CRYOCOR INC
Form 10-Q
November 08, 2006
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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, 2006

OR

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

Commission File Number 000-51410

CryoCor, Inc.

(Exact name of Registrant as specified in its Charter)

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

9717 Pacific Heights Boulevard

San Diego, California 92121

(Address of Principal Executive Offices, including Zip Code)

(858) 909-2200

(Registrant s Telephone Number, Including Area Code)

N/A

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

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

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

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

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

The number of shares of the Registrant s common stock outstanding as of October 31, 2006 was 10,801,785.

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CRYOCOR, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE PERIOD ENDED SEPTEMBER 30, 2006

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

CryoCor, Inc.

Consolidated Balance Sheets

(in thousands except share amounts)

	September 30, 2006 (Unaudited)	December 31, 2005
Assets		
Current assets:		
Cash and cash equivalents	$ 4,925	$ 10,583
Short-term investments	16,272	20,363
Accounts receivable, net	73	100
Inventories, net	877	718
Prepaid expenses and other current assets	773	756
Total current assets	22,920	32,520
Property and equipment, net	614	680
Other assets	208	244
Total assets	$ 23,742	$ 33,444
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 181	$ 488
Accrued compensation	772	758
Accrued clinical development liabilities	845	751
Accrued liabilities	337	427
Deferred revenue	93	205
Short-term debt	6,785	
Capital lease obligation, current portion		2
Total current liabilities	9,013	2,631
Long-term debt		6,570
Stockholders equity:		
Common stock, $0.001 par value, 75,000,000 shares authorized; 10,799,228 and 10,643,999 shares issued and outstanding at September 30, 2006 and December 31, 2005, respectively	11	11
Additional paid in capital	95,773	99,089
Deferred stock compensation		(4,964)
Accumulated other comprehensive income	109	67
Accumulated deficit	(81,164)	(69,960)
Total stockholders equity	14,729	24,243
Total liabilities and stockholders equity	$ 23,742	$ 33,444

See accompanying notes.

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CryoCor, Inc.

Consolidated Statements of Operations

(in thousands except per share amounts)

(Unaudited)

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2006	2005	2006	2005
Product sales	$ 214	$ 152	$ 486	$ 682
Operating expenses:				
Cost of sales	542	728	1,852	2,325
Research and development	1,369	1,677	4,295	5,492
Selling, general and administrative	1,672	1,764	5,618	4,895
Total costs and expenses	3,583	4,169	11,765	12,712
Loss from operations	(3,369)	(4,017)	(11,279)	(12,030)
Interest income	274	252	883	297
Interest expense	(268)	(327)	(808)	(751)
Net loss	(3,363)	(4,092)	(11,204)	(12,484)
Dividends and accretion to redemption value of redeemable convertible preferred stock				(2,662)
Cumulative dividends on Series C preferred stock				(102)
Net loss attributable to common stockholders	$ (3,363)	$ (4,092)	$ (11,204)	$ (15,248)
Basic and diluted net loss per share attributable to common stockholders	$ (0.31)	$ (0.45)	$ (1.04)	$ (4.86)
Shares used to compute basic and diluted net loss per share attributable to common stockholders	10,768	9,089	10,726	3,136

See accompanying notes.

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CryoCor, Inc.

Consolidated Statements of Cash Flows

(in thousands)

(Unaudited)

	Nine months ended September 30,	
	2006	**2005**
Operating activities		
Net loss	$ (11,204)	$ (12,484)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	221	351
Non-cash stock based compensation	1,534	1,545
Amortization of warrants	215	155
Amortization of premium/discount on short-term investments.	(98)	(1)
Changes in operating assets and liabilities:		
Accounts receivable	33	(156)
Inventories	(148)	154
Prepaid expenses and other assets	24	(530)
Accounts payable	(309)	6
Deferred revenue	(123)	(18)
Accrued liabilities	34	(216)
Net cash used in operating activities	(9,821)	(11,194)
Investing activities		
Purchases of property and equipment	(155)	(163)
Purchases of investments	(17,027)	(13,135)
Maturities of investments	21,275	
Net cash provided by (used in) investing activities	4,093	(13,298)
Financing activities		
Net proceeds from issuance of common stock		35,426
Proceeds from exercise of stock options	92	142
Proceeds from long-term debt		7,000
Principal payments on capital lease	(2)	(68)
Principal payments on long term debt		(2,084)
Net cash provided by financing activities	90	40,416
Effect of exchange rate changes on cash and cash equivalents	(20)	(12)
Net increase (decrease) in cash and cash equivalents	(5,658)	15,912
Cash and cash equivalents at beginning of period	10,583	5,436
Cash and cash equivalents at end of period	$ 4,925	$ 21,348
Supplemental disclosures of cash flow information:		
Cash payments for interest	$ 591	$ 746

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, is a medical technology company that has developed and manufactures a minimally invasive, disposable catheter system based on proprietary cryoablation technology for the treatment of cardiac arrhythmias.

In 2001, the Company established a wholly owned German subsidiary, CryoCor GmbH, in order to market and support the Company s products to the European community. In 2002, the Company received European regulatory approval for the commercial sale of the Company s products. The majority of the Company s revenues relate to sales to European customers. In November 2005, the Company announced its intention to close CryoCor GmbH and sell its products in Europe through distributors. The Company has recorded charges of approximately $252,000 in restructuring costs as of September 30, 2006 and $103,000 remains accrued at that date, primarily due to payments owed on the remaining term of the facility lease, which will run through June 2008. The Company has not incurred any additional restructuring costs related to this restructuring subsequent to June 30, 2006.

In January 2006, we received a non-approvable letter from the United States Food and Drug Administration related to our application for premarket approval for the treatment of atrial flutter, a cardiac arrhythmia. As a result of that letter, we restructured our operations in early March 2006 whereby we reduced our staffing levels to reduce our monthly cash requirements. As of September 30, 2006, we had recorded severance expenses of $280,000 and sales and marketing contract termination expenses of $50,000 associated with our restructuring, of which $28,000 remains accrued at that date. The Company s San Diego facilities were not impacted by the restructuring plan and all restructuring activities were substantially completed as of July 2006.

Basis of Presentation

We have prepared the accompanying unaudited consolidated financial statements in accordance with United States generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by GAAP for complete financial statements. In the opinion of our management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Intercompany accounts have been eliminated in consolidation. Operating results for the nine months ended September 30, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006. For further information see our financial statements and related disclosures thereto for the year ended December 31, 2005 in our Annual Report on Form 10-K filed on March 24, 2006 with the Securities and Exchange Commission (SEC).

The Company believes that it has sufficient working capital to fund its operations until December 2007. Accordingly, the accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. This basis of accounting contemplates the recovery of the Company s assets and the satisfaction of liabilities in the normal course of business. Successful completion of the Company s development program and its transition to attaining profitable operations is dependent upon obtaining additional financing adequate to fulfill its research and development activities and achieving a level of revenue adequate to support its cost structure. The Company does not anticipate having significant commercial operations until 2007, if at all; therefore, it will need to obtain additional financing to fund its operations until it becomes cash flow positive. There can be no assurances that there will be sufficient amounts of financing available at the time the Company seeks to raise additional capital.

2. Balance Sheet Details

Cash and Cash Equivalents

The Company considers all highly-liquid investments purchased with an original maturity of three months or less to be cash equivalents. As of September 30, 2006 and December 31, 2005, the Company s cash and cash equivalents were held in financial institutions in the United States and consist of deposits in money market funds and U.S. government securities, which were unrestricted as to withdrawal or use.

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Investment Securities

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

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

As of September 30, 2006 and December 31, 2005, the contractual maturity of all investment securities was less than one year. The composition of investments and gross unrealized gains and losses at September 30, 2006 and December 31, 2005 were as follows (in thousands):

	September 30, 2006				December 31, 2005			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Corporate debt securities	14,771	7		14,778	15,924		(48)	15,876
U.S. government securities	1,497		(3)	1,494	4,495		(8)	4,487
	$ 16,268	$ 7	$ (3)	$ 16,272	$ 20,419	$	$ (56)	$ 20,363

Inventories

Inventories consist of the following (in thousands):

	September 30, 2006	December 31, 2005
Raw materials	$ 646	$ 504
Work-in-progress	35	94
Finished goods	251	170
	932	768
Less reserves for excess and obsolete inventories	(55)	(50)
Inventory, net	$ 877	$ 718

At September 30, 2006, we had purchase commitments outstanding totaling approximately $91,000 for console materials, $69,000 in deposits on inventory components, and $636,000 in console inventory which is recorded within inventory on our balance sheet. The increase in the combined commitments and deposits from prior quarters is related to the decision to pay for and receive additional console components on order since 2005, rather than cancel the order and incur high cancellation fees. This total inventory represents approximately 11 consoles in finished goods, components to build an additional 20 complete consoles, and components that could be used in the production of additional consoles. These materials are not expected to be obsolete in the time period anticipated for commercialization. At September 30, 2006, we had disposables inventory totaling $241,000, of which $191,000 is raw materials. This inventory level represents approximately 1,100 finished catheters. We anticipate that the existing inventory levels, including the open purchase commitments, will be needed in either 2007 or 2008 to the extent we are able to commercialize our products in the United States.

