

CRYOCOR INC
Form 424B3
June 05, 2007
Table of Contents

Filed Pursuant to Rule 424(b)(3)
Registration No. 333-143052

PROSPECTUS

1,631,247 Shares

CRYOCOR, INC.

Common Stock

This prospectus relates to the resale from time to time of up to 1,631,247 shares of our common stock by the selling stockholders named in this prospectus and the selling stockholders' donees, pledgees or successors, which includes 1,052,423 shares of our common stock and 578,824 shares of our common stock issuable upon the exercise of warrants. The shares of common stock offered under this prospectus were issued to the selling stockholders in a private placement that closed on April 24, 2007 and is more fully described on pages 24 to 27 of this prospectus under the heading Selling Stockholders. We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholders.

The selling stockholders may sell the common stock being offered by this prospectus from time to time on terms to be determined at the time of sale through ordinary brokerage transactions or through any other means described in this prospectus under Plan of Distribution. The selling stockholders may sell the shares in negotiated transactions or otherwise, at the prevailing market price for the shares or at negotiated prices. We will not be paying any underwriting discounts or commissions in this offering.

Our common stock is listed on The NASDAQ Global Market under the symbol CRYO. The closing sale price of our common stock, as reported on The NASDAQ Global Market on June 4, 2007, was \$6.00 per share.

Investing in our common stock involves a high degree of risk. You are urged to read the section entitled Risk Factors beginning on page 3 of this prospectus, which describes specific risks and other information that should be considered before you make an investment decision.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is June 5, 2007.

Table of Contents

TABLE OF CONTENTS

	PAGE
<u>Prospectus Summary</u>	1
<u>Risk Factors</u>	3
<u>Use of Proceeds</u>	23
<u>Selling Stockholders</u>	24
<u>Plan of Distribution</u>	28
<u>Legal Matters</u>	29
<u>Experts</u>	29
<u>Where You Can Find More Information</u>	29
<u>Information Incorporated by Reference</u>	30
<u>Special Note Regarding Forward-Looking Statements</u>	31

You should rely only on the information contained or incorporated by reference in this prospectus and any applicable prospectus supplement. We have not, and the selling stockholders have not, authorized anyone to provide you with additional information or information different from that contained or incorporated by reference in this prospectus and any applicable prospectus supplement. The selling stockholders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted.

The information contained in this prospectus is accurate only as of the date of this prospectus and information appearing in any applicable prospectus supplement is accurate only as of the date of the applicable prospectus supplement. Additionally, information from other documents incorporated by reference in this prospectus or any applicable prospectus supplement is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of the prospectus or prospectus supplement or any sale of our common stock. Our business, financial condition, results of operations and prospectus may have changed since that date.

Whenever we refer to CryoCor, our company, we, our or us in this prospectus, we mean CryoCor, Inc., unless the context indicates otherwise.

Table of Contents

PROSPECTUS SUMMARY

This prospectus contains forward-looking statements which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors appearing under Risk Factors and elsewhere in, or incorporated by reference into, this prospectus. The following summary does not contain all the information that may be important to you. You should read the entire prospectus, including the financial statements and other information and documents incorporated by reference in this prospectus, before making an investment decision.

CryoCor, Inc.

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

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

We are currently enrolling a pivotal trial for the treatment of AF, and expect to complete enrollment in our trial in the next several months. As of June 4, 2007, we need to enroll four to eight additional patients to allow us to have the required population of evaluable patients. We will need to collect safety and effectiveness data on 140 evaluable patients, 70 that have been treated with cryoablation and 70 that have been treated with medical management. We anticipate needing to enroll between 166-173 patients to generate the required number of evaluable patients. In January 2007, the FDA approved our request to increase the size of our pivotal trial, as the trial was initially planned to enroll 160 patients. Some patients in our trial withdrew for various reasons, including being randomized to medical management or being denied coverage for the procedure by their insurance company. Based upon the anticipated timelines for completion of enrollment of our pivotal trial and the time required to follow our patients subsequent to their cryoablation treatments, we anticipate that we will file a PMA for the treatment of AF in the second half of 2008 and that a decision from the FDA on whether or not to approve our cryoablation system for the treatment of AF will be received in 2009.

Table of Contents

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

A copy of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished to the SEC can be obtained free of charge at our website www.cryocor.com, or without exhibits by sending a request to our Corporate Secretary at 9717 Pacific Heights Boulevard, San Diego, CA 92121 our principal executive offices. Our telephone number is (858) 909-2200.

The Offering

Common stock to be offered by the selling stockholders

1,631,247 shares

Common stock outstanding as of May 31, 2007

12,120,738 shares

Use of proceeds

We will not receive any proceeds from the sale of the shares of common stock covered by this prospectus

Nasdaq Global Market symbol

CRYO

Table of Contents

RISK FACTORS

Except for the historical information contained in this prospectus or incorporated by reference, this prospectus and the information incorporated in this prospectus by reference contain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed here or incorporated by reference. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the following section, as well as those discussed elsewhere in this prospectus and in any other documents incorporated herein by reference.

Investment in our shares involves a high degree of risk. You should consider the following discussion of risks as well as other information contained in or incorporated by reference in this prospectus before purchasing any shares. Each of these risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock.

