The resulting effect on net loss pursuant to SFAS No. 123 is not likely to be representative of the effects on net loss pursuant to SFAS No. 123 in future years, since future years are likely to include additional grants and the irregular impact of future years vesting.

The following table illustrates the weighted-average assumptions for the Black-Scholes option pricing model used in determining the fair value of options granted to employees:

	Three months ended September 30,		Nine months ended September 30,	
	2005	2004	2005	2004
Dividend yield	0%	0%	0%	0%
Risk-free interest rate	3.25%	3.25%	3.25%	3.25%
Expected volatility	70%	%	70%	%
Expected life	6 years	6 years	6 years	6 years

The volatility of the options granted prior to the completion of our initial public offering was assumed to be zero. Upon completion of the initial public offering in July 2005, we began using a volatility of 70% to estimate fair value.

During 2004 and 2005, prior to the completion of our initial public offering, stock options were granted at exercise prices that were below the reassessed fair value of the common stock on the date of grant. Accordingly, deferred stock compensation of $8,171,000 was recorded during 2004 and 2005 in accordance with APB Opinion No. 25. The deferred stock compensation will be amortized on a straight-line basis over the vesting period of the related awards, which is generally four years. The related stock-based compensation expense was $479,000 and $1,426,000 during the three and nine months ended September 30, 2005, respectively.

The table below illustrates the effect on net loss and net loss per share attributable to common stockholders had the Company applied the fair value provisions of SFAS No. 123 to employee stock compensation.

	Three months ended September 30,		Nine months ended September 30,	
	2005	2004	2005	2004
	(in thousands, except share and per share amounts)			
Net loss attributable to common stockholders, as reported	$ (4,092)	$ (5,545)	$ (15,248)	$ (13,869)
Deduct: Stock-based employee compensation expense included in net loss	479	304	1,426	306
Add: Stock-based employee compensation expense determined under fair value method	(513)	(358)	(1,428)	(375)
Pro forma net loss attributable to common stockholders	$ (4,126)	$ (5,599)	$ (15,250)	$ (13,938)
Basic and diluted net loss per share attributable to common stockholders	$ (0.45)	$ (236.54)	$ (4.86)	$ (606.88)
Pro forma basic and diluted net loss per share attributable to common stockholders	$ (0.45)	$ (238.84)	$ (4.86)	$ (609.90)

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CRYOCOR, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

Recently Issued Accounting Standards

On December 16, 2004, the Financial Accounting Standards Board, or FASB, issued FASB Statement No. 123 (revised 2004), *Share-Based Payment* (Statement 123R). Statement 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statements of operations over the related service period based on their fair values on the date of grant. Pro forma disclosure is no longer an alternative. Statement 123R must be adopted by public companies no later than January 1, 2006.

The Company plans to adopt Statement 123R using the modified-prospective method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of Statement 123R for all share-based payments granted after the effective date and (b) based on the requirements of Statement 123 for all awards granted to employees prior to the effective date of Statement 123R that remain unvested on the effective date.

As permitted by SFAS No. 123, the Company currently accounts for share-based payments to employees using APB Opinion No. 25 s intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options in the statement of operations. Accordingly, the adoption of Statement 123R s fair value method will have a significant impact on the Company s results of operations, although it will have no impact on the Company s overall financial position. The impact of adoption of Statement 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had the Company adopted Statement 123R in prior periods, the impact of that standard would have approximated the impact under SFAS No. 123 as described in the disclosure of pro forma net loss and loss per share above.

5. 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.

The calculation of pro forma basic and diluted net loss per share attributable to common stockholders assumes the conversion of all shares of Series A, Series B and Series C convertible preferred stock and Series D redeemable convertible preferred stock into shares of common stock using the as-if-converted method, as if such conversion had occurred as of January 1, 2002, or the original issuance date, if later. The calculation of pro forma net loss per share attributable to common stockholders excludes incremental common stock issuable upon exercise of options and outstanding warrants, as their effect would be antidilutive.

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CRYOCOR, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

	Three months ended September 30,		Nine months ended September 30,	
	2005	2004	2005	2004
	(in thousands, except share and per share amounts)			
Historical				
Numerator:				
Net loss attributable to common stockholders	$ (4,092)	$ (5,545)	$ (15,248)	$ (13,869)
Denominator:				
Weighted-average common shares outstanding	9,172,928	23,457	3,218,134	22,903
Weighted-average unvested common shares subject to repurchase	(83,770)	(15)	(82,313)	(50)
Denominator for basic and diluted net loss per share attributable to common stockholders	9,089,158	23,442	3,135,821	22,853
Basic and diluted net loss per share attributable to common stockholders	$ (0.45)	$ (236.54)	$ (4.86)	$ (606.88)
Pro forma				
Net loss attributable to common stockholders	$ (4,092)	$ (5,545)	$ (15,248)	$ (13,869)
Pro forma basic and diluted net loss per share attributable to common stockholders	$ (0.41)	$ (0.89)	$ (2.00)	$ (2.79)
Shares used above	9,089,158	23,442	3,135,821	22,853
Pro forma adjustments to reflect assumed weighted-average effect of conversion of preferred stock	906,653	6,242,080	4,470,925	4,947,480
Pro forma shares used to compute basic and diluted net loss per share attributable to common stockholders	9,995,811	6,265,522	7,606,746	4,970,333
Historical outstanding anti-dilutive securities not included in diluted net loss per share attributable to common stockholders calculation				
Redeemable convertible preferred stock (1)		2,808,521		2,808,521
Convertible preferred stock (1)		1,561,820		1,561,820
Options to purchase common stock	1,083,644	1,156,485	1,083,644	1,156,485
Warrants to purchase common and convertible preferred stock	83,491	166,307	83,491	166,307
	1,167,135	5,693,133	1,167,135	5,693,133

