

CRYOCOR INC
Form 10-Q
November 08, 2005
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2005

OR

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

For the transition period from _____ to _____

Commission File Number 000-51410

CryoCor, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware
(State or Other Jurisdiction of Incorporation or Organization)

33-0922667
(I.R.S. Employer Identification Number)

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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 NO

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

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

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

Table of Contents

CRYOCOR, INC.

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

TABLE OF CONTENTS

	Page
	No.

PART I. <u>FINANCIAL INFORMATION</u>	3
Item 1. <u>Financial Statements</u>	3
<u>Consolidated Balance Sheets as of September 30, 2005 (Unaudited) and December 31, 2004</u>	3
<u>Consolidated Statements of Operations (Unaudited) for the three and nine months ended September 30, 2005 and 2004</u>	4
<u>Consolidated Statements of Cash Flows (Unaudited) for the nine months ended September 30, 2005 and 2004</u>	5
<u>Notes to Consolidated Financial Statements (Unaudited)</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	11
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	33
Item 4. <u>Controls and Procedures</u>	33
PART II. <u>OTHER INFORMATION</u>	33
Item 1. <u>Legal Proceedings</u>	33
Item 2. <u>Use of Proceeds</u>	33
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	34
Item 6. <u>Exhibits</u>	35
<u>SIGNATURES</u>	36

Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Financial Statements.****CryoCor, Inc.****Consolidated Balance Sheets***(in thousands except share and per share amounts)*

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

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Stockholders' equity (deficit):

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

See accompanying notes.

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

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2005	2004	2005	2004
Product sales	\$ 152	\$ 141	\$ 682	\$ 458
Operating expenses:				
Cost of sales	650	638	2,125	1,965
Research and development ⁽¹⁾	1,831	2,056	5,885	5,494
Selling, general and administrative ⁽¹⁾	1,688	1,565	4,702	3,650
Total costs and expenses	4,169	4,259	12,712	11,109
Loss from operations	(4,017)	(4,118)	(12,030)	(10,651)
Interest income	252	35	297	73
Interest expense	(327)	(59)	(751)	(144)
Net loss	(4,092)	(4,142)	(12,484)	(10,722)
Dividends and accretion to redemption value of redeemable convertible preferred stock		(1,342)	(2,662)	(2,966)
Cumulative dividends on Series C preferred stock		(61)	(102)	(181)
Net loss attributable to common stockholders	\$ (4,092)	\$ (5,545)	(15,248)	(13,869)
Basic and diluted net loss per share attributable to common stockholders	\$ (0.45)	\$ (236.54)	(4.86)	(606.88)
Shares used to compute basic and diluted net loss per share attributable to common stockholders	9,089,158	23,442	3,135,821	22,853
⁽¹⁾ Includes non-cash stock-based compensation expense as follows:				
Research and development	\$ 338	\$ 194	\$ 952	\$ 202
Selling, general and administrative	195	159	593	162
	\$ 533	\$ 353	\$ 1,545	\$ 364

See accompanying notes.

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

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

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

See accompanying notes.

Table of Contents

CRYOCOR, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

1. Organization and Basis of Presentation

Organization

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

We have prepared the accompanying unaudited consolidated financial statements in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by generally accepted accounting principles for complete financial statements. In the opinion of our management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Intercompany accounts have been eliminated in consolidation. Operating results for the three and nine months ended September 30, 2005 are not necessarily indicative of the results that may be expected for the year ending December 31, 2005. For further information, see the financial statements and disclosures thereto for the year ended December 31, 2004 included in our prospectus filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the Securities and Exchange Commission on July 14, 2005.

Reclassifications

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

2. Balance Sheet Details

Cash and Cash Equivalents

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

Investment Securities

Investment securities consist of high-grade auction rate securities and U.S. government or corporate debt securities. We classify all securities as available-for-sale, as the sale of such securities may be required prior to maturity to implement management strategies. These securities are carried at fair value, with the unrealized gains and losses reported as a component of other comprehensive income (loss) until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis. A decline in the market value of any available-for-sale security below cost that is determined to be other than temporary results in a revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method. Interest income is recognized when earned.

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

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

Table of Contents**CRYOCOR, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****(UNAUDITED)*****Inventories***

Inventories consist of the following:

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

Long-Term Debt

On March 18, 2005, the Company entered into an agreement whereby we borrowed \$7.0 million from a financial institution. As part of this transaction, the Company paid off its existing term loan which had an outstanding balance of \$1.8 million. This facility places restrictive covenants on the Company's operations, which preclude the Company from incurring new debt or placing liens on its assets, disposing of property, making dividend payments or distributions to stockholders, or entering into transactions that would result in a change of control. The new debt facility bears interest at a rate of 11.25% per annum and requires monthly interest-only payments through June 2007, at which time all remaining principal is due and payable. In conjunction with the facility, the Company issued two warrants to purchase a total of 68,288 shares of its common stock redeemable at \$6.15 per share. The fair value of the warrants was \$657,000 based upon an estimated fair value upon the date of grants of \$13.43 per common share, an estimated life of six years, a volatility rate of 70% and a risk free interest rate of 4.34%. The fair value of the warrant is recorded as a discount to the new debt facility, and will be amortized to interest expense on a straight-line basis over the term of the loan. The warrants are exercisable through 2015.