Long-Term Debt

In March 2005, the Company entered into an agreement whereby it 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 at the time of the pay off. 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 common stock. The fair value of the warrants was

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$657,000 based upon an estimated fair value upon the date of grant 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 was recorded as a discount to the new debt facility and is being amortized to interest expense on a straight-line basis over the term of the loan. The remaining unamortized fair value of the warrants is $215,000 at September 30, 2006. The warrants are exercisable through 2015.

3. Stock-Based Compensation

Share-based Compensation Plans

The Company currently has three active share-based employee compensation plans: the 2000 Stock Option Plan (2000 Plan), the 2005 Equity Incentive Plan (2005 Plan) and the 2005 Employee Stock Purchase Plan (ESPP). In addition, the Company has a Non-Employee Director Plan (NED Plan). As of September 30, 2006, 1,626,115 shares of the Company s common stock were reserved for issuance upon exercise of options granted by the Company and 84,023 shares were available for future grant for issuance under the 2000 Plan, 2005 Plan and NED Plan combined. As of September 30, 2006, the Company had issued 9,612 shares over the life of our ESPP, and 151,678 shares were reserved for future issuance under the ESPP.

Adoption of SFAS 123(R)

Effective January 1, 2006, the Company adopted the fair value recognition provisions of the Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)) as interpreted by the SEC s Staff Accounting Bulletin No. 107 (SAB 107) using the prospective method and the modified prospective method. Therefore, we have not restated our financial results for prior periods. In accordance with SFAS 123(R), we utilized the prospective method for equity share options granted prior to our initial public offering as we had previously used the minimum value method of measuring the fair value of these options for pro forma disclosure purposes under SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123). Therefore, unless modified in the future, these options are excluded from the adoption of SFAS 123(R). We utilized the modified prospective method for equity share options granted subsequent to our initial public offering as we had used the fair-value-based method for pro forma disclosure purposes under SFAS 123. Under these transition methods, compensation cost recognized in the three and nine months ended September 30, 2006 includes the following: (a) share-based compensation cost associated with options granted prior to our initial public offering with exercise prices less than the deemed fair value of the common stock at the date of grant, (b) compensation cost related to any share-based payments granted subsequent to the date of our initial public offering through, but not vested as of, December 31, 2005, and (c) compensation cost for any share-based payments granted subsequent to December 31, 2005, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R).

During 2004 and 2005, prior to the completion of our initial public offering, stock options were granted at exercise prices that were below the deemed fair value of the common stock on the date of grant. Accordingly, deferred stock compensation was recorded during 2004 and 2005 in accordance with Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations (APB 25). The deferred stock compensation was being amortized on a straight-line basis over the vesting period of the related awards, which is generally four years. In accordance with SFAS 123(R), the Company reversed the balance of deferred compensation from shareholders equity on the date of adoption but, as noted above, continues to recognize the related compensation cost in the statement of operations.

Compensation Costs

The compensation costs that have been included in our results of operations that we recognized on our statement of operations for these employee and non-employee director share-based compensation arrangements were as follows (in thousands):

	Three months ended September 30, 2006	Three months ended September 30, 2005	Nine months ended September 30, 2006	Nine months ended September 30, 2005
Share-based employee compensation costs included in:				

Cost of sales	$ 99	$ 78	$ 300	$ 200
Research and development	130	147	359	499
Selling, general, and administrative	280	254	844	727
Total share-based employee compensation costs	509	479	1,503	1,426
Income tax benefit recognized				
Impact on net loss	$ 509	$ 479	$ 1,503	$ 1,426

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Because the amount of share-based compensation associated with our cost of production is not significant, we did not capitalize any share-based compensation cost as part of inventory during the three or nine months ended September 30, 2006, or for any periods in 2005. Net cash proceeds from the exercise of stock options were $21,000 and $96,000 for the three and nine month periods ended September 30, 2006. Because of our net operating loss, no income tax benefit was realized from stock option exercises during the three or nine month periods ended September 30, 2006.

There were no significant modifications to our share-based employee payment plans during the periods presented that resulted in any incremental compensation cost.

Prior to January 1, 2006, we accounted for our share-based compensation plans under the recognition and measurement provisions of APB 25, as permitted by SFAS 123, as amended by SFAS 148, *Accounting for Stock-Based Compensation-Transition and Disclosure* (SFAS 148). We recognized share-based employee compensation costs in our statements of operations prior to January 1, 2006, as several options granted prior to our initial public offering during 2004 and 2005 under our 2000 Plan had exercise prices less than the estimated fair market value of the underlying common stock on the date of grant. As required by SFAS 148 prior to the adoption of SFAS 123(R), we provided pro forma net loss and pro forma net loss per common share disclosures for stock-based awards, as if the fair-value-based method defined in SFAS 123 had been applied.

The table below illustrates the pro forma effect on net loss and net loss per share attributable to common stockholders if the Company had applied the fair value provisions of SFAS 123 to options granted under our share-based employee compensation arrangements during the three and nine months ended September 30, 2005 (in thousands, except per share amounts):

	Three months ended September 30, 2005	Nine months ended September 30, 2005
Net loss attributable to common stockholders, as reported	$ (4,092)	$ (15,248)
Add: Stock-based employee compensation expense included in loss from operations	479	1,426
Deduct: Stock-based employee compensation expense determined under fair value method	(8)	(8)
Pro forma net loss attributable to common stockholders	$ (3,621)	$ (13,830)
Basic and diluted net loss per share attributable to common stockholders	$ (0.45)	$ (4.86)
Pro forma basic and diluted net loss per share attributable to common stockholders	$ (0.40)	$ (4.41)

For purposes of this pro forma disclosure, we estimated the value of the options using a Black-Scholes-Merton closed-form option pricing formula and amortized that value to expense over the options vesting periods. We allocated this fair value to the pro forma compensation expense using the straight-line attribution method. Per the requirements of FAS 123(R), the deduction of stock-based compensation expense in the above table excludes all option grants historically valued under the minimum value method.

Valuation of Stock Option Awards

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton closed-form option valuation model that uses the assumptions noted in the following table. Expected volatilities are based on historical volatility of our stock as well as the stock of comparable medical device companies. As permitted by SAB 107, we utilized the shortcut approach to estimate the options expected term, which represents the period of time that options are expected to be outstanding. We utilized this approach as we believe our historical share option exercise experience does not provide a reasonable basis upon which to estimate an expected term. The risk-free interest rate for the expected term of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

	Three months ended		Nine months ended	
	September 30, 2006	September 30, 2005	September 30, 2006	September 30, 2005
Expected volatility	78%	70%	78%	70%
Expected term	5.84 years	6 years	5.72 years	6 years
Risk-free interest rate	4.89%	3.25%	4.75%	3.25%
Expected dividends	0%	0%	0%	0%

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Summary of Stock Options

A summary of options under all of our share-based compensation plans as of September 30, 2006 and activity during the nine months then ended are as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Options outstanding at December 31, 2005	1,085,914	$ 1.32		
Options granted	863,376	$ 2.72		
Options exercised	(150,682)	$ 0.64		
Options forfeited	(172,493)	$ 2.30		
Options outstanding at September 30, 2006	1,626,115	$ 2.03	8.77	$ 2,422
Options vested and expected to vest at September 30, 2006	1,563,147	$ 2.01	8.75	$ 2,352
Options vested and exercisable at September 30, 2006	429,563	$ 1.72	8.05	$ 891

Aggregate intrinsic value is the sum of the amounts by which the quoted market price of our stock exceeded the exercise price of the options at September 30, 2006 (in-the-money options). The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2006 was $1.89. The total intrinsic value of options exercised during the nine months ended September 30, 2006 was $316,000.

As of September 30, 2006, $4.7 million of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under our various plans is expected to be recognized over a weighted-average period of 2.2 years.

Employee Stock Purchase Plan

Our ESPP allows eligible employees to purchase our stock through payroll deductions at 85% of the lower of the closing prices for the stock at the beginning of the offering or the end of the purchase period. Purchases are limited to 15% of each employee s compensation and cannot exceed an amount set by the Board of Directors. In addition, the Board of Directors has specified a maximum number of shares of Common Stock that may be purchased by any participant on any purchase date during the current offerings of 483 shares.