(1) Preferred stock is shown on an if-converted to common stock basis.

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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 our 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, the timing for product sales in the U.S., if any, our anticipated continuing net losses and anticipated increases in research and development and selling, general and administrative expenses, the amount and timing of future spending to develop existing and new product candidates, 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 U.S. for our cryoablation system for use in treating AFL and AF, risks associated with our ability to successfully commercialize our cryoablation system in the U.S. and elsewhere if our cryoablation system is approved for use in the U.S., 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 below and in the section of this Form 10-Q entitled Risk Factors Related to Our Business 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 Item 1 of Part I of this Form 10-Q. We also urge readers to review and consider our disclosures describing various factors that affect our business set forth in the section of this Form 10-Q entitled Risk Factors Related to Our Business, as well as in our prospectus filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the Securities and Exchange Commission on July 14, 2005, including the disclosures under the captions Management s Discussion and Analysis of Financial Condition and Results of Operations and Risk Factors Related to Our Business and the audited financial statements and notes thereto contained therein.

Overview

We have developed and manufacture a minimally invasive, disposable catheter system based on our proprietary cryoablation technology for the treatment of cardiac arrhythmias. We have focused our initial development efforts on atrial fibrillation, or AF, and atrial flutter, or AFL, the two most common and difficult to treat arrhythmias. AF is the most prevalent arrhythmia; AFL can lead to, and often coexists with, AF. Since inception, we have devoted substantially all of our resources to developing our cryoablation system, raising capital and preparing for the possible United States commercialization of our cryoablation system.

We obtained our CE Mark in early 2002 and are approved in Europe for the treatment of AF, AFL and other supraventricular tachycardias. We began our U.S. pivotal trial for AFL in late 2003, and our U.S. pivotal trial for AF in late 2004. In July 2005, we submitted the final module, the results of our clinical trial, of our PMA for AFL to the U.S. Food and Drug Administration, or FDA. If the outcome of the FDA s regulatory review of our PMA application is favorable, we may receive regulatory approval for our cryoablation system in the U.S. for AFL in 2006. If our AF clinical trial and the regulatory review proceed as anticipated, we may receive regulatory approval in the U.S. for our cryoablation system for the treatment of AF in 2008.

At present, we have a wholly owned subsidiary in Cologne, Germany that sells our product in Germany, Belgium, and the Netherlands. We have signed distributor agreements for the sale of our cryoablation system in the United Kingdom and Italy. In 2006, we intend to begin selling our products in Europe only through distributors with support provided by one or two CryoCor employees. If we obtain marketing approval from the FDA, we plan to commercialize in the U.S. with a direct CryoCor sales force.

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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 U.S., and for at least some time after any commercial launch of our product in the U.S. We have financed our operations primarily through private placements of 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 expenses and commissions and transaction costs.

Clinical Status

In July 2005, we submitted the final module of our PMA for AFL, with the results of our clinical trial, to the FDA. In September 2005, as part of the standard PMA review process, the FDA completed its inspection of CryoCor s San Diego facility. Additionally, in late October 2005, the Company received a request from the FDA for additional data to allow for the FDA s continued review of the PMA. The Company has provided the information to the FDA and is awaiting further comment. The questions presented by the FDA were primarily related to additional statistical analysis of the patient data and queries on clinical interpretations and data related to specific patients. The FDA indicated in its letter that its review may take an additional 180 days. If the outcome of the FDA s regulatory review of our PMA application is favorable, we believe we may receive approval in 2006.

We are continuing to enroll patients for our pivotal trial for AF that began in December 2004, and have enrolled 77 patients as of November 1, 2005. We currently have 20 clinical sites that are open for patient enrollment and we expect to add between two to four additional clinical sites. At our expected patient enrollment rate of 10 patients per month, we believe we will complete enrollment in our AF pivotal trial by mid-2006, with an expected PMA submission to the FDA in mid-2007.

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 U.S., which has prevented us from providing the resources necessary to broadly market our cryoablation system in Europe or 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 U.S. product approval is obtained, because European approvals, which are designed primarily to demonstrate product safety, are not as compelling for European physician adoption as U.S. approvals, which must demonstrate efficacy and safety. We do not expect to generate revenues in the U.S. until our PMA for AFL has been approved by the FDA and we initiate the sales of our products. If such approval is obtained, sales will not occur until 2006 at the earliest. 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, costs associated with clinical trials, pre-clinical activities, regulatory activities, research-related overhead expenses and fees paid to external service providers and contracts with research organizations, which conduct certain research and development activities on our behalf. We expense research and development costs as they are incurred. We expect our research and development expenses to increase as we complete the development of our next generation product, the Quantum catheter, research new product opportunities and conduct additional clinical trials, as necessary.