3. Stockholders' Equity***Redeemable convertible preferred stock***

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

Initial Public Offering

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

2005 Equity Incentive Plan

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

2005 Non-Employee Directors Stock Option Plan

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

Table of Contents**CRYOCOR, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****(UNAUDITED)*****2005 Employee Stock Purchase Plan***

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

4. Stock-Based Compensation

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

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

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

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

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

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

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

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

Table of Contents

CRYOCOR, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

Recently Issued Accounting Standards

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

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

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

5. Net Loss Per Common Share

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

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

Table of Contents**CRYOCOR, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****(UNAUDITED)**

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

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

Table of Contents

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

The statements in this Form 10-Q that are not descriptions of historical facts may be forward-looking statements that are subject to risks and uncertainties. These include statements related to the timing for regulatory approvals, if any, for our cryoablation system in the United States for use in treating atrial flutter, or AFL, and atrial fibrillation, or AF, the timing for when we will complete enrollment in our AF pivotal trial and submit an application for premarket approval, or PMA, for AF, the timing for product sales in the U.S., if any, our anticipated continuing net losses and anticipated increases in research and development and selling, general and administrative expenses, the amount and timing of future spending to develop existing and new product candidates, and the period over which our existing cash reserves will be sufficient to fund our ongoing operations, all of which are prospective. Such statements are only predictions and reflect our expectations and assumptions as of the date of this Form 10-Q based on currently available operating, financial, and competitive information. The actual events or results may differ materially from those projected in such forward-looking statements due to a number of factors, including risks involved with our ability to obtain regulatory approval in the U.S. for our cryoablation system for use in treating AFL and AF, risks associated with our ability to successfully commercialize our cryoablation system in the U.S. and elsewhere if our cryoablation system is approved for use in the U.S., risks associated with our dependence on patents and proprietary rights, risks associated with our protection and enforcement of our patents and proprietary rights, risks associated with the development or availability of competitive products or technologies, risks associated with our ability to obtain additional financing as necessary, and the other risks and uncertainties identified below and in the section of this Form 10-Q entitled Risk Factors Related to Our Business and in our other publicly available documents. These forward-looking statements speak only as of the date of this Form 10-Q. We expressly disclaim any intent or obligation to update any of these forward-looking statements after the filing of this Form 10-Q to reflect actual results, changes in our expectations, or otherwise.

The following information should be read in conjunction with the consolidated financial statements and the notes thereto included in Item 1 of Part I of this Form 10-Q. We also urge readers to review and consider our disclosures describing various factors that affect our business set forth in the section of this Form 10-Q entitled Risk Factors Related to Our Business, as well as in our prospectus filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the Securities and Exchange Commission on July 14, 2005, including the disclosures under the captions Management's Discussion and Analysis of Financial Condition and Results of Operations and Risk Factors Related to Our Business and the audited financial statements and notes thereto contained therein.

Overview

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

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

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

Table of Contents

To date, we have generated minimal revenues and we have incurred net losses in each year since our inception. We expect these losses to continue as we complete our clinical trial activities and continue to develop our product candidates for potential commercial launch in the U.S., and for at least some time after any commercial launch of our product in the U.S. We have financed our operations primarily through private placements of preferred stock, convertible promissory notes, bank debt, and the proceeds of our initial public offering completed in July 2005, which raised aggregate net proceeds of \$35.4 million after deducting underwriting expenses and commissions and transaction costs.

Clinical Status

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

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

Financial Operations

Product Sales. Our product sales to date have come from a limited number of commercial sites in Europe. To date, we have not generated substantial revenues in Europe, as our financial resources have primarily been dedicated to product development and clinical trials in the U.S., which has prevented us from providing the resources necessary to broadly market our cryoablation system in Europe or from increasing the number of consoles placed in Europe. We believe that European product revenues for companies with new medical technologies typically remain modest until U.S. product approval is obtained, because European approvals, which are designed primarily to demonstrate product safety, are not as compelling for European physician adoption as U.S. approvals, which must demonstrate efficacy and safety. We do not expect to generate revenues in the U.S. until our PMA for AFL has been approved by the FDA and we initiate the sales of our products. If such approval is obtained, sales will not occur until 2006 at the earliest. We expect that any revenues we generate from sales of our products will fluctuate from quarter-to-quarter.

Research and Development Expenses. Our research and development expenses primarily consist of costs incurred to further our research and development activities and include salaries and related employee benefits, costs associated with clinical trials, pre-clinical activities, regulatory activities, research-related overhead expenses and fees paid to external service providers and contracts with research organizations, which conduct certain research and development activities on our behalf. We expense research and development costs as they are incurred. We expect our research and development expenses to increase as we complete the development of our next generation product, the Quantum catheter, research new product opportunities and conduct additional clinical trials, as necessary.

Selling, General and Administrative Expenses. Our selling, general and administrative expenses consist primarily of cash and non-cash stock based compensation for executive, finance and administrative personnel. Other significant costs include professional fees for accounting and

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legal services, including legal services associated with our efforts to obtain and maintain protection for the intellectual property related to our cryoablation system. We expect our selling, general and administrative expenses to increase substantially due to the costs associated with operating as a publicly-traded company and the infrastructure necessary to support any commercialization of our product candidates.

Results of Operations

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

Table of Contents

Three months ended September 30, 2004 and 2005

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

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

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

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

Nine months ended September 30, 2004 and 2005

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

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

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

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

Liquidity and Capital Resources

We have incurred losses since our inception in August 2000. As of September 30, 2005, we had an accumulated deficit of \$65.3 million. We have funded our operations to date from private placements of equity and debt securities for aggregate net cash proceeds of \$51.2 million through September 30, 2005, as well as bank debt and the proceeds of our initial public offering, which was closed in July 2005 and raised aggregate net proceeds of \$35.4 million after deducting underwriting expenses and commissions and transaction costs. Concurrent with the closing of the initial public offering, all of our outstanding preferred shares converted into shares of common stock.

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

Table of Contents

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

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

Net Cash Used in Investing Activities. Net cash used in investing activities increased \$13.1 million to \$13.3 million for the nine months ended September 30, 2005, compared to \$167,000 for the nine months e