The fair value of each option element of the ESPP is estimated on the date of grant using the Black-Scholes-Merton closed-form option valuation model that uses the assumptions noted in the following table. Expected volatilities are based on historical volatility of our stock as well as the stock of comparable medical device companies. Expected term represents the four purchase periods within a 24-month offering period for the ESPP. The risk-free interest rate for periods within the expected term of the award is based on the U.S. Treasury yield curve in effect at the time of grant.

	Three months ended	Nine months ended

	September 30, 2006	September 30, 2006
Expected volatility	78%	78%
Expected term	0.5 -2 years	0.5 -2 years
Risk-free interest rate	4.9% -5.1%	2.0% -5.1 %
Expected dividends	0%	0%

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Disclosures Pertaining to All Share-Based Compensation Plans

Cash received from option exercises and ESPP contributions under all share-based payment arrangements for the nine months ended September 30, 2006 and 2005 was $103,000 and $148,000, respectively. Because of our net operating losses, we did not realize any tax benefits for the tax deductions from share-based payment arrangements during the nine months ended September 30, 2006 and 2005.

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.

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2006	2005	2006	2005
	(in thousands, except per share amounts)			
Historical				
Numerator:				
Net loss attributable to common stockholders	$ (3,363)	$ (4,092)	$ (11,204)	$ (15,248)
Denominator:				
Weighted-average common shares outstanding	10,773	9,173	10,739	3,218
Weighted-average unvested common shares subject to repurchase	(5)	(84)	(13)	(82)
Denominator for basic and diluted net loss per share attributable to common stockholders	10,768	9,089	10,726	3,136
Basic and diluted net loss per share attributable to common stockholders	$ (0.31)	$ (0.45)	$ (1.04)	$ (4.86)
Historical outstanding anti-dilutive securities not included in diluted net loss per share attributable to common stockholders calculation:				
Options to purchase common stock	1,626	1,084	1,626	1,084
Warrants to purchase common and convertible preferred stock	83	83	83	83
	1,709	1,167	1,709	1,167

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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 of an amendment to our PMA for AFL ,statements related to our restructuring, the timing for product sales in the United States, if any, our anticipated continuing net losses and anticipated increases in selling, general and administrative expenses, the amount and timing of future spending to develop existing and new product candidates, including in connection with related clinical trials and PMA filings, if any, and the period over which our existing cash reserves will be sufficient to fund our ongoing operations, all of which are prospective. Such statements are only predictions and reflect our expectations and assumptions as of the date of this Form 10-Q based on currently available operating, financial, and competitive information. The actual events or results may differ materially from those projected in such forward-looking statements due to a number of factors, including risks involved with our ability to obtain regulatory approval in the United States for our cryoablation system for use in treating AFL and AF, risks associated with our ability to complete enrollment in our AF pivotal trial and submit a PMA for AF, risks involved with our estimates of the size, make-up and costs involved with the Company s restructuring, risks associated with our ability to amend our PMA for AFL and ultimately receive approval from the United States Food and Drug Administration, or FDA, for the use of our cryoablation system to treat AFL, risks associated with our ability to successfully commercialize our cryoablation system in the United States and elsewhere if our cryoablation system is approved for use in the United States, risks associated with our dependence on patents and proprietary rights, risks associated with our protection and enforcement of our patents and proprietary rights, risks associated with the development or availability of competitive products or technologies, risks associated with our ability to obtain additional financing as necessary, and the other risks and uncertainties identified in the section of this Form 10-Q entitled Risk Factors and elsewhere in this Form 10-Q and in our other publicly available documents. These forward-looking statements speak only as of the date of this Form 10-Q. We expressly disclaim any intent or obligation to update any of these forward-looking statements after the filing of this Form 10-Q to reflect actual results, changes in our expectations, or otherwise. The following information should be read in conjunction with the consolidated financial statements and the notes thereto included in this Form 10-Q.

This Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the consolidated financial statements, including related notes, appearing in the Form 10-K for the year ended December 31, 2005 filed with the Securities and Exchange Commission, or SEC.

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 raising capital, developing our cryoablation system, evaluating its performance in clinical trials, and preparing for the possible United States commercialization of our cryoablation system.

We obtained a CE Mark for our cryoablation system in early 2002 and are approved in Europe for the treatment of AF, AFL and other supraventricular tachycardias. We began our United States pivotal trial for AFL in late 2003 and our United States pivotal trial for AF in late 2004. In July 2005, we submitted the final module of our PMA for AFL to the United States Food and Drug Administration, or FDA, which included the safety and effectiveness results of our clinical trial. In January 2006, we were notified by the FDA that our PMA for the treatment of AFL was not approvable as submitted, and that the data presented did not meet the FDA s chronic effectiveness criteria. After receipt of this FDA letter, we retained experts independent of CryoCor to conduct an evaluation of our chronic effectiveness data. The evaluation was completed in June 2006, and we met with the FDA in July 2006 to discuss the results of, and the process around, our independent evaluation. While we have not completed our statistical analysis, we believe that for the patients with a successful initial procedure, approximately 80% of those patients did not have a recurrence of atrial flutter in the six month period following treatment. We anticipate amending our PMA in November 2006; however, there can be no assurance that the FDA will determine that the data presented in the amended PMA meets the FDA s chronic effectiveness criteria and there can be no assurance that we will receive approval for our amended PMA.

As a result of this non-approvable letter, in March 2006 we restructured our operations and reduced our staffing levels to reduce our monthly cash requirements. This restructuring has reduced our manufacturing capabilities, impacted the timing of some of our internal research and development efforts, and reduced our ability to expand our commercial presence in Europe, but has not impacted our ability to conduct our AF pivotal trial or delayed our efforts to introduce our next generation catheter, Quantum, into clinical testing. We believe, and the FDA has informally indicated to us, that its decision not to approve our cryoablation system for

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the treatment of AFL based on the data we submitted does not impact our ongoing AF pivotal trial. If our AF clinical trial and the regulatory review proceed as anticipated, we may receive regulatory approval in the United States for our cryoablation system for the treatment of AF as early as 2008.

At present, we are currently selling our products through distributors, and our products are sold in the United Kingdom, Germany, Denmark, Belgium, the Netherlands and Italy. We may expand our current network of distributors, however our recent restructuring is expected to delay our commercial expansion in Europe and we may never sign additional distribution agreements. If we obtain marketing approval from the FDA, we plan to commercialize in the United States with a direct CryoCor sales force and/or with a marketing partner.

To date, we have generated minimal revenues and we have incurred net losses in each year since our inception. We expect these losses to continue as we complete our clinical trial activities and continue to develop our product candidates for potential commercial launch in the United States, and for at least some time after any commercial launch of our product in the United States. 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 fees, 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. During 2005, our San Diego facility was inspected by the FDA. In January 2006, we were notified by the FDA that our PMA for the treatment of AFL was not approvable as submitted, and that the data presented did not meet the FDA s chronic effectiveness criteria. After receipt of this FDA letter, we retained experts independent of CryoCor to conduct an evaluation of our chronic effectiveness data. The evaluation was completed in June 2006, and we met with the FDA in July 2006 to discuss the results of, and the process around, our independent evaluation. While we have not completed our statistical analysis, we believe that for the patients with a successful initial procedure, approximately 80% of those patients did not have a recurrence of atrial flutter in the six month period following treatment. We anticipate amending our PMA in November 2006; however, there can be no assurance that the FDA will determine that the data presented in the amended PMA will meet the FDA s chronic effectiveness criteria and there can be no assurance that we will receive approval for our amended PMA.

We are continuing to enroll patients for our pivotal trial for AF that began in December 2004, and have enrolled 141 patients as of November 7, 2006 in our 160 patient clinical trial. Our enrollment over the last three months has been at a slower pace than previous periods, and we are considering opening several new sites to complete the enrollment process as soon as possible. We believe we will complete enrollment in our AF pivotal trial in the first half of 2007, with an expected PMA submission to the FDA during the first half of 2008. We believe, and the FDA has informally indicated to us, that its decision at present to not approve our cryoablation system for the treatment of AFL does not impact their expectations about our ongoing AF pivotal trial.

Financial Operations

Product Sales. Our product sales to date have come from a limited number of commercial sites in Europe. To date, we have not generated substantial revenues in Europe as our financial resources have primarily been dedicated to product development and clinical trials in the United States. This has prevented us from providing the resources necessary to broadly market our cryoablation system in Europe and from increasing the number of consoles placed in Europe. We believe that European product revenues for companies with new medical technologies typically remain modest until United States product approval is obtained because European approvals, which are designed primarily to demonstrate product safety, are not as compelling for European physician adoption as United States approvals, which must demonstrate effectiveness and safety. We do not expect to generate revenues in the United States unless, and until, our cryoablation system has been approved by the FDA and we initiate the sales of our products. We expect that any revenues we generate from sales of our products will fluctuate from quarter-to-quarter.