Selling, General and Administrative Expenses. Our selling, general and administrative expenses consist primarily of cash and non-cash stock 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. We expect our selling, general and administrative expenses to increase substantially due to the costs associated with operating as a publicly-traded company and the infrastructure necessary to support any commercialization of our product candidates.

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.

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Three months ended September 30, 2004 and 2005

Product Sales. Product sales increased $11,000 to $152,000 for the three months ended September 30, 2005, compared to $141,000 for the three months ended September 30, 2004. The increase was primarily due to a modest increase in catheter shipments in Europe during 2005. We had $245,000 in deferred revenue as of September 30, 2005 related to catheters that have been shipped to European customers, but for which product sales revenue may not yet be recognized under our revenue recognition policies.

Cost of Sales. Cost of sales increased $12,000 to $650,000 for the three months ended September 30, 2005, compared to $638,000 for the three months ended September 30, 2004. The increase reflected the increased catheter shipments during the three months ended September 30, 2005.

Research and Development Expenses. Research and development expense decreased $225,000 to $1.8 million for the three months ended September 30, 2005, compared to $2.1 million for the three months ended September 30, 2004. The decrease was primarily related to lower pre-clinical costs and lower clinical trial costs related to our AF pivotal trial as compared to costs incurred in 2004 from the AFL pivotal trial and our AF and AFL feasibility studies. This decrease of $340,000 was partially offset by higher non-cash stock based compensation expenses of $144,000.

Selling, General and Administrative Expenses. Selling, general and administrative expense increased $123,000 to $1.7 million for the three months ended September 30, 2005, compared to $1.6 million for the three months ended September 30, 2004. The increase was primarily due to an increase in non-cash stock-based compensation expenses of $36,000 and general increased costs associated with being a public company.

Nine months ended September 30, 2004 and 2005

Product Sales. Product sales increased $224,000 to $682,000 for the nine months ended September 30, 2005, compared to $458,000 for the nine months ended September 30, 2004. The increase was due to increased catheter shipments and usage in Europe during 2005. We had $245,000 in deferred revenue as of September 30, 2005 related to catheters that have been shipped to European customers, but for which product sales revenue may not yet be recognized under our revenue recognition policies.

Cost of Sales. Cost of sales increased $160,000 to $2.1 million for the nine months ended September 30, 2005, compared to $2.0 million for the nine months ended September 30, 2004. The increase reflected the increased catheter shipments during the nine months ended September 30, 2005, and included additional costs of approximately $200,000 to recall our Model 1200 catheter out of Europe and to withdraw the use of the Model 1200 catheter from use in our clinical trials in the U.S.

Research and Development Expenses. Research and development expense increased $391,000 to $5.9 million for the nine months ended September 30, 2005, compared to $5.5 million for the nine months ended September 30, 2004. The increase was primarily related to an increase in non-cash stock-based compensation expenses of $750,000, partially offset by lower payroll costs and lower clinical trial costs related to our AF pivotal trial as compared to higher costs incurred in 2004 associated with our AFL pivotal trial and our AF and AFL feasibility studies.

Selling, General and Administrative Expenses. Selling, general and administrative expense increased $1.0 million to $4.7 million for the nine months ended September 30, 2005, compared to $3.7 million for the nine months ended September 30, 2004. The increase was primarily due to an increase in non-cash stock-based compensation expenses of $431,000 and $317,000 in other compensation-related costs and general increases in costs associated with being a public company.

Liquidity and Capital Resources

We have incurred losses since our inception in August 2000. As of September 30, 2005, we had an accumulated deficit of $65.3 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 September 30, 2005, 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 expenses and commissions and transaction costs. Concurrent with the closing of the initial public offering, all of our outstanding preferred shares converted into shares of common stock.

As of September 30, 2005, we had long-term debt and capital lease obligations outstanding of $6.5 million, working capital of $34.0 million and cash and cash equivalents and investments totaling $34.5 million. We currently invest our cash in money market funds and U.S. government or corporate bond securities. Based upon our current level of expenditures, we believe the proceeds from our initial public offering, together with cash flows from operating activities will be adequate to

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meet our anticipated cash requirements for working capital at least through 2006. In March 2005, we entered into a debt facility and borrowed $7.0 million thereunder. As part of that transaction, we repaid in full an outstanding bank loan of $1.8 million. The new debt facility bears interest at a rate of 11.25% per year and requires interest-only payments through June 2007, at which time the principal is due and payable.

Net Cash Used in Operating Activities. Net cash used in operating activities increased $1.7 million to $11.2 million for the nine months ended September 30, 2005, compared to $9.5 million for the nine months ended September 30, 2004. The net cash used in each of these periods primarily reflects the net loss for those periods, offset in part by depreciation, non-cash stock based compensation and changes in operating assets and liabilities.