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

We will need to raise substantial additional capital to:

fund our operations and clinical trials;

continue our research and development;

enforce our proprietary rights;

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

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

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

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

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

the costs and timing of seeking regulatory approvals;

clinical trial results;

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

Edgar Filing: CRYOCOR INC - Form 424B3

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;

our ability to restructure or refinance our existing debt;

the extent and level of reimbursement for cryoablation;

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

the effect of competing products and technologies; and

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

Table of Contents

Until we can generate sufficient product revenue, which may never occur, we expect to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants. Examples of such restrictive covenants, all of which we are subject to under our current loan agreement, include limitations on our ability to incur additional debt or liens on any of our assets, dispose of our property, make dividend payments or distributions to our stockholders or enter into transactions that would result in a change in control of us. The terms of any additional debt or equity financing may not be favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets or delay, reduce the scope of or eliminate some or all of our clinical or product development programs or commercialization efforts, which may harm our business, financial condition, results of operations and future growth prospects.

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

In our Annual Report on Form 10-K, our independent registered public accounting firm included an explanatory paragraph in their report on our 2006 financial statements related to the uncertainty in our ability to continue as a going concern. Accordingly, there is considerable doubt as to whether we will be able to continue as a going concern beyond 2007 without access to additional working capital. Although we recently completed a private placement of \$5.5 million, there can be no assurance that we will be able to obtain additional funds on satisfactory terms, or at all, to fund our operations beyond May 2008, which is when we anticipate our existing cash resources, including the proceeds from the private placement, will have been expended. If we cannot obtain sufficient additional financing in the short-term, we may be forced to restructure or significantly curtail our operations, file for bankruptcy or cease operations. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should we be forced to take any such actions.

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

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

As of March 31, 2007, we had an accumulated deficit of \$88.4 million. We have incurred net losses in each year since our inception in August 2000, including net losses of \$15.1 million, \$17.1 million, and \$15.8 million for the years ended December 31, 2006, 2005, and 2004, respectively. We expect to continue to incur significant and increasing operating losses, in the aggregate and on a per share basis, for the next several years. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, net current assets and working capital. Because of the risks and uncertainties associated with developing medical devices, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

We expect that our primary expenses for the next 24 months will be for conducting our clinical trial for AF, costs associated with preparing our PMA for AF, other costs associated with new product development and costs associated with our PMA for AFL. We expect that our general and administrative and legal costs will continue to increase due to the additional operational and regulatory burdens applicable to public companies. If we do not restructure or refinance our existing debt, we expect to pay off our existing debt of \$7.0 million when due in June 2007. In addition, we anticipate that the interference we have filed with the USPTO will be declared in 2007 and substantial financial resources will be required to support this action. If we receive FDA marketing approval of

Table of Contents

our cryoablation system for either AFL or AF, we expect to incur increased sales, marketing, manufacturing, and compliance expenses. We do not currently have the required approvals to market our cryoablation system in the United States and we may not receive them. We may not become profitable even if we obtain FDA approval and succeed in commercializing our cryoablation system in the United States. As a result, we cannot be sure when we will become profitable, if at all.

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

In late January 2006, we received a letter from the FDA informing us that our PMA for the treatment of AFL using the cryoablation system was not approvable at that time. The FDA stated that its interpretation of the data presented by us from our trial did not meet the FDA's chronic effectiveness criteria. Since receiving the letter from the FDA, CryoCor retained expert physicians in the field of electrophysiology to review the clinical data for all patients treated in its pivotal trial to independently determine the success of each procedure. Additionally, CryoCor engaged external regulatory consultants to assist with its efforts to reevaluate the clinical data and advise CryoCor on a potential amendment to its PMA based on additional information. Based upon these efforts and after a meeting held with the FDA on July 26, 2006, where the process around and results from CryoCor's reevaluation of the AFL clinical data for purposes of determining chronic effectiveness were discussed, CryoCor announced that it would file an amendment to its PMA for the treatment of AFL, and in November 2006, the amendment was filed. The FDA has decided to convene an Advisory Panel meeting to advise the FDA on whether our analysis of chronic effectiveness is sufficient to warrant marketing approval of our PMA for AFL. The Advisory Panel meeting has been scheduled for June 27, 2007, and we anticipate that the FDA will render a final decision on the approval of our PMA by August 2007. Although we believe our clinical data demonstrate adequate safety and effectiveness to support FDA approval, there can be no assurance that our product will be recommended for approval for the treatment of AFL at the Advisory Panel meeting, or that our product will be approved by the FDA for the treatment of AFL.

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

the OPCs against which we measured the safety and effectiveness of our cryoablation system were derived from RF ablation studies and the FDA has indicated that they may not be applicable to our AFL pivotal trial;

selection of endpoints, including the use of acute effectiveness rather than chronic effectiveness as the primary measure of product effectiveness in the AFL pivotal trial;

interfering effects of medication; and

protocol deviations by our clinical investigators.