Research and Development Expenses. Our research and development expenses primarily consist of costs incurred to further our research and development activities and include salaries and related employee benefits, including non-cash stock-based compensation, 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.

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 due to the costs associated with operating as a publicly-traded company.

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Results of Operations

We anticipate that our results of operations will fluctuate for the foreseeable future due to several factors, such as the progress of our research and development efforts, the timing and outcome of regulatory submissions, and quarterly variations in sales activities and results. Due to these uncertainties, results of future operations are difficult to predict.

Three months ended September 30, 2006 and 2005

Product Sales. Product sales increased $62,000 to $214,000 for the three months ended September 30, 2006, compared to $152,000 for the three months ended September 30, 2005. The increase was primarily due to the recognition of deferred revenue which resulted from increased cash collections on our outstanding receivables from our two distributors in Europe. Deferred revenue decreased from $205,000 at December 31, 2005 to $93,000 at September 30, 2006 due both to increased cash collections and lower product shipments versus previous periods.

Cost of Sales. Cost of sales decreased $186,000 to $542,000 for the three months ended September 30, 2006, compared to $728,000 for the three months ended September 30, 2005. The decrease during the three months ended September 30, 2006 is primarily related to personnel costs of $109,000 as a result of our staff restructuring. Cost of sales is high relative to the volume of sales due to the fixed costs associated with manufacturing our product. Included in cost of sales for the three months ended September 30, 2006 and 2005 were non-cash stock-based compensation of $103,000 and $78,000, respectively.

Research and Development Expenses. Research and development expenses decreased $308,000 to $1.4 million for the three months ended September 30, 2006, compared to $1.7 million for the three months ended September 30, 2005. The decrease in 2006 was primarily related to lower personnel costs of $230,000 and lower non-cash stock-based compensation expense of $52,000, both due to decreased headcount related to our staff restructuring. Included in research and development expenses for the three months ended September 30, 2006 and 2005 were non-cash stock-based compensation of $131,000 and $183,000, respectively.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $92,000 to $1.7 million for the three months ended September 30, 2006, compared to $1.8 million for the three months ended September 30, 2005. The decrease was primarily due to lower personnel costs as a result of our staff restructuring of $302,000, as well as lower costs in the following areas: legal and accounting of $35,000, marketing consulting services of $47,000, travel of $80,000 and recruiting of $42,000. These decreases were partially offset by an increase in separation costs of $464,000 related to the departure of our former Chief Executive Officer. Included in general and administrative expenses for the three months ended September 30, 2006 and 2005 were non-cash stock-based compensation of $290,000 and $272,000, respectively.

Nine months ended September 30, 2006 and 2005

Product Sales. Product sales decreased $196,000 to $486,000 for the nine months ended September 30, 2006, compared to $682,000 for the nine months ended September 30, 2005. The decrease was due to the reduced sales activities in Europe associated with the restructuring and closure of our German subsidiary. The decreased level of sales activity is anticipated to recur for the foreseeable future, and we anticipate that we will enter into additional markets in Europe only in the event that our product is approved in the United States. We had $93,000 in deferred revenue as of September 30, 2006 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 decreased $473,000 to $1.9 million for the nine months ended September 30, 2006, compared to $2.3 million for the nine months ended September 30, 2005. The decrease during the nine months ended September 30, 2006 is primarily related to lower personnel costs as a result of the staff restructuring that occurred during March 2006 of $258,000 as well as lower depreciation of $136,000, partially offset by increased non-cash stock-based expense of $104,000. In addition, the nine months ended September 30, 2005 included costs from the recall of our Model 1200 catheter of approximately $200,000. Cost of Sales is high relative to the volume of sales due to the fixed costs associated with manufacturing our product. Included in cost of sales for the nine months ended September 30, 2006 and 2005 were non-cash stock-based compensation of $304,000 and $200,000, respectively.

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Research and Development Expenses. Research and development expenses decreased $1.2 million to $4.3 million for the nine months ended September 30, 2006, compared to $5.5 million for the nine months ended September 30, 2005. The decrease in 2006 was primarily related to lower personnel costs of $935,000 and lower non-cash stock-based compensation expense of $196,000 due to decreased headcount related to our staff restructuring in March 2006. Included in research and development expenses for the nine months ended September 30, 2006 and 2005 were non-cash stock-based compensation of $362,000 and $558,000, respectively.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $723,000 to $5.6 million for the nine months ended September 30, 2006, compared to $4.9 million for the nine months ended September 30, 2005. The increase was primarily due to increased cash and non-cash costs associated with our sales and marketing efforts in preparation for commercializing the United States of $287,000, costs associated with our restructuring of $354,000, and general increased costs associated with being a public company. Included in general and administrative expenses for the nine months ended September 30, 2006 and 2005 were non-cash stock-based compensation of $868,000 and $787,000, respectively.

Liquidity and Capital Resources

We have incurred losses since our inception in August 2000. As of September 30, 2006, we had an accumulated deficit of $81.2 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, 2006, as well as bank debt and the proceeds of our initial public offering, which was closed in July 2005 and raised aggregate net proceeds of $35.4 million after deducting underwriting fees and commissions and transaction costs. 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, 2006, we had short-term debt outstanding of $7.0 million (excluding debt discount for warrants of $215,000), working capital of $13.9 million and cash and cash equivalents and short-term investments totaling $21.2 million. Our short-term debt will mature on June 30, 2007, and we will need to pay our debt in full. Based upon our current level of expenditures, we believe that our existing funds will be adequate to meet our anticipated cash requirements until December 2007, and that to continue to fund our operations, we will need to seek additional financing.

Net Cash Used in Operating Activities. Net cash used in operating activities decreased $1.4 million to $9.8 million for the nine months ended September 30, 2006, compared to $11.2 million for the nine months ended September 30, 2005. The net cash used in both of these periods primarily reflects the net loss for each period, offset in part by depreciation and amortization, non-cash stock-based compensation, amortization of debt discount and changes in operating assets and liabilities. Our operating losses have been within our expectations.

Net Cash Provided by (Used in) Investing Activities. Net cash provided by investing activities increased $17.4 million to $4.1 million provided by investing activities for the nine months ended September 30, 2006, compared to $13.3 million used in investing activities for the nine months ended September 30, 2005. Cash provided by investing activities relates to purchases and maturities of short-term investments as well as purchases of property and equipment. The increase in net cash provided by investing activities for the nine months ended September 30, 2006 is related to purchases and maturities of short-term 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 decreased $40.3 million to $90,000 for the nine months ended September 30, 2006, compared to $40.4 million for the nine months ended September 30, 2005. Net cash provided by financing activities during the nine months ended September 2006 was primarily attributable to cash inflows from the exercise of CryoCor stock options by employees. Net cash provided by financing activities during the nine months ended September 30, 2005 was primarily attributable to the Company s initial public offering in July 2005, as well as borrowing under the Company s new debt facility of $7.0 million, offset by the $1.8 million pay-off of an existing term loan and payments on capital leases.

Operating Capital and Capital Expenditure Requirements

To date, we have had limited commercial sales in Europe, no commercial sales in the United States, and we have not yet achieved profitability. We do not currently have any products approved for sale in the United States. We anticipate that we will continue to incur net losses for the next several years as we continue to develop our products, continue our clinical programs, expand our corporate infrastructure and prepare for the potential commercial launch of our cryoablation system in the United States. We expect that we will need to generate significant product revenues to achieve profitability.

In August 2006, we created an incentive compensation program for our non-executive full-time employees. Under the terms of the program, employees that remain with CryoCor through August 31, 2007 will receive a payment of 20% of their 2006 annual salary. The incentive

payments will be paid in September 2007 and could total approximately $538,000, if all employees eligible for the program remain through August 31, 2007. Additionally, at the end of August, we did not extend the employment agreement with our former CEO, Gregory Ayers. Under the terms of his employment agreement, he will receive separation compensation for one year s salary, or $450,000, over the 12 months subsequent to his departure from CryoCor.

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We do not expect to generate significant product revenues unless and until we obtain marketing approval for and begin selling our cryoablation system in the United States. We believe that our cash, cash equivalent and short-term investment balances will be sufficient to meet our anticipated cash requirements until December 2007. We believe that our available cash, cash equivalents and short-term investments will be insufficient to satisfy our liquidity requirements and we expect to sell additional equity or debt securities or obtain an additional credit facility. The sale of additional equity and debt securities will 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 expect to 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.

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

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

As of September 30, 2006, we had recorded severance expenses of $280,000 and sales and marketing contract termination expenses of $50,000 associated with our restructuring, of which $28,000 remains accrued at that date. The Company s San Diego facilities are not impacted by the restructuring plan, and all restructuring activities were substantially completed by July 2006.