Net Cash Used in Investing Activities. Net cash used in investing activities increased $13.1 million to $13.3 million for the nine months ended September 30, 2005, compared to $167,000 for the nine months ended September 30, 2004. Cash used in investing activities relates to purchases and disposals of property and equipment as well as purchases and maturities of investments. The increase in net cash used in investing activities for the nine months ending September 30, 2005 is related to purchases of investments subsequent to the receipt of proceeds from the Company s initial public offering in July 2005.

Net Cash Provided by Financing Activities. Net cash provided by financing activities increased $29.1 million to $40.4 million for the nine months ended September 30, 2005, compared to $11.3 million for the nine months ended September 30, 2004. Net cash provided by financing activities during the nine months ended September 30, 2004 was primarily attributable to our issuance of convertible preferred stock, offset by payments against capital leases and bank debt. Net cash provided by financing activities during the nine months ended September 30, 2005 was primarily attributable to the Company s initial public offering which had net proceeds of $35.4 million as well as borrowing under the Company s new debt facility of $7.0 million, offset by the pay-off of an existing term loan and payments on existing capital leases.

Operating Capital and Capital Expenditure Requirements.

To date, we have had limited commercial sales in Europe, no commercial sales in the U.S., and we have not yet achieved profitability. We do not currently have any products approved for sale in the U.S. 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 and selling infrastructure and prepare for the potential commercial launch of our cryoablation system in the U.S. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need to generate significant product revenues to achieve profitability.

We incurred additional costs in the second quarter of 2005 of approximately $200,000 to recall our Model 1200 out of Europe and to withdraw the use of the Model 1200 from our clinical trial use in the U.S. These costs covered the return of the affected Model 1200 catheters, the costs to manufacture and issue replacement CryoBlator catheters, related shipping and travel costs and issuance of credits to customers in the event they declined a replacement catheter. Consistent with our revenue recognition policies, no revenue had been recognized related to any of the Model 1200 catheters that were returned. All Model 1200 catheters have been accounted for and the recall has been completed.

We do not expect to generate significant product revenues until we obtain marketing approval for and begin selling our cryoablation system in the U.S. We believe that the net proceeds from our initial public offering, together with our cash and cash equivalent balances, will be sufficient to meet our anticipated cash requirements through 2006. If our available cash and cash equivalents and net proceeds from our initial public offering are insufficient to satisfy our liquidity requirements, or if we develop additional products, we may seek to sell additional equity or debt securities or obtain an additional credit facility. The sale of additional equity and debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of 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, which could harm our business.

We anticipate spending at least $1.8 million in external costs over the next 24 months for clinical trials and regulatory activities related to using our cryoablation system to treat AFL and AF. In addition, if we receive FDA regulatory approval of our cryoablation system for the treatment of AFL, we expect to incur increased sales, marketing, manufacturing and compliance expenses. We believe the costs for our clinical trials for AFL and AF, any increased sales and marketing expenses, and the development of our existing product candidates will require approximately $14.1 million over the next 15 months, with our remaining cash and cash equivalents being used to prosecute and maintain our intellectual property portfolio, to produce consoles, to fund our facility, manufacturing and quality system operations and to fund our working capital and general corporate requirements during this same period. We estimate that the development of new product

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candidates that are still being researched will cost between $5.5 million and $7.5 million per product candidate, will take at least three years to complete and will require additional financial resources beyond our existing financial resources.

At present, we have a wholly owned subsidiary in Cologne, Germany that sells our product in Germany, Belgium, and the Netherlands. We have signed distributor agreements for the sale of our cryoablation system in the United Kingdom and Italy. We intend to broaden our commercial reach in Europe through additional distributor agreements and we intend to restructure our Germany subsidiary and sell our products in Europe only through distributors. If we obtain marketing approval from the FDA, we plan to commercialize in the U.S. with our own sales force. We expect to incur approximately $350,000 in costs in connection with the anticipated restructuring of our German subsidiary.

We have filed requests with the U.S. Patent and Trademark Office seeking to invoke interference proceedings involving two patents owned by CryoCath Technologies, Inc. and two of our patent applications to determine who was the first to invent certain primary and pre-cooling refrigeration system designs, and certain heat exchanger designs. If 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 U.S. We may incur substantial costs in pursuit of these proceedings.

Our forecasts of the period of time through which our financial resources will be adequate to support our operations and the costs to complete 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 Related to Our Business section of this Form 10-Q, and in our prospectus filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the Securities and Exchange Commission on July 14, 2005, as well as our other publicly available documents. We have based these estimates on assumptions that may prove to be wrong, and we may be required to utilize our available capital resources sooner than we currently expect.

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

- the 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 likely FDA advisory panel review;
- 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 establishing sales, marketing and distribution capabilities;
- the extent and level of reimbursement for cryoablation;
- the commercial acceptance of our product following the initiation of our sales efforts in the U.S.;

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 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.