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

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

In the AFL pivotal trial, our chronic effectiveness data indicate that 81.6% of patients that had a successful initial procedure did not have a recurrence of AFL during the six month period following treatment, but did not meet the chronic effectiveness OPC established by the FDA for RF ablation. We are aware of other companies that have received PMA approval despite not meeting OPC's for RF ablation; but we cannot assure you that the

Table of Contents

FDA will agree that the data presented in our amendment to our AFL PMA has demonstrated sufficient chronic effectiveness to receive marketing approval. If the FDA does not accept our proposed approach, the FDA may conclude that we have failed to demonstrate the effectiveness of our cryoablation system and delay or deny marketing approval of our cryoablation system for the treatment of AFL.

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

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

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

We have expended significant time, money and effort in the development of our cryoablation system, which is still in clinical testing, has not yet received FDA approval for any indication and may never be commercialized in the United States. In our public announcements, we have provided estimates for the timing of the accomplishment of various clinical, regulatory and other product development goals relating to our cryoablation system, which we sometimes refer to as milestones. These milestones include the enrollment of subjects in our clinical trials, the submission of data from our clinical trials to the FDA, the timing of FDA approval for our cryoablation system and other clinical and regulatory events. These estimates are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control, and we may never achieve some or all of these milestones. For example, in January 2006, the FDA informed us that our PMA for the treatment of AFL is not approvable based on the data we submitted. In response, we analyzed our clinical data and amended our PMA for AFL in a manner that is acceptable to the FDA, and filed an amendment to our PMA in November 2006. The FDA has decided to convene an Advisory Panel meeting to advise the FDA on whether our analysis of chronic effectiveness is sufficient to warrant marketing approval of our PMA for AFL. The Advisory Panel meeting has been scheduled for June 27, 2007, and we anticipate that the FDA will render a final decision on the approval of our PMA by August 2007. However, there can be no assurance that our amended PMA will be approved by the FDA. Additionally, our enrollment for our AF pivotal trial has progressed more slowly than we expected. We have opened new centers and have taken efforts to stimulate enrollment, which has improved the pace of our enrollment. However, it may take us longer than we anticipate to complete the enrollment of our AF pivotal trial. If we do not meet our estimated milestones as publicly disclosed for both AF and AFL, we may be unable to commercialize our products in the United States, or any commercialization of our products in the United States may be delayed and, as a result, our business may be harmed and our stock price may decline. If our cryoablation system is not approved by the FDA for any indication for commercialization in the United States, we may be forced to cease operations.

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

Table of Contents

are required to submit detailed and comprehensive scientific data demonstrating safety and effectiveness of our cryoablation system to the FDA's satisfaction. The marketing approval process also requires passing FDA inspection of our manufacturing facilities and of the clinical trial records for data integrity and compliance with regulatory requirements. The FDA's PMA approval review process generally takes one to three years after filing, but may take longer. The FDA has not approved any medical device for treating AF and has approved four devices for AFL, all of which use radiofrequency, or RF, energy.

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

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

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

To obtain FDA approval for marketing, our pivotal trials must generate data demonstrating that our cryoablation system is safe and effective for each indication for which approval is sought. The FDA's grant of permission to proceed with the AFL and AF pivotal trials does not constitute a binding commitment that the FDA will consider either trial design adequate to support approval for our cryoablation system. In addition, there can be no assurance that the data generated during the pivotal trials will meet our chosen safety and effectiveness endpoints or otherwise produce results that will lead the FDA to grant marketing approval. For example, in January 2006, the FDA informed us that our PMA for the treatment of AFL using the cryoablation system was not approvable at that time. After receipt of this FDA letter, we conducted an independent evaluation of our chronic effectiveness data, and based upon the results of this evaluation, we met with the FDA in July 2006 to discuss the process around and results from our independent review of the AFL clinical data. We filed an amendment to our PMA in November 2006, and the FDA has decided to convene an Advisory Panel meeting to advise the FDA on whether our analysis of chronic effectiveness is sufficient to warrant marketing approval of our PMA for AFL. The Advisory Panel meeting has been scheduled for June 27, 2007, and we anticipate that the FDA will render a final decision on the approval of our PMA by August 2007. However, there can be no assurance that the FDA will determine that the data presented in the amended PMA meets the FDA's chronic effectiveness criteria and there can be no assurance that we will receive approval for our amended PMA. If our PMA is not approved by the FDA, we will not be able to market our cryoablation system for the treatment of AFL in the United States.

Table of Contents

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

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

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

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

the FDA places our pivotal trial on hold;

insufficient capital to fund the pivotal trial;

supply shortages of the catheters used in the pivotal trial;

recalls of the catheters used in the pivotal trial;

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

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

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

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

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

the reimbursement by governmental and other third party payers changes;

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

Edgar Filing: CRYOCOR INC - Form 424B3

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

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

complications occur during cryoablation procedures that result in a decision by our Data Safety and Monitoring Board to delay or stop the clinical trial; or

third parties, investigators and contract laboratories conducting our pivotal trial do not perform as contractually required or expected. Subject enrollment in clinical trials and successful completion of subject follow-up in clinical trials depend on many factors, including the size of the subject population, the nature of the trial protocol, the proximity of subjects to clinical sites, the eligibility criteria for the trial, and subject compliance. Subjects may be discouraged from enrolling or continuing to participate in our clinical trial if the trial protocol requires them to undergo extensive pre- and post-treatment procedures to assess the safety and effectiveness of our cryoablation system. For example, two of the 160 patients originally enrolled in our AFL trial withdrew from the trial prior to completing the trial. In addition, we have seen a higher withdrawal rate of patients than we originally anticipated in our AF clinical trial. Withdrawal rates may continue to increase as we conduct our AF clinical trial because the follow up period for the AF trial is 12 months as opposed to six months for the AFL trial. In addition, subjects participating in our clinical trial may die before completion of their follow-up. Moreover, it may be difficult to successfully follow our subjects for the required 12-month period. Although to date we have successfully