We anticipate spending at least $2.7 million in external costs over the next 18 months for clinical trials and regulatory activities related to using our cryoablation system to treat AFL and AF, including estimated regulatory counsel costs related to amending our PMA for AFL in 2006 and an anticipated clinical trial for our next generation catheter, Quantum. As of September 30, 2006, we believe the total costs for our clinical trials for AFL and AF and the development of our existing product candidates will require approximately $8.6 million over the next 18 months, with a portion of our existing cash, cash equivalents and short-term investments being used to prosecute and maintain our intellectual property portfolio, to fund our facility, manufacturing and quality system operations and to fund our working capital and general corporate requirements during this same period.

At present, we have a wholly owned subsidiary in Germany that previously sold our products in Germany, Belgium, and the Netherlands. We are in the process of dissolving this subsidiary. As of September 30, 2006, we have recorded charges of $252,000 for the closing of our subsidiary to date and $103,000 remains accrued at that date. This restructuring is expected to be completed during 2006 and the Company has not incurred any additional restructuring charges related to this restructuring subsequent to June 30, 2006. We have signed distribution agreements for the sale of our cryoablation system in the United Kingdom and Italy, and our UK distributor has the rights to sell products to our EU clinical sites. We may expand our current network of distributors, however our recent restructuring is expected to delay our commercial expansion in Europe, and we may never sign additional distribution agreements. If we obtain marketing approval from the FDA, we plan to commercialize in the United States with a direct CryoCor sales force and/or with a marketing partner.

We have filed requests with the United States Patent and Trademark Office, or USPTO, seeking to invoke interference proceedings involving two patents owned by CryoCath Technologies, Inc. and two of our patent applications to determine who 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 United States. 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 section of this Form 10-Q, and in our other securities filings filed with the SEC. We have based these estimates on assumptions that may prove to be wrong, and we may be required to utilize our available capital resources sooner than we currently expect.

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

- our ability to obtain FDA approval or other regulatory approval for our products;
- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- the costs and timing of seeking regulatory approvals, including costs associated with analyzing the data associated with, and amending, our PMA for AFL as well as a potential 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 filing, prosecuting, and maintaining our owned and licensed patent applications and patents, and defending and enforcing these patents and other intellectual property rights;
- the costs of establishing sales, marketing and distribution capabilities;
- the extent and level of ablation procedure reimbursements in general and for cryoablation specifically;
- the commercial acceptance of our product following the initiation of our sales efforts in the United States;
- the effect of competing products and technologies; and
- the terms and timing of any collaborative, licensing and other arrangements that we may establish.

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

At September 30, 2006, we had purchase commitments outstanding totaling approximately $91,000 for console materials, $69,000 in deposits on inventory components, and $636,000 in console inventory which is recorded within inventory on our balance sheet. The increase in the combined commitments and deposits from prior quarters is related to the decision to pay for and receive additional console components on order since 2005, rather than cancel the order and incur high cancellation fees. This total inventory represents approximately 11 consoles in finished goods, components to build an additional 20 complete consoles, and components that could be used in the production of additional consoles. These materials are not expected to be obsolete in the time period anticipated for commercialization. At September 30, 2006, we had disposables inventory totaling $241,000, of which $191,000 is raw materials. This inventory level represents approximately 1,100 finished catheters. We anticipate that the existing inventory levels, including the open purchase commitments, will be needed in either 2007 or 2008 to the extent we are able to commercialize our products in the United States.

We also have service agreements with clinical sites, individuals and contract research organizations for the conduct of our AF pivotal trial. We make payments to these sites and organizations based upon the actual number of patients enrolled and the period of follow-up in the trials, and we have accrued approximately $796,000 in fees and expenses through September 30, 2006 payable in connection with our AF pivotal trial. We

do not have minimum payment obligations under these agreements and the amount to be paid to each center and the timing of those payments will vary based on the negotiated amount paid for each patient to be treated and for each patient screened who fails to or declines to participate in the clinical trial. We anticipate that the external cash outlay of completing our AF pivotal trial and submitting a PMA for the treatment of AF with our cryoablation system will be approximately $2.1 million over the next 18 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 and when they will incur. We expect to incur additional expenses in connection with the preparation of our regulatory filings, including costs associated with employees and consultants and related legal expenses.

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

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

Revenue Recognition

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

Historically, customers have had the right to return products until one month following expiration of the product, which has been six months after its production. Effective October 1, 2006, our products now expire one year after production, and we modified our return policy such that we will no longer grant a right to return products upon expiration of their one year product life. As we have had limited sales of our products, we currently recognize revenues when the customer has paid for the product and, if applicable, the right of return, if any, has expired.

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

Clinical Trial Expenses

Clinical trial costs are a component of research and development expenses and include fees paid to participating hospitals and other service providers which conduct clinical trial activities 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.

Stock-Based Compensation

We have four share-based compensation plans: three stock option programs and an employee stock purchase plan. Prior to January 1, 2006, we accounted for these plans under the recognition and measurement provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB 25, and related guidance, as permitted by Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation,* or SFAS 123. Effective January 1, 2006, the Company adopted the fair value recognition provisions of the SFAS No. 123 (revised 2004), *Share-Based Payment,* or SFAS 123(R), as interpreted by the SEC s Staff Accounting Bulletin No. 107, or SAB 107, using the prospective method and the modified prospective method. Therefore, we have not restated our financial results for prior periods. In accordance with SFAS 123(R), we utilized the prospective method for equity share options granted prior to our initial public offering as we had used the minimum value method of measuring these options for pro forma disclosure purposes under SFAS No. 123, *Accounting for Stock-Based Compensation*, or SFAS 123. Therefore, unless modified in the future, these options are excluded from the adoption of SFAS 123(R). We utilized the modified prospective method for equity share options granted subsequent to our initial public offering as we had used the fair-value-based method for pro forma disclosure purposes under SFAS 123. Under these transition methods, compensation cost recognized in the three and nine months ended September 30, 2006 includes the following: (a) share-based compensation cost associated with options granted prior to our initial public offering with exercise prices less than the deemed fair value of the common stock at the date of grant, (b) compensation cost related to any share-based payments granted subsequent to the date of our initial public offering through, but not vested as of, December 31, 2005, and (c) compensation cost for any share-based payments granted subsequent to December 31, 2005, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R).

During 2004 and 2005, prior to the completion of our initial public offering, stock options were granted at exercise prices that were below the deemed fair value of the common stock on the date of grant. Accordingly, in accordance with APB 25, deferred stock compensation was recorded during 2004 and 2005 and was being amortized on a straight-line basis over the vesting period of the related awards, which is generally four years. In accordance with SFAS 123(R), the Company reversed the balance of deferred compensation from shareholders equity on the date of adoption but, as noted above, continues to recognize the related compensation cost in the statement of operations.

As a result of adopting SFAS 123(R), we recognized additional share-based employee compensation expense of $165,000 and $349,000 during the three and nine months ended September 30, 2006 in addition to $344,000 and $1.2 million in compensation expense previously recorded under APB 25. We calculated this expense based on the fair values of the share-based compensation

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awards as estimated using the Black-Scholes-Merton closed-form option valuation model. Use of this model requires us to make assumptions about expected future volatility of our stock price and the expected term of the options that we grant. Calculating share-based compensation expense under SFAS 123(R) also requires us to make assumptions about expected future forfeiture rates for our option awards. As of September 30, 2006, total unrecognized compensation expense related to unvested share-based compensation arrangements already granted under our various plans was $4.7 million, which we expect will be recognized over a weighted-average period of 2.2 years. However, it is difficult to predict the actual amount of share-based compensation expense that we will recognize in future periods because that expense can be affected by changes in the amount or terms of our share-based compensation awards issued in the future, changes in the assumptions used in our model to value those future awards, changes in our stock price, and changes in interest rates, among other factors.

We issue stock options to non-employees, generally for services, which we account for under the provisions of SFAS 123 and Emerging Issues Task Force Abstract No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. These options are valued using the Black-Scholes option valuation model and are subject to periodic adjustment as the underlying options vest. Changes in fair value are amortized over the vesting period on a straight-line basis.

Inventory

As of September 30, 2006, we had raw materials, work-in-process and finished goods console inventory totaling $636,000 as well as open purchase commitments totaling $91,000 for console components ordered that will be received and paid for during 2006 as well as $69,000 in deposits on inventory components. The increase in the combined commitments and deposits from prior quarters is related to the decision to pay for and receive additional console components on order since 2005, rather than cancel the order and incur high cancellation fees. This total inventory represents approximately 11 consoles in finished goods, components to build an additional 20 complete consoles, and raw materials that could be used in the production of additional consoles. Further, at September 30, 2006, we had disposables inventory totaling $241,000, of which $191,000 is raw materials. This inventory level represents approximately 1,100 finished catheters. We evaluated whether these levels of console and catheter inventory was excessive based upon the recent communication from the FDA indicating that our cryoablation system was not approvable at present for the treatment of AFL. We concluded that the existing inventory levels, including the open purchase commitments, were not excessive for the following reasons:

Consoles

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

Disposables

- we anticipate the sale of approximately 700-750 catheters in Europe in the remainder of 2006 and 2007;
- we believe we will receive approval to sell our product in the United States in either 2007 or 2008; and
- the catheter raw materials are not subject to obsolescence in the time period contemplated for commercialization.