We also have service agreements with clinical sites, individuals and contract research organizations for the conduct of our AF clinical 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 were obligated to pay approximately $450,000 in fees and expenses through September 30, 2005 in connection with our AF pivotal study. 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 cost of completing our AF pivotal study will be approximately $1.2 million in the next 15 months. 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

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connection with the preparation of our regulatory filings, including costs associated with employees and consultants and related legal expenses.

Critical Accounting Policies and Significant Judgments and Estimates

Our management s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. 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.

Stock-Based Compensation.

We account for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, Financial Accounting Standards Board, or FASB, Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation*, APB Opinion No. 25, an interpretation of APB Opinion No. 25 and related interpretations. We have adopted the disclosure-only provisions of Statement of Financial Accounting Standards, or SFAS, No. 123, *Accounting for Stock-Based Compensation*, as amended.

The information regarding net loss as required by SFAS No. 123, presented in Note 3 to our consolidated financial statements, has been determined as if we had accounted for our employee stock options under the fair value method. The resulting effect on net loss pursuant to SFAS No. 123 is not likely to be representative of the effects on net loss pursuant to SFAS No. 123 in future years, since future years are likely to include additional grants and the irregular impact of future years vesting.

Stock compensation expense, which is a non-cash charge, results from employee stock option grants at exercise prices that, for financial reporting purposes, are deemed to be below the estimated fair value of the underlying common stock on the date of grant. Given the absence of an active market for our common stock and the lack of prospective acquirors of CryoCor through 2004, our board of directors determined the estimated fair value of our common stock on the date of grant based on several factors, including liquidation preferences on our preferred stock of $44.9 million and $65.3 million at December 31, 2003 and 2004, respectively, progress and milestones achieved in our business, our financial condition, including our working capital which ranged from $2.9 million to $11.6 million during 2004, sales of convertible preferred stock, valuations at which other private companies at a similar stage of development had been acquired, and changes in valuation of existing comparable publicly-traded companies. The board concluded that the preferred stockholders held securities representing the majority of the fair value of CryoCor on the date of grant under each of these scenarios.

In connection with the initiation in 2005 of our initial public offering efforts, we reassessed the estimated fair value of our common stock during 2004. Stock compensation expense per share equals the difference between the reassessed fair value of our common stock and the option

exercise price on the date of grant and is amortized on a straight-line basis over the vesting period of the option which is generally four years.

Revenue Recognition.

We comply with SEC Staff Accounting Bulletin No. 101, *Recognition in Financial Statements*, or SAB 101, as amended by SAB 104, and SFAS No. 48, *Revenue Recognition When Right of Return Exists*. SAB 101 and SFAS No. 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.

Customers have the right to return products until one month following expiration of the product, which is currently six months after its production. As we have had limited sales of our products, we currently recognize revenues when the customer has paid for the product and the right of return has expired.

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As our products 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 services and we accrue the cost as the services to the patient are provided.

Recently Issued Accounting Standards

On December 16, 2004, the FASB issued FASB Statement No. 123 (revised 2004), *Share-Based Payment* (Statement 123R), which is a revision of SFAS No. 123. Statement 123R supersedes APB Opinion No. 25 and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in Statement 123R is similar to the approach described in SFAS No. 123. However, Statement 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statement of operations based on their fair values. Pro forma disclosure is no longer an alternative. Statement 123R must be adopted by public companies by January 1, 2006.

We plan to adopt Statement 123R using the modified-prospective method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of Statement 123R for all share-based payments granted after the effective date and (b) based on the requirements of Statement 123 for all awards granted to employees prior to the effective date of Statement 123R that remain unvested on the effective date.

As permitted by SFAS No. 123, we currently account for share-based payments to employees using APB Opinion No. 25 s intrinsic value method and, as such, generally recognize no compensation cost for employee stock options. Accordingly, the adoption of Statement 123R s fair value method will have a significant impact on our results of operations, although it will have no impact on our overall financial position. The impact of adoption of Statement 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had we adopted Statement 123R in prior periods, the impact of that standard would have approximated the impact under SFAS No. 123 as described in the disclosure of pro forma net loss and loss per share in Note 4 to our consolidated financial statements.

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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 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 are still being developed, and all but our cryoablation system are still in early stages of development. Our product candidates will require significant additional development, clinical trials, regulatory clearances or approvals by the FDA and additional investment before they can be commercialized in the U.S. We anticipate that our cryoablation system will not be approved for commercialization in the U.S. by the FDA for any indication until 2006, if at all.

As of September 30, 2005, we had an accumulated deficit of $65.3 million. We have incurred net losses in each year since our inception in August 2000, including net losses of $11.2 million for the year ended December 31, 2003, $15.8 million for the year ended December 31, 2004 and $12.5 million for the nine months ended September 30, 2005. 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 12 months will be for research and development and conducting our clinical trials. We expect that our general and administrative and legal costs will increase due to the additional operational and regulatory burdens applicable to public companies. In addition, if we receive FDA marketing approval of our cryoablation system, 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 U.S., and we may not receive it. We may not become profitable even if we obtain FDA approval and succeed in commercializing our cryoablation system in the U.S. As a result, we cannot be sure when we will become profitable, if at all.