Table of Contents

followed all our subjects from our AF feasibility study for the required 12-month period, historical results may not be indicative of our future performance. Additionally, we may experience delays in the enrollment of our pivotal trial. For example, our enrollment for our AF pivotal trial has progressed more slowly than we expected. We have opened new centers and have taken efforts to stimulate enrollment, which has improved the pace of our enrollment. However, it may take us longer than we anticipate to complete the enrollment of our AF pivotal trial. Additionally, we have seen a higher withdrawal rate of patients than we originally anticipated, which required us to request from the FDA that we be able to enroll more than the 160 patients originally planned. In January 2007, the FDA approved our request to increase the size of our pivotal trial. Delays in subject enrollment or failure of subjects to continue to participate in a trial may cause an increase in costs and delays in our clinical trial or result in the failure of the trial, which could cause us to fail to secure FDA marketing approval of our cryoablation system in a timely manner, if at all.

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

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

When we designed the size of our AF pivotal trial, we made certain assumptions about the number of patients to be enrolled to permit us to evaluate the results of each arm of our clinical trial. During the conduct of our pivotal trial, patients have withdrawn from our clinical study for reasons not in our control, such as, they were randomized to medical management or were not covered by insurance, and withdrew from the trial. If we do not have a sufficiently large evaluable patient population for our analysis when we have completed enrollment, we may need to increase enrollment until we can generate a sufficiently large evaluable patient population. For example, the FDA has approved our request to enroll an additional 20 patients, up to 180 patients in total. While the exact number of additional patients needed is not known at this time, we anticipate that we will need to enroll at least 166-173 patients to achieve a dataset of evaluable patients.

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

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

Table of Contents

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

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

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

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

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

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

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

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

Table of Contents

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

Even if we obtain regulatory approval of our cryoablation system or any other product candidate that we may develop, these products may not gain market acceptance among physicians, patients, healthcare payers or the medical community. The degree of market acceptance of any product that we may develop will depend on a number of factors, including:

the perceived safety and effectiveness of the product;

the prevalence and severity of any side effects;

the procedure time associated with the use of the product;

potential advantages over alternative treatments;

our ability to adequately fund the commercialization of the product;

the strength of marketing and distribution support; and

sufficient third party coverage or reimbursement.

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

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

Even if we obtain FDA approval to market our products, our product candidates could be recalled and any failure to comply with FDA regulations could subject us to enforcement action.

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

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

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

Table of Contents

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:

fining, 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;

Edgar Filing: CRYOCOR INC - Form 424B3

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

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

We attempt to protect our intellectual property position by filing United States patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. Currently, we own or license 36 issued United States patents and a number of pending United States patent applications covering various aspects of our products and technology.

We also own or license 24 patents issued outside of the United States and have a number of pending patent applications outside the United States. Limitations on patent protection in some countries outside the United States, and the differences in what constitutes patentable subject matter in these countries, may limit the

Table of Contents

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 Spemby Medical Ltd. These third parties or our other competitors may have issued patents that cover technologies that we use in producing our product candidates, or that we use in treating patients with our product candidates. 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

Table of Contents

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.

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.

Table of Contents

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

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

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

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

We currently have limited resources, facilities and experience to commercially manufacture our product candidates. In the first half of 2006, we restructured our workforce, including reductions in our manufacturing staffing that has reduced our capacity to manufacture catheters and consoles. Currently, we can only produce sufficient quantities of catheters to support our existing clinical trials and our expected commercial sales in Europe for 2007 and 2008. To produce our cryoablation system in the quantities that we believe will be required to meet anticipated market demand in the United States in the event that we receive regulatory approval for AF, we will need to increase, or scale up, the production process by a significant factor over the current level of production. There are technical challenges to scaling up manufacturing capacity, and developing commercial-scale manufacturing facilities would require the investment of substantial additional funds and hiring and retaining additional management and technical personnel who have the necessary manufacturing experience. We may not successfully complete any required scale up in a timely manner, or at all due to such technical difficulties and/or insufficient funds. If we are unable to do so, we may not be able to produce our cryoablation system in sufficient quantities to meet the requirements for the launch of the product in the United States if we receive the required regulatory approval from the FDA for AF, or to meet demand for our cryoablation system in Europe. If we obtain regulatory approval from the FDA for our cryoablation system for AF but are unable to manufacture a sufficient supply of our cryoablation systems, our revenues, business and financial prospects would be materially adversely affected. In addition, if we obtain regulatory approval for our cryoablation system for AF, but the scaled up production process is not efficient or produces cryoablation systems that do not meet quality and other standards, our future gross margins, if any, will be adversely affected.