Based on the above, we concluded that no reserves were needed at September 30, 2006 for either the existing console and catheter inventory or the materials on order, to be delivered in 2006. We will continue to evaluate these inventory levels based on our clinical progress.

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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. 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.

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PART II - OTHER INFORMATION.

Item 1. Legal Proceedings.

From time to time, we may be involved in litigation relating to claims arising out of our operations. Other than the interference proceedings previously described under the heading Legal Proceedings in our Form 10-K for the period ending December 31, 2005, filed with the Securities and Exchange Commission on March 24, 2006, we are not currently involved in any material legal proceedings.

Item 1A. Risk Factors.

The risk factors included in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2005 included uncertainty regarding whether or not CryoCor would file an amendment to its PMA for AFL. The Company has concluded, based upon results from its evaluation of the clinical data set from the AFL pivotal trial, and discussions held with the FDA in July 2006, that it will amend its PMA for AFL and anticipates filing the amended PMA in November 2006. The following risk factors reflect these changes:

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

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

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

We are dependent on the success of our cryoablation system, which has not been approved by the FDA for any indication for commercialization in the United States. If we are unable to achieve our product development goals, gain FDA approval to commercialize our cryoablation system in the United States, or experience significant delays in doing so, our stock price may decline and we may be forced to cease operations; and

If the data from our clinical trials do not demonstrate the safety and effectiveness of our cryoablation system to the FDA s satisfaction, we will not receive FDA approval to market our cryoablation system in the United States.

The Company has also included a new risk factor to the risk factors included in Part I, Item IA of our Annual Report on Form 10-K for the year ended December 31, 2005 with respect to its chronic effectiveness computation not meeting the objective performance criteria, or OPC, for RF ablation.

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

Additionally, we have added two new risk factors to the risk factors included in Part I, Item IA of our Annual Report on Form 10-K for the year ended December 31, 2005, to reflect the possibility that we may need to enroll additional patients in our AF pivotal trial, and the difficulties associated with manufacturing our Quantum catheter. They are included in the following risk factors:

We may need to enroll additional patients in our AF pivotal trial, if our dataset of evaluable patients is not large enough; and

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

Except as discussed above, the risk factors set forth below do not contain any other material changes from the Risk Factors set forth in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2005.

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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 United States. We anticipate that our cryoablation system will not be approved for commercialization in the United States by the FDA for any indication until 2007 or 2008 at the earliest, if at all.

As of September 30, 2006, we had an accumulated deficit of $81.2 million. We have incurred net losses in each year since our inception in August 2000, including net losses of $11.2 million for the nine months ended September 30, 2006 and $17.1 million, $15.8 million and $11.2 million for the years ended December 31, 2005, 2004 and 2003, respectively. We expect to continue to incur significant and increasing operating losses, in the aggregate and on a per share basis, for the next several years. These losses, among other things, have had and will continue to have an adverse effect on our stockholders equity, net current assets and working capital. Because of the risks and uncertainties associated with developing medical devices, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

We expect that our primary expenses for the next 24 months will be for conducting our clinical trial for AF, costs associated with preparing our PMA for AF, other costs associated with new product development and costs associated with amending our PMA for AFL. 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 United States and we may not receive them. We may not become profitable even if we obtain FDA approval and succeed in commercializing our cryoablation system in the United States. As a result, we cannot be sure when we will become profitable, if at all.

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

We may need to raise substantial additional capital to:

- fund our operations and clinical trials;
- continue our research and development;
- enforce our proprietary rights;
- defend, in litigation or otherwise, any claims that we infringe third party patents or other intellectual property rights; and
- commercialize any of our products that may be approved by the FDA.

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We believe that the net proceeds from our initial public offering, together with our existing cash, cash equivalents and short-term investment balances, will be sufficient to meet our anticipated cash requirements until December 2007. However, our future funding requirements will depend on many factors, including but not limited to:

- our ability to obtain FDA approval or other regulatory approval for our products;
- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- the costs and timing of seeking regulatory approvals, including costs associated with amending our PMA for AFL as well as potential FDA advisory panel reviews for AF and AFL;
- 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 filing, prosecuting and maintaining our owned and licensed patent applications and patents, and defending and enforcing these patents and other intellectual property rights;
- the costs of establishing sales, marketing and distribution capabilities;
- the extent and level of reimbursement for cryoablation;
- the commercial acceptance of our product following the initiation of our sales efforts in the United States;
- the effect of competing products and technologies; and
- the terms and timing of any collaborative, licensing and other arrangements that we may establish.

Until we can generate sufficient product revenue, which may never occur, we expect to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants. Examples of such restrictive covenants, all of which we are subject to under our current loan 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.

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

In late January 2006, we received a letter from the FDA informing us that our PMA for the treatment of AFL using the cryoablation system is not approvable at present. The FDA stated that its interpretation of the data presented by us from our trial did not meet the FDA s chronic effectiveness criteria. Since receiving the letter from the FDA, CryoCor has retained expert physicians in the field of electrophysiology to review the clinical data for all patients treated in its pivotal trial to independently determine the success of each procedure. Additionally, CryoCor engaged external regulatory consultants to assist with its efforts to reevaluate the clinical data and advise CryoCor on a potential amendment to its PMA based on additional information. Based upon these efforts and after a meeting held with the FDA on July 26, 2006, where the results from CryoCor s reevaluation of the AFL clinical data for purposes of determining chronic effectiveness were discussed. In November 2006, the Company intends to file an amendment to its PMA for the treatment of AFL. There can be no assurance that the FDA will determine that the data presented in the amendment meet the FDA s chronic effectiveness criteria or that the amended PMA will be approved by the FDA.

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

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

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

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

In the AFL pivotal trial, our chronic effectiveness data indicate that approximately 80% of patients that had a successful initial procedure did not have a recurrence of atrial flutter during the six month period following treatment, but did not meet the chronic effectiveness OPC established by the FDA for RF ablation. We are aware of other companies that have received PMA approval despite not meeting OPC s for RF ablation; but we cannot assure you that the FDA will agree that the data we will present in our amendment to our AFL PMA has demonstrated sufficient chronic effectiveness to receive marketing approval. If the FDA does not accept our proposed approach, the FDA may conclude that we have failed to demonstrate the effectiveness of our cryoablation system and delay or deny marketing approval.

We are dependent on the success of our cryoablation system, which has not been approved by the FDA for any indication for commercialization in the United States. If we are unable to achieve our product development goals, gain FDA approval to commercialize our cryoablation system in the United States, or experience significant delays in doing so, our stock price may decline and we may be forced to cease operations.

We have expended significant time, money and effort in the development of our cryoablation system, which is still in clinical testing, has not yet received FDA approval for any indication and may never be commercialized in the United States. In our public announcements, we have provided estimates for the timing of the accomplishment of various clinical, regulatory and other product development goals relating to our cryoablation system, which we sometimes refer to as milestones. These milestones include the enrollment of subjects in our clinical trials, the submission of data from our clinical trials to the FDA, the timing of FDA approval for our cryoablation system and other clinical and regulatory events. These estimates are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control, and we may never achieve some or all of these milestones. For example, in January 2006, the FDA informed us that our PMA for the treatment of AFL is not approvable based on the data we submitted. In response, we have analyzed our clinical data and evaluated our ability to amend our PMA for AFL in a manner that is acceptable to the FDA, and we anticipate filing an amendment to our PMA in November 2006. However, there can be no assurance that our amended PMA will be approved by the FDA. Additionally, our enrollment for our AF pivotal trial has progressed more slowly than we expected, and we are attempting to stimulate enrollment by taking actions such as the opening of new clinical sites to enroll patients. However, these efforts may not increase the pace of our enrollment, and it may take us longer than we anticipate to complete the enrollment of our AF pivotal trial. If we do not meet our estimated milestones as publicly disclosed for both AF and AFL, we may be unable to commercialize our products in the United States, or any commercialization of our products in the United States may be delayed and, as a result, our business may be harmed and our stock price may decline. If our cryoablation system is not approved by the FDA for any indication for commercialization in the United States, we may be forced to cease operations.