We may 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, product development programs or commercialization efforts.

We may need to raise substantial additional capital to:

fund our operations and clinical trials;

continue our research and development;

scale up our manufacturing operations;

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 the net proceeds from our initial public offering, together with our existing cash and cash equivalent balances, will be sufficient to meet our anticipated cash requirements into the second half of 2006. However, our future funding requirements will depend on many factors, including:

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 FDA advisory panel review;

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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;

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 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 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 are dependent on the success of our cryoablation system, which has not been approved by the FDA for any indication for commercialization in the U.S. If we are unable to achieve our product development goals, gain FDA approval to commercialize our cryoablation system in the U.S., 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 U.S. 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 estimates, in some cases for reasons beyond our control, and we may never achieve some or all of these milestones. If we do not meet these estimated milestones as publicly disclosed for both indications, we may be unable to commercialize our products in the U.S., or any commercialization of our products in the U.S. 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 U.S., 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.

We cannot assure you that we will obtain FDA approval to market our cryoablation system in the U.S. 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 U.S. 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.

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Although we investigated a number of allegations regarding our FDA compliance process made by a former senior executive and found the allegations to be without substance, if the FDA finds problems with our compliance process, it could withhold approval for our products or cause us to suspend our operations until the problems are corrected.

In 2004, a lawyer representing our former CFO sent a letter to us making certain claims against us for wrongful termination of our former CFO based on theories of breach of contract and violations of public policy. The letter also contained allegations that there were irregularities and improprieties in our clinical trials and our FDA compliance process. The letter did not contain any specific evidence to support these allegations. Our board of directors formed a special committee to specifically investigate the FDA related allegations. The special committee engaged our outside regulatory counsel, who had advised us previously in matters relating to our FDA compliance process, to assist in the investigation. The investigation by our outside regulatory counsel was limited in time and scope and, as with any investigation, cannot be expected to or be relied upon to detect all instances of impropriety. The investigation did not address the likelihood of FDA marketing approval of our cryoablation system nor did it address the accuracy or completeness of our clinical trial data or the medical interpretations of any such data. Therefore, this investigation cannot be relied upon as an assurance that our clinical trial data are accurate or complete or as an indicator of the likelihood of FDA approval for any of our products. Our outside regulatory counsel reported that it had found no evidence of fraud, lack of data credibility, or that any false or misleading information had been provided to the FDA. The special committee concluded that the allegations in the letter concerning clinical trial irregularities and FDA compliance matters were without substance. However, the results of these investigations do not provide assurance that the FDA will not find problems with our compliance with FDA regulations and either withhold approval for our products or cause us to suspend operations until the problems are corrected to its satisfaction.

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 U.S.

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, although we believe the efficacy data in the AFL pivotal trial will meet the predefined objective performance criterion, or OPC, the assessment of efficacy is subject to interpretation, and the FDA could determine that the data do not meet the OPC. Additionally, the FDA has advised us that our chronic efficacy data will be considered as an important factor for marketing approval for the AFL indication and that it must meet the chronic efficacy OPC for RF ablation. If the FDA concludes that the AFL or AF trials have failed to demonstrate safety and effectiveness, we will not receive FDA approval to market our cryoablation system in the U.S. for those indications.

The FDA has expressed concerns about aspects of our clinical trials, which could lead the FDA to delay or deny marketing approval.

The FDA has expressed concerns about many aspects of our clinical trials, including the following:

- we did not conduct a randomized trial against an RF ablation device in our AFL pivotal trial;
- the objective performance criteria, or OPCs, against which we measure 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;

applicability of the RF precedents that we used to guide the design of our clinical trials;

determination of appropriate endpoints, including the use of acute efficacy rather than chronic efficacy 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 agree that we have demonstrated safety and effectiveness even if our data were to meet all of our chosen endpoints. 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.

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Modifications to our cryoablation system and protocol during our pivotal AFL trial could lead the FDA to conclude that the trial data are not sufficient to establish safety and effectiveness, which could delay or prevent marketing approval.

During our pivotal AFL trial, we modified our cryoablation system and the protocol used during the trial. Measurement of the acute efficacy endpoint was modified while the trial was ongoing. About one half of the subjects were treated under a protocol requiring the investigator to wait 60 minutes after ablation to measure acute efficacy, while the remainder were treated under a revised protocol requiring only a 30 minute wait. In addition, about one half of the subjects were treated with the Model 1100 catheter of our cryoablation system and the remainder were treated with the Model 1200 catheter. Additionally, we are filing our AFL PMA with our CryoBlator catheter, which was not used in the trial. The FDA could delay or deny approval for our AFL PMA because no patients were treated with our CryoBlator catheter in the pivotal AFL trial.