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

Our Quantum catheter is more complicated to manufacture than our CryoBlator catheter, and our experience in manufacturing the initial prototypes indicate that it may take longer to manufacture a single Quantum catheter than as required to manufacture a single CryoBlator catheter. This complexity may delay our ability to advance

Table of Contents

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

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

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

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

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

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

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

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

Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government sponsored healthcare and private insurance. To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical data, which may involve one or more clinical trials, that compares the cost-effectiveness of our products to other available therapies. We may not obtain

Table of Contents

international reimbursement or pricing approvals in a timely manner, or at all. Our failure to receive international reimbursement or pricing approvals would negatively impact market acceptance of our products in the international markets in which those approvals are sought.

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

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

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

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

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

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

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

We do not have a sales organization in the United States and have limited experience as a company in the sales, marketing and distribution of medical devices. If our cryoablation system is approved by the FDA, we plan to establish our own sales force to market our cryoablation system in the United States. Developing a sales force is expensive and time consuming and could delay or limit the success of any product launch. We may not be able to develop this capacity on a timely basis or at all. Additionally, if we are approved for the treatment of AFL, due to our limited cash resources, we do not intend to broadly commercialize our product in the United States until our financial condition improves. We may choose to contract with third parties, including distributors or agents, to perform sales, marketing and distribution services in the United States. If we enter into arrangements with third parties to perform sales, marketing and distribution services in the United States, our product revenues could be lower than if we directly sold, marketed and distributed our cryoablation system, or any other product that we may develop. Furthermore, if we enter into co-promotion or other marketing and sales arrangements with

Table of Contents

third parties, any revenues received will depend in part on the skills and efforts of these third parties, and we do not know whether these efforts will be successful. Some or all of our future distributors may have products or product candidates that compete with ours, and they may have an incentive not to devote their best efforts to marketing our products.

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

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

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

Our competitors may:

develop and patent processes or products earlier than us;

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

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

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

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

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices. We may be subject to product liability claims, including frivolous lawsuits, if our cryoablation system causes, or appears to have caused, an injury. Claims may be made by consumers, healthcare providers, third party strategic collaborators or others selling our products. Although we have product liability and clinical trial liability insurance that we believe is appropriate for our company, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, the coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will

Table of Contents

be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

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

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

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

Table of Contents

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.

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

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

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

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

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

Testing and maintaining internal controls also involves significant costs and could divert our management's attention from other matters that are important to our business. We may not be able to conclude on an ongoing

Table of Contents

basis that we have effective internal controls over financial reporting in accordance with Section 404, and our independent auditors may not be able or willing to issue a favorable assessment of our conclusions. Failure to achieve and maintain an effective internal control environment could harm our operating results and could cause us to fail to meet our reporting obligations. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

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

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

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

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

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

results of our clinical trials;

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

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

regulatory developments in the United States and foreign countries;

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

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

ability to manufacture our products to commercial standards;

public concern over our products;

the departure of key personnel;

future sales of our common stock;

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

changes in the structure of healthcare payment systems;

investors' perceptions of us; and

general economic, industry and market conditions.

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

Table of Contents

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

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

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

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

prohibiting stockholder actions by written consent;

limiting the persons who may call special meetings of stockholders;

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

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

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

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

Our executive officers, current directors and holders of five percent or more of our common stock, as of May 31, 2007, beneficially owned approximately 76.1% 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.

Table of Contents

USE OF PROCEEDS

We will not receive any proceeds from the sale of shares of our common stock by the selling stockholders. The proceeds from the sale of the common stock offered pursuant to this prospectus, including shares of our common stock issued upon exercise of the warrants, are solely for the accounts of the selling stockholders.

The selling stockholders will pay any underwriting discounts and commissions and expenses incurred by the selling stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholders in disposing of the shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees and fees and expenses of our counsel and our accountants.

A portion of the shares covered by this prospectus are issuable upon exercise of warrants to purchase our common stock. Upon any exercise for cash of the warrants, the selling stockholders will pay us the exercise price of the warrants. The cash exercise price of the warrants is \$5.14 per share. The warrants are also exercisable on a cashless basis. We will not receive any cash payment from the selling stockholders upon any exercise of the warrants on a cashless basis.

Table of Contents

SELLING STOCKHOLDERS

We are registering for resale shares of our common stock that have been sold to the selling stockholders identified below or that may be issued upon exercise of the warrants that have been issued to the selling stockholders identified below. Pursuant to a securities purchase agreement dated as of April 20, 2007 between us and the selling stockholders, referred to as the Purchase Agreement, we issued and sold, for an aggregate purchase price of \$5,449,971.90:

an aggregate of 1,052,423 shares of our common stock; and

warrants to purchase an aggregate of 578,824 shares of our common stock at an exercise price of \$5.14 per share, which warrants became exercisable on the date six months after issuance and expire five years from the date of issuance.

Throughout this prospectus, when we refer to the shares of our common stock being registered on behalf of the selling stockholders, we are referring to the shares of common stock issued to the selling stockholders and the shares of common stock issuable upon exercise of the warrants issued to the selling stockholders under the Purchase Agreement.