We will need separate FDA approval supported by a separate clinical trial for each proposed indication for our cryoablation system. We intend to seek FDA approval of our cryoablation system to treat both AFL and AF, and will only be able to market our cryoablation system for an indication for which we receive FDA approval. If the FDA does not approve our cryoablation system for treating both AFL and AF, we intend to market our cryoablation system only for the indication for which we receive FDA approval. For each indication, the FDA s marketing approval process is expensive and the outcome is uncertain. To obtain FDA marketing approval, we are required to submit detailed and comprehensive scientific data demonstrating safety and effectiveness of our

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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. In addition, the FDA process for reviewing our amended PMA could take one to three years after filing of the amended PMA. The FDA has not approved any medical device for treating AF and has approved four devices for AFL, all of which use radiofrequency, or RF, energy.

As discussed above, in January 2006, the FDA informed us that our PMA for the treatment of AFL using the cryoablation system is not approvable at present. After receipt of this FDA letter, we conducted an independent evaluation of our chronic effectiveness data, and based upon the results of this evaluation, we met with the FDA in July 2006 to discuss the results of our independent review of the AFL clinical data for purposes of determining chronic effectiveness. We expect to file an amendment to our PMA in November 2006, however, there can be no assurance that the FDA will determine that the data presented in the amended PMA meets the FDA s chronic effectiveness criteria and there can be no assurance that we will receive approval for our amended PMA.

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

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 Chief Financial Officer, or 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 United States

To obtain FDA approval for marketing, our pivotal trials must generate data demonstrating that our cryoablation system is safe and effective for each indication for which approval is sought. The FDA s grant of permission to proceed with the AFL and AF pivotal trials does not constitute a binding commitment that the FDA will consider either trial design adequate to support approval for our cryoablation system. In addition, there can be no assurance that the data generated during the pivotal trials will meet our chosen safety and effectiveness endpoints or otherwise produce results that will lead the FDA to grant marketing approval. For example, although we believed the effectiveness data in the AFL pivotal trial would meet the predefined objective performance criterion, or OPC, in January 2006, the FDA informed us that our PMA for the treatment of AFL using the cryoablation system is not approvable at present based on their analysis of chronic effectiveness. After receipt of this FDA letter, we conducted an independent evaluation of our chronic effectiveness data, and based upon the results of this evaluation, we met with the FDA in July 2006 to discuss the results of our independent review of the AFL clinical data for purposes of determining chronic effectiveness. We intend to file an amendment of our PMA in November 2006, but, there can be no assurance that the FDA will determine that the data presented in the amended PMA meets the FDA s chronic effectiveness criteria and there can be no assurance that we will receive approval for our amended PMA. If our PMA is not approved by the FDA, we will not be able to market our cryoablation system for the treatment of AFL in the United States. 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 United States for those indications.

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

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

- subjects do not enroll in our pivotal trial at the rate we currently expect;
- 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 are not followed-up at the rate we currently expect;
- subjects experience an unacceptable rate or severity of adverse side effects;
- third party clinical investigators do not perform our pivotal trial on our anticipated schedule or consistent with the clinical trial protocol, Good Clinical Practice and regulatory requirements, or other third party organizations do not perform data collection and analysis in a timely or accurate manner;
- inspections of our clinical trial sites by the FDA or Institutional Review Boards, or IRBs, find regulatory violations that require us to undertake corrective action, suspend or terminate one or more sites, or prohibit us from using some or all of the data in support of our PMA application;
- changes in laws, governmental regulations or administrative actions force us to modify the conduct of our trials or otherwise create unexpected burdens;
- the reimbursement by governmental and other third party payers changes;
- the interim results of our clinical trials are inconclusive or negative;
- one or more of our IRBs suspends or terminates our trial at an investigational site, precludes enrollment of additional subjects, or withdraws its approval of our trial;
- one or more of our clinical investigators withdraws from our trial or deviates from our approved protocol; 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 as we conduct our AF clinical trial because the follow up period for the AF trial is 12 months as opposed to six months for the AFL trial. In addition, subjects participating in our clinical trial may die before completion of their follow-up. Moreover, it may be difficult to successfully follow our subjects for the required 12-month period. Although to date we have successfully followed all our subjects from our AF feasibility study for the required 12-month period, historical results may not be indicative of our future performance. Additionally, we may experience delays in the enrollment of our pivotal trial. For example, our enrollment for our AF pivotal trial has progressed more slowly than we expected, and we are attempting to stimulate enrollment by taking actions such as the opening of new clinical sites to enroll patients. However, these efforts may not increase the pace of our enrollment, and it may take us longer than we anticipate to complete the enrollment of our AF pivotal trial. 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.

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

When we designed the size of our AF pivotal trial, we made certain assumptions about the number of patients to be enrolled to permit us to evaluate the results of each arm of our clinical trial. During the conduct of our pivotal trial, patients have withdrawn from our clinical study for reasons not in our control, such as, they were randomized to medical management, and withdrew from the trial to pursue another treatment alternative. If we do not have a sufficiently large evaluable patient population for our analysis when we have enrolled 160 patients, we may need to increase enrollment until we can generate a sufficiently large evaluable patient population. While the exact number of additional patients needed, if any, is not known at this time, it could approximate between 10-20 additional patients. Additionally, after we have enrolled 160 patients and held discussions with the FDA, our dataset of evaluable patients may be deemed sufficient, and it may not be necessary to enroll additional patients to determine the safety and effectiveness of our device for the treatment of atrial fibrillation.

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

Completion of our clinical trials and any subsequent commercialization of our product candidates require access to, or the development of, manufacturing facilities that meet applicable regulatory and quality standards to manufacture a sufficient supply of our products. If we receive FDA approval for our cryoablation system for the treatment of AF or AFL, we believe we will need to obtain additional commercial-scale manufacturing facilities. These facilities must be evaluated and qualified under our quality system to ensure that they meet our production and quality standards. The FDA also must inspect and approve facilities that manufacture our products for United States commercial purposes, as well as the manufacturing processes and specifications for our products prior to granting marketing approval of our cryoablation system. Suppliers of components of, and products used to manufacture, our products also must comply with FDA and foreign regulatory requirements, which often require significant resources and subject us and our suppliers to potential regulatory inspections and stoppages. We or our suppliers may not satisfy these requirements. If we or our suppliers do not achieve and maintain required regulatory approval for our manufacturing operations, including for any additional commercial-scale manufacturing facilities that we may obtain in the future, our commercialization efforts in the United States, if any, could be delayed, which could impair our business and financial condition and could require us to cease operations.

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

Our cryoablation system works by utilizing a pressurized system that delivers nitrous oxide to cool the tip of a catheter to freeze cardiac tissue in contact with the catheter tip while the catheter is in contact with the patient s heart. Although our cryoablation system is designed to prevent leaks in the catheter and to prevent the flow of nitrous oxide into the catheter if the catheter has been ruptured, nitrous oxide could enter the blood stream if the catheter developed a leak, which could result in serious injury to a patient, or even death. In April 2005, during routine quality control testing of a lot of Model 1200 catheters, we identified several instances of inadequate seals in the joint where the articulation section is welded to the catheter shaft, which could 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.

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.

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

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

The PVI procedure has been associated with pulmonary vein stenosis, a narrowing of the pulmonary vein that can have serious adverse health implications. Other technologies used for AF ablation have been associated with risks such as the formation of 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.

We believe that another factor that will impact the degree of market acceptance of any of our products is our ability to educate physicians to change their screening and referral practices in order to ensure physician acceptance of our system. For example, despite the lack of

effectiveness of treating AF and AFL with drugs, many physicians routinely prescribe drugs to patients suffering from AF and AFL without offering any treatment alternatives even when drug therapy is failing. We intend to target our sales efforts to interventional cardiologists and electrophysiologists because they are often the physicians treating both AF and AFL. However, the initial point of contact for many patients may be general practitioners who commonly treat patients experiencing AF and AFL. If referring physicians are not properly educated about AF and AFL and the potential benefits of using our cryoablation system over drug therapy in particular in circumstances where drug therapy fails, they may not refer AF and AFL patients who have been unsuccessfully treated with drug therapy to interventional cardiologists or electrophysiologists for our cryoablation system procedure, which may impair our business, financial condition and results of operations.

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

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commercialized, a government mandated or voluntary recall by us could occur as a result of component failures, device malfunctions, adverse events, such as serious injuries or deaths, or quality-related issues such as manufacturing errors or design or labeling defects. Recalls of our cryoablation system would divert managerial and financial resources, harm our reputation with customers and have an adverse effect on our financial condition and results of operations. A recall announcement could also negatively affect our stock price.

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

- compliance with the Quality System Regulations, which require manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process;
- the FDA s general prohibition against promoting products for unapproved or off-label uses;
- the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and
- the Reports of Corrections and Removals regulation, which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce the risk to health posed by the device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act, or FDCA.