Although the FDA granted regulatory approval to study clinically the Model 1200 catheter and to assess acute efficacy at 30 minutes rather than 60 minutes in the pivotal AFL trial, it could determine upon review of the study data that it is not scientifically valid to pool the data from subjects treated before the changes with those treated after the changes were implemented. If so, the FDA could deny approval for marketing, or require us to gather additional supporting data through the conduct of continued or additional clinical trials, which could cause a significant delay in obtaining marketing approval and harm our business, financial condition and results of operations. These same issues could arise during our AF pivotal trial if additional modifications to our cryoablation system or to the protocol become necessary during that trial.

In the AFL pivotal trial, our acute safety data did not meet the 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 acute safety data for serious adverse events, or SAEs, exceeded the OPC for RF ablation. We intend to have these SAEs reviewed by an independent body to determine whether they are related to the device or procedure or to the subject s underlying cardiac disease. We cannot assure you that the FDA will accept the body s determinations or that the FDA will accept a revised safety analysis that excludes the SAEs that are determined to be unrelated to the device and procedure. If the FDA does not accept our proposed approach, the FDA may conclude that we have failed to demonstrate the safety of our cryoablation system and delay or deny marketing approval.

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

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

- the FDA places our pivotal trial on hold;
- supply shortages of the catheters used in the pivotal trial;
- recalls of the catheters used in the pivotal trial;
- subjects do not enroll in our pivotal trial at the rate we currently expect;

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;

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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; 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 dropped out of the trial prior to completing the trial. Drop out rates may increase when 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. 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.

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 eventually need 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 U.S. 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 U.S., 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 freeze the tip of a catheter 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 allow 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. Although no adverse events in patients have been reported associated with a leak of a Model 1200 catheter, we cannot assure you that none will occur.

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At the time of the discovery of the inadequate seals in the Model 1200 catheters, we were phasing it out and replacing it with our CryoBlator catheter. Although similar in form and function to our Model 1200 catheter, the CryoBlator is engineered differently at the joint where the potential for poor seals in the Model 1200 catheter occurred. We cannot assure you that our CryoBlator catheter will not experience similar problems as those experienced with the Model 1200 catheter, or other problems including problems that could cause adverse events in patients, or that our CryoBlator catheter will not be subject to a product recall in the future.

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

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

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

The PVI procedure has been associated with pulmonary vein stenosis, a narrowing of the pulmonary vein that can have serious adverse health implications. Other techniques for AF ablation have been associated with risks such as the formation of esophageal fistulas, or holes, 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, 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;

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.

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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 efficacy 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.

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 QSRs, 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 a 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.

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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 U.S. patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. Currently, we own or license 28 issued U.S. patents and 30 pending U.S. patent applications covering various aspects of our products and technology.

We also own or license 18 patents issued outside of the U.S. and have a number of pending patent applications outside the U.S. Limitations on patent protection in some countries outside the U.S., 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 U.S. In addition, laws of foreign countries may not protect our intellectual property to the same extent as would laws of the U.S. 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 U.S. 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.

For example, statements attributed to employees of CryoCath suggest that CryoCath may believe that aspects of our cryoablation system may be covered by one or more U.S. patents owned by CryoCath. Some of these patents relate to cryosurgical devices and methods of using such devices for treating patients.

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.

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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 U.S., 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 U.S. Patent and Trademark Office or in other proceedings outside the U.S., including oppositions, to determine priority of invention or patentability. For example, we have filed requests with the U.S. Patent and Trademark Office 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.

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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 U.S. 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 U.S. and additional sales of our cryoablation system in Europe and adversely impact our business.

If we are unable to manage our expected growth, our future revenue and operating results may be adversely affected.

If we receive FDA approval for 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 is expected to 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 anticipated growth. To manage our growth and to commercialize our cryoablation system in the U.S., we will 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 are 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 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 clinical trials and any subsequent commercialization efforts in the U.S., 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. To produce our cryoablation system in the quantities that we believe will be required to meet anticipated market demand in the event that we receive regulatory approval, 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. 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 U.S. if we receive the required regulatory approval from the FDA, or to meet demand for our cryoablation system in Europe. If we obtain regulatory approval from the FDA for our cryoablation system 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, 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.

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 maintain stringent quality controls, or if contamination problems arise, our clinical development and potential

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commercialization efforts in the U.S. 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 efficacy, 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 U.S. 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 U.S., 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 U.S. and have limited experience as a company in the sales, marketing and distribution of medical devices. We plan to establish our own sales force to market our cryoablation system in the U.S. Developing a sales force is expensive and time 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. We may choose to contract with third parties, including distributors or agents, to perform sales, marketing and distribution services in the U.S. If we enter into arrangements with third parties to perform sales, marketing and distribution services in the U.S., our product revenues could be lower than if we

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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 entered into a distribution agreement with CryoCor GmbH, our wholly-owned subsidiary organized under the laws of Germany to sell our products in The Netherlands, Germany, Belgium, and Luxembourg. We have also signed distribution agreements with third parties in Europe to market and sell our cryoablation system in Italy and the United Kingdom. These distribution agreements are generally short-term in duration, and we will have to pursue alternative distributors if we or our distributors terminate or the agreements are not renewed. If our relationships with our distributors do not progress as anticipated, if we are unable to identify alternative distributors, 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 anticipate that we will have to enter into additional distribution arrangements to market and sell our cryoablation system internationally.