Under the Purchase Agreement, we agreed to file a registration statement, of which this prospectus is a part, with the Securities and Exchange Commission, or SEC, to register the disposition of the shares of our common stock that were issued to the selling stockholders and the shares of common stock issuable upon exercise of the warrants issued to the selling stockholders under the Purchase Agreement and to use our reasonable best efforts to keep the registration effective until the earliest of the following: (i) such time as all of such shares have been sold as contemplated by the registration statement, (ii) the third anniversary of the date the registration statement is first declared effective, or (iii) the date on which we deliver an opinion of our counsel that (1) the holder may sell in a single transaction all such shares then held or issuable to the holder on a registered securities exchange under an applicable exemption from the registration requirements of the Securities Act of 1933, as amended, or the Securities Act (pursuant to Rule 144 under the Securities Act or otherwise), and (2) all transfer restrictions and restrictive legends with respect to such shares will be removed upon the consummation of the sale. Under the Purchase Agreement, if the selling stockholders' use of the prospectus forming a part of the registration statement is suspended for more than 45 days in any 12-month period, other than due to any action by the holder, we may incur penalties equal to up to approximately \$55,000 per month and up to approximately \$1.1 million in the aggregate under certain conditions set forth in the Purchase Agreement.

The warrants held by the selling stockholders are exercisable at any time on or after October 24, 2007 in whole or in part and expire on April 24, 2012. Pursuant to the terms of the warrants, if certain changes occur to our capitalization, such as a stock split or stock dividend of the common stock, then the exercise price and number of shares issuable upon exercise of the warrants will be adjusted appropriately. In addition, pursuant to the terms of the warrants, if at any time we grant, issue or sell any securities, if right to purchase securities pro rata to holders of our common stock, the selling stockholders will have a right of participation upon equivalent terms on the basis as though the warrant had been fully exercised immediately prior to the date as of which the record holders of shares of our common stock are to be determined for the sale, grant or issuance, as applicable.

We are registering the above-referenced shares of our common stock to permit each of the selling stockholders and their donees, pledgees, transferees or other successors-in-interest that receive their shares after the date of this prospectus to resell or otherwise dispose of the shares, or the interests therein, in the manner contemplated under the Plan of Distribution.

Table of Contents

The table below presents information regarding the selling stockholders and the shares of our common stock that they may offer and sell from time to time under this prospectus. The shares of common stock covered, as to their resale, under this prospectus include shares of common stock sold under the Purchase Agreement and shares of common stock that are issuable upon exercise of warrants issued to the selling stockholders. Except as noted in the footnotes, no selling stockholder has had, within the past three years, any position, office, or material relationship with us or any of our predecessors or affiliates.

The information in the following table for the selling stockholders is based upon information provided by each selling stockholder, or in Schedules 13G and other public documents filed with the SEC. The number of shares in the column **Number of Shares Being Offered** represents all of the shares that a selling stockholder may offer under this prospectus, and assumes the exercise of all the warrants for common stock held by the selling stockholders. In addition, the table assumes that the selling stockholders sell all of such shares. However, because the selling stockholders may sell all or some of their shares under this prospectus from time to time, or in another permitted manner, we cannot assure you as to the actual number of shares that will be sold by the selling stockholders or that will be held by the selling stockholders after completion of the sales. We do not know how long the selling stockholders will hold the shares before selling them. Information concerning the selling stockholders may change from time to time and changed information will be presented in a supplement to this prospectus if and when necessary and required. The applicable percentages of ownership are based upon an aggregate of 12,117,041 shares of our common stock issued and outstanding as of April 24, 2007, including the shares of common stock issued to the selling stockholders in connection with the Purchase Agreement. Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

Selling Stockholders	Number of Shares Beneficially Owned Prior to Offering (1)	Number of Shares Being Offered	Beneficially Owned After Offering	
			Number	Percent
Cross Creek Capital, L.P. (2)	476,928	476,928	0	*
Cross Creek Capital Employees Fund, L.P. (3)	46,870	46,870	0	*
Far West Capital Partners, LP (4)	925,340	224,484	700,856	5.8%
Iroquois Master Fund, Ltd. (5)	74,827	74,827	0	*
MPM BioVentures II, LP (6)	228,929	11,118	217,811	1.8%
MPM BioVentures II-QP, LP (7)	2,074,261	100,748	1,973,513	16.3%
MPM BioVentures GmbH & Co. Parallel-Beteiligungs KG (8)	730,241	35,468	694,773	5.7%
MPM Asset Management Investors 2000B LLC (9)	47,752	2,318	45,434	*
Nite Capital Master, Ltd. (10)	59,862	59,862	0	*
Robert G. Schiro (11)	1,278,298	74,827	1,203,471	9.9%
Wasatch Micro Cap Fund (12)	633,834	299,314	334,520	2.8%
Wasatch Micro Cap Value Fund (13)	174,827	74,827	100,000	*
William Blair Capital Partners VII QP, L.P. (14)	1,930,385	144,103	1,786,282	14.7%
William Blair Capital Partners VII L.P. (15)	80,581	5,553	75,028	*

* Less than 1%.