Even if our products are approved, stringent FDA conditions of approval may significantly impact our sales and earnings depending on the scope and complexity of such conditions. The FDA enforces these requirements with inspections and market surveillance. If the FDA finds that we have failed to comply with one of these requirements, it could institute a wide variety of enforcement actions, ranging from a Warning Letter to more severe sanctions, including the following:

- fines, injunctions and civil penalties;
- recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing requests for 510(k) clearance or PMA approval of new products;
- withdrawing 510(k) clearance or PMA approvals already granted; and
- criminal prosecution.

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

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

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

- any patents issued to us, our collaborators or our licensors, may not provide a basis for a commercially viable product or provide us with any competitive advantage;
- any patents issued to us, our collaborators or our licensors may be challenged, circumvented or invalidated by third parties;
- all pending patent applications may not result in issued patents; and
- any additional proprietary technologies that we develop may not be patentable.

We attempt to protect our intellectual property position by filing United States. Patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. Currently, we own or license 34 issued United States patents and a number of pending United States patent applications covering various aspects of our products and technology.

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We also own or license 22 patents issued outside of the United States and have a number of pending patent applications outside the United States. Limitations on patent protection in some countries outside the United States, and the differences in what constitutes patentable subject matter in these countries, may limit the protection we have under patents issued to us outside of the United States. In addition, laws of foreign countries may not protect our intellectual property to the same extent as would laws of the United States. In determining whether or not to seek a patent or to license any patent in a particular foreign country, we weigh the relevant costs and benefits, and consider, among other things, the market potential of our product candidates in the jurisdiction, and the scope and enforceability of patent protection afforded by the law of the jurisdiction. Failure to obtain adequate patent protection for our proprietary product candidates and technology would impair our ability to be commercially competitive in these markets.

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

We are aware of numerous United States patents owned or licensed by third parties in areas potentially related to the technology used in our cryoablation system. These third parties include CryoCath Technologies, Inc., Johnson & Johnson, the Regents of the University of California and Spembly Medical Ltd. These third parties or our other competitors may have issued patents that cover technologies that we use in producing our product candidates, or that we use in treating patients with our product candidates. Owners of these patents or their licensees may assert that the manufacture, use or sale of our cryoablation system infringes one or more claims of their patents.

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

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

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

The medical device industry is characterized by a large number of patents, patent filings and frequent litigation based on allegations of patent infringement. Competitors may have filed applications for or have been issued patents and may obtain additional patents and proprietary rights related to products or processes that we compete with or are similar to ours. We may not be aware of all of the patents potentially adverse to our interests that may have been issued to others. Based on the litigious nature of the medical device industry and the fact that we may pose a competitive threat to some companies who own or control various patents, we believe that as we proceed toward commercialization in the United States, there is a significant risk that one or more third parties will assert a patent infringement claim against the manufacture, use or sale of our cryoablation system. Such a lawsuit may have already been filed against us without our knowledge. Any lawsuit could seek to prevent us from commercializing our cryoablation system or enjoin us from selling it, may seek damages from us, and would likely be expensive for us to defend against. We cannot predict if or when any third party patent holder, including those mentioned above, will file suit for patent infringement. Holders and prospective holders of our common stock should consider the possibility of a patent infringement suit a significant risk.

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

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

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

- pay actual damages, plus increased damages up to triple the actual damages and the other party s attorneys fees, which may be substantial;
- obtain licenses to the infringed intellectual property, which may not be available to us on acceptable terms, or at all;
- cease the development, manufacture, use and/or sale of products that infringe the patent rights of others through a court-imposed sanction called an injunction;
- expend significant resources to redesign our technology so that it does not infringe others patent rights, or to develop or acquire non-infringing technology, which may not be possible; and/or
- discontinue manufacturing or other processes incorporating infringing technology.

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

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

We depend on single source suppliers for our cryoablation system components and the loss of these suppliers could prevent or delay our clinical trials, possible commercialization of our cryoablation system in the United States and additional sales of our cryoablation system in Europe.

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

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

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

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

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

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We currently have limited resources, facilities and experience to commercially manufacture our product candidates. We have recently restructured our workforce, including reductions in our manufacturing staffing that has reduced our capacity to manufacture catheters and consoles. Currently, we can only produce sufficient quantities of catheters to support our existing clinical trials and our expected commercial sales in Europe for 2006 and 2007. To produce our cryoablation system in the quantities that we believe will be required to meet anticipated market demand in the United States in the event that we receive regulatory approval, 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 United States 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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enter into arrangements with third parties to perform sales, marketing and distribution services in the United States, our product revenues could be lower than if we directly sold, marketed and distributed our cryoablation system, or any other product that we may develop. Furthermore, if we enter into co-promotion or other marketing and sales arrangements with third parties, any revenues received will depend in part on the skills and efforts of these third parties, and we do not know whether these efforts will be successful. Some or all of our future distributors may have products or product candidates that compete with ours, and they may have an incentive not to devote their best efforts to marketing our products.

We have signed distribution agreements with third parties in Europe to market and sell our cryoablation system in the United Kingdom. We may seek additional distribution agreements to sell our cryoablation system in other countries in Europe, however our recent restructuring will delay commercial expansion in Europe, and we may never sign additional distribution agreements. 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 are closing our subsidiary in Germany through which we historically distributed our product in Belgium, the Netherlands and Germany and we may no longer sell our product in these geographic areas.

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

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

Our competitors may:

- develop and patent processes or products earlier than us;
- obtain regulatory approvals for competing products more rapidly than us; and
- develop safer, more effective and/or less expensive products or technologies that render our technology or product candidates obsolete or non-competitive.

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

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

Our business exposes us to the risk of product liability claims that 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.

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

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

We expect that a key element of our strategy will be to discover, develop and commercialize new products for the treatment of AFL and AF as extensions of, or in addition to, our cryoablation system. For example, we are completing development of our next generation catheter, Quantum, which we expect to introduce into clinical testing in 2007. However, our recent restructuring has caused us to delay or eliminate other internal research programs. Research programs to identify new product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research may not be successful in identifying potential product candidates;
- there is a high rate of attrition for product candidates in preclinical trials;
- competitors may develop alternatives that render our product candidates obsolete; and
- product candidates may on further study be shown to have harmful side effects or other characteristics that indicate they are unlikely to be effective.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- results of our clinical trials;
- failure of any of our products to receive FDA or other regulatory approvals;
- regulatory developments in the United States and foreign countries;
- developments, disputes or litigation concerning patents or other proprietary rights;
- failure of any of our product candidates, if approved for commercial sale, to achieve commercial success;
- ability to manufacture our products to commercial standards;
- public concern over our products;
- the departure of key personnel;
- future sales of our common stock;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- investors perceptions of us; and
- general economic, industry and market conditions.

A decline in the market price of our common stock could cause our stockholders to lose some or all of their investment and may adversely impact our ability to attract and retain employees and raise capital. In addition, stockholders may initiate securities class action lawsuits if the market price of our stock drops significantly, which may cause us to incur substantial costs and could divert the time and attention of our management. For example, on February 2, 2006, we announced that the FDA informed us that our PMA for the treatment of AFL is not approvable at present. In response to this news, the market price of our stock dropped significantly.

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

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

- dividing our board of directors into three classes serving staggered three-year terms;
- authorizing our board of directors to issue preferred stock without stockholder approval;
- prohibiting stockholder actions by written consent;
- limiting the persons who may call special meetings of stockholders;
- prohibiting our stockholders from making certain changes to our certificate of incorporation or bylaws except with 66 2/3% stockholder approval; and
- requiring advance notice for raising business matters or nominating directors at stockholders meetings.

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

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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 31, 2006, beneficially owned approximately 65.3% 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 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 was declared effective by the SEC on July 13, 2005. The offering commenced the same day and 3,709,090 shares of common stock were sold on our behalf at $11.00 per share, for an aggregate offering price of $40.8 million. Following the sale of shares, the offering was terminated. The net offering proceeds to us, after deducting underwriting discounts and commissions and estimated offering expenses, were approximately $35.4 million.

Of the net offering proceeds, approximately $7.2 million of the net proceeds have been used for research and development activities, which include clinical trial activities, and approximately $2.3 million have been used for sales and marketing activities through September 30, 2006. In addition, approximately $1.8 million have been used for our facility, manufacturing and quality system operations, and approximately $4.6 million 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 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)
10.1	Employment Offer Letter dated August 3, 2006, between the Registrant and Dr. Helen S. Barold (2)
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities and Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities and Exchange Act of 1934, as amended
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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

(2) Indicates management contract or compensatory plan.

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CryoCor, Inc.

SIGNATURES

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

Date: November 8, 2006

CryoCor, Inc.

By: /s/ Gregory J. Tibbitts
Gregory J. Tibbitts

Vice President, Finance and

Chief Financial Officer

(Principal Financial and Accounting Officer)