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 occur, 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 is 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.

We intend to market 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.

A key element of our strategy is to discover, develop and commercialize new products for the treatment of AFL and AF as extensions of, or in addition to, our cryoablation system. We are seeking to do so through our internal research programs and we may explore strategic collaborations for the development of new products utilizing our core technology. 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;
- product candidates may on further study be shown to have harmful side effects or other characteristics that indicate they are unlikely to be effective; and

If we fail to develop and commercialize new product candidates, our business will suffer.

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, particularly Dr. Gregory M. Ayers, our Chief Executive Officer. The loss of services of Dr. Ayers, or one or more of our other members of senior management, could delay or prevent the successful completion of our pivotal trials or the commercialization of our cryoablation system in the U.S. Although we have employment agreements with each of our executive officers, their employment with us is at will, and each executive officer can terminate his agreement with us at any time. We do not carry key person life insurance on any of our officers other than Dr. Ayers. This insurance may not continue to be available on commercially reasonable terms and may prove inadequate to compensate us for the loss of his services.

Our vice president of research and development recently left CryoCor and we may need to hire a replacement. We will need to hire additional qualified scientific, commercial, regulatory, quality assurance and control and administrative personnel as we continue to expand our manufacturing, research and development activities. We may not be able to attract and retain qualified personnel on acceptable terms given the competition for such personnel among medical device

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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.

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 Securities and Exchange Commission, or the SEC, and the NASDAQ Stock Market, 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 profitably, if at all. In the U.S. 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 are 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 annual management assessments of the effectiveness of our internal controls over financial reporting and 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 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 can 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 U.S. currency exchange rates may increase our expenses or reduce our revenues.

We market our cryoablation system in certain foreign markets through CryoCor GmbH and other European distributors. The related distribution agreements may provide for payments in a foreign currency. Accordingly, if the U.S. dollar strengthens against the euro, our U.S. 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;
- 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;

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regulatory developments in the U.S. and foreign countries;

ability to manufacture our products to commercial standards;

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.

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 October 15, 2005, beneficially owned approximately 65% 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.

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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 and corporate debt 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. However, we do not expect fluctuations in foreign exchange rates to have a material impact on our financial condition or results of operations.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Regulations under the Securities Exchange Act of 1934, or the Exchange Act, require public companies to maintain disclosure controls and procedures which are defined to mean a company s controls and other procedures that are designed to ensure that information required to be disclosed in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in 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-Q for the period ending June 30, 2005, filed with the Securities and Exchange Commission on August 26, 2005, we are not currently involved in any material legal proceedings.

Item 2. 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 became effective July 13, 2005, and the offering commenced the same day. The offering has been terminated. The net offering proceeds to us after deducting underwriters discounts and commissions and expenses totaled approximately $35.4 million. Of the net offering proceeds, through September 30, 2005, approximately $1.5 million of the net proceeds have been used for research and development activities, which include clinical trial activities, approximately $456,000 have been used for sales and marketing activities, and approximately $921,000 have been used for working capital and general corporate purposes. We have invested 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 4. Submission of Matters to a Vote of Security Holders

On July 6, 2005, our stockholders acted by written consent to approve and adopt (i) an amendment to our Amended and Restated Certificate of Incorporation then in effect, or the Pre-IPO Certificate, in order to effect a 1-for-31 reverse split of our Common Stock immediately prior to the effective time of the initial public offering, (ii) an amendment and restatement of our Pre-IPO Certificate, as amended by the amendment discussed above, in order to, among other things, delete the provisions in the Pre-IPO Certificate designating the rights and preferences of our Preferred Stock, all of which was converted into Common Stock immediately prior to the closing of our initial public offering, adjust the authorized number of shares of Common Stock to 75,000,000 shares, provide for 5,000,000 shares of undesignated Preferred Stock and provide for certain stockholder protection measures; (iii) an amendment to our Bylaws then in effect, or the Pre-IPO Bylaws, to among other things, delete the provisions in the Pre-IPO Bylaws that were not applicable to public companies and to provide for certain stockholder protection measures; and (iv) the 2005 Equity Incentive Plan, 2005 Employee Stock Purchase Plan, 2005 Non-Employee Directors Stock Option Plan and form of Indemnity Agreement for our executive officers and directors.

Stockholders holding an aggregate of 4,343,750 shares of Common Stock, 1,620,368 shares of Series B Preferred Stock, 4,085,640 shares of Series C Preferred Stock and 123,779,301 shares of Series D Preferred Stock approved the matters set forth above, which were contained in the written consent, and stockholders holding approximately 4,219,984 shares of Common Stock, 291,456 shares of Series A Preferred Stock, 370,370 shares of Series C Preferred Stock and 15,196,572 shares of Series D Preferred Stock did not vote with respect to the matters set forth above, which were contained in the written consent. The above action was effected pursuant to an action by written consent of our stockholders in compliance with Section 228 of the Delaware General Corporation.

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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.

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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: November 7, 2005

CryoCor, Inc.

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