- (1) Prior to the Offering means (1) as of April 24, 2007 and (2) including the shares of common stock issued to the selling stockholders and the shares of common stock issuable to the selling stockholders upon exercise of the warrants in connection with the Purchase Agreement. Prior to the Offering also means prior to the offering by the selling stockholders of the shares registered under this prospectus for resale.
- (2) Wasatch Advisors, Inc. is the sole member of Cross Creek Capital, LLC, which is the general partner of Cross Creek Capital GP, L.P., which is the general partner of Cross Creek Capital, L.P. Wasatch Advisors, Inc., through a four-person investment committee, has voting and dispositive authority over the shares. Decisions by the investment committee are made by a vote of a majority of its members. Karey Barker, Sam

Table of Contents

- Stewart, Robert Gardiner and Greg Bohlen are the members of the investment committee and each disclaims beneficial ownership of these shares, except to the extent of their pecuniary interest therein.
- (3) Wasatch Advisors, Inc. is the sole member of Cross Creek Capital, LLC, which is the general partner of Cross Creek Capital GP, L.P., which is the general partner of Cross Creek Capital Employees Fund, L.P. Wasatch Advisors, Inc., through a four-person investment committee, has voting and dispositive authority over the shares. Decisions by the investment committee are made by a vote of a majority of its members. Karey Barker, Sam Stewart, Robert Gardiner and Greg Bohlen are the members of the investment committee and each disclaims beneficial ownership of these shares, except to the extent of their pecuniary interest therein.
 - (4) Robert G. Schiro is the General Partner of Far West Capital Partners, LP and has voting and investment power with respect to the shares held by Far West Capital Partners, LP.
 - (5) Joshua Silverman is the Authorized Signatory of Iroquois Master Fund, Ltd. and has voting and investment power with respect to the shares held by Iroquois Master Fund, Ltd. Mr. Silverman disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein.
 - (6) MPM Asset Management II, LLC is the general partner of MPM Asset Management II, L.P., the general partner of MPM BioVentures II, L.P. Kurt Wheeler, one of our directors, Ansbert Gadicke, Michael Steinmetz, Luke Evnin, and Nicholas Galakatos, as investment managers of MPM Asset Management II, LLC, share voting and investment power with respect to shares held by MPM BioVentures II, L.P. Each of Messrs. Wheeler, Gadicke, Steinmetz, Evnin and Galakatos disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.
 - (7) MPM Asset Management II, LLC is the general partner of MPM Asset Management II, L.P., the general partner of MPM BioVentures II-QP, LP. Kurt Wheeler, one of our directors, Ansbert Gadicke, Michael Steinmetz, Luke Evnin, and Nicholas Galakatos, as investment managers of MPM Asset Management II, LLC, share voting and investment power with respect to shares held by MPM BioVentures II-QP, LP. Each of Messrs. Wheeler, Gadicke, Steinmetz, Evnin and Galakatos disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.
 - (8) MPM Asset Management II, LLC is the general partner of MPM Asset Management II, L.P., the general partner of MPM BioVentures GmbH & Co. Parallel-Beteiligungs KG. Kurt Wheeler, one of our directors, Ansbert Gadicke, Michael Steinmetz, Luke Evnin, and Nicholas Galakatos, as investment managers of MPM Asset Management II, LLC, share voting and investment power with respect to shares held by MPM BioVentures GmbH & Co. Parallel-Beteiligungs KG. Each of Messrs. Wheeler, Gadicke, Steinmetz, Evnin and Galakatos disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.
 - (9) MPM Asset Management II, LLC is the general partner of MPM Asset Management II, L.P. Kurt Wheeler, one of our directors, Ansbert Gadicke, Michael Steinmetz, Luke Evnin, and Nicholas Galakatos, as investment managers of MPM Asset Management II, LLC, the general partner of MPM Asset Management Investors 2000B LLC, share voting and investment power with respect to shares held by MPM Asset Management Investors 2000B LLC. Each of Messrs. Wheeler, Gadicke, Steinmetz, Evnin and Galakatos disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.
 - (10) Keith A. Goodman is the Authorized Signatory of Nite Capital Master, Ltd. and has voting and investment power with respect to the shares held by Nite Capital Master, Ltd. Mr. Goodman disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.
 - (11) Beneficial ownership includes shares held outright by Mr. Schiro as well as shares held by Far West Capital Partners, LP, shares held by the Endurance Fund, of which Mr. Schiro is the Investment Manager, and shares held by the Susan Schiro & Peter Manus Foundation, of which Mr. Schiro is the Investment Manager. Mr. Schiro has voting and investment power with respect to the shares held by Far West Capital Partners, LP, the Endurance Fund and the Susan Schiro & Peter Manus Foundation.
 - (12) Wasatch Advisors, Inc. is the investment adviser for Wasatch Micro Cap Fund. Wasatch Advisors, Inc., through two of its portfolio managers, has voting and dispositive authority over the shares. John Malooly has voting authority and Dan Chace has dispositive authority over these shares and each disclaims beneficial ownership of these shares.

Table of Contents

- (13) Wasatch Advisors, Inc. is the investment adviser for Wasatch Micro Cap Value Fund. Wasatch Advisors, Inc., through one of its portfolio managers, has voting and dispositive authority over the shares. John Malooly has voting and dispositive authority over these shares and disclaims beneficial ownership of these shares.
- (14) Consists of shares of common stock and 6,451 vested options to purchase common stock granted in May 2006 held by William Blair Capital Partners VII QP, L.P. William Blair Capital Management VII, L.P. is the general partner of William Blair Capital Partners VII, QP L.P. William Blair Capital Management VII, L.L.C. is the general partner of William Blair Capital Management VII, L.P. William Blair Capital Management VII, L.L.C., through a seven-person board of managers composed of certain of its members, has voting and dispositive authority over the shares held by William Blair Capital Partners VII QP, L.P. Decisions of the board of managers are made by a majority vote of its members and, as a result, no single member of the board of managers has voting or dispositive authority over the shares. Arda Minocherhomjee, Ph.D., one of our directors, Robert D. Blank, Timothy Burke, David G. Chandler, John Ettelson, Robert P. Healy and Timothy M. Murray are the members of the board of managers and each disclaims beneficial ownership of these shares, except to the extent of their pecuniary interest therein. Pursuant to contractual arrangements between Dr. Minocherhomjee and William Blair Capital Management VII, L.P. and among William Blair Capital Management VII, L.L.C., William Blair Capital Partners VII QP, L.P. and William Blair Capital Partners VII L.P., the four entities may be deemed to have a pecuniary interest in the option to purchase 6,451 shares of common stock discussed above. Each of the four entities disclaims beneficial ownership of such option except to the extent of its pecuniary interest therein.
- (15) Consists of shares of common stock and 6,451 vested options to purchase common stock granted in May 2006 held by William Blair Capital Partners VII L.P. William Blair Capital Management VII, L.P. is the general partner of William Blair Capital Partners VII L.P. William Blair Capital Management VII, L.L.C. is the general partner of William Blair Capital Management VII, L.P. William Blair Capital Management VII, L.L.C., through a seven-person board of managers composed of certain of its members, has voting and dispositive authority over the shares held by William Blair Capital Partners VII L.P. Decisions of the board of managers are made by a majority vote of its members and, as a result, no single member of the board of managers has voting or dispositive authority over the shares. Arda Minocherhomjee, Ph.D., one of our directors, Robert D. Blank, Timothy Burke, David G. Chandler, John Ettelson, Robert P. Healy and Timothy M. Murray are the members of the board of managers and each disclaims beneficial ownership of these shares, except to the extent of their pecuniary interest therein. Pursuant to contractual arrangements between Dr. Minocherhomjee and William Blair Capital Management VII, L.P. and among William Blair Capital Management VII, L.L.C., William Blair Capital Partners VII QP, L.P. and William Blair Capital Partners VII L.P., the four entities may be deemed to have a pecuniary interest in the option to purchase 6,451 shares of common stock discussed above. Each of the four entities disclaims beneficial ownership of such option except to the extent of its pecuniary interest therein.

Table of Contents

PLAN OF DISTRIBUTION

We have registered the 1,631,247 shares of our common stock offered in this prospectus on behalf of the selling stockholders. We will pay all expenses of this registration and we will not receive any proceeds from the sale of the selling stockholders' shares. The selling stockholders are responsible for paying any commissions, discounts, or other brokerage fees incurred in connection with their sale of any of the shares.

The shares of common stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market prices, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected at various times in one or more of the following transactions, or in other kinds of transactions:

on The NASDAQ Global Market (or any other exchange on which the shares may be listed);

in the over-the-counter market;

in private transactions and transactions otherwise than on an exchange or in the over-the-counter market;

in connection with short sales of the shares;

by pledge to secure debt and other obligations;

through the writing of options, whether the options are listed on an options exchange or otherwise;

in connection with the writing of non-traded and exchange-traded call options, in hedge transactions and in settlement of other transactions in standardized or over-the-counter options; or

through a combination of any of the above transactions.

Each selling stockholder and its or his successors, including its transferees, pledgees or donees or their successors, may sell the common stock directly to purchasers or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions from the selling stockholder or the purchasers. These discounts, concessions or commissions as to any particular underwriter, broker-dealer or agent may be in excess of those customary in the types of transactions involved.

Under the terms of the private placement, we have agreed to indemnify the selling stockholders, and each director, officer or controlling person of each selling stockholder within the meaning of Section 15 of the Securities Act against all losses, claims, damages, liabilities and expenses, (or action in respect thereof) including any of the foregoing incurred in settlement of any litigation, commenced or threatened, arising out of or based on (i) any untrue statement or alleged untrue statement of a material fact contained in, or information incorporated by reference into, any registration statement or prospectus (or any amendment or supplement thereto) or any preliminary prospectus prepared in connection with the registration contemplated by the Purchase Agreement, or (ii) any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading in light of the circumstances under which any statements are made.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance on Rule 144 under the Securities Act of 1933, if they meet the criteria and conform to the requirements of that rule.

The selling stockholders and any broker-dealers or agents that participate with the selling stockholders in the sale of shares may be underwriters within the meaning of the Securities Act. Any commissions received by broker-dealers or agents on the sales and any profit on the resale of shares purchased by broker-dealers or agents may be deemed to be underwriting commissions or discounts under the Securities Act.

Edgar Filing: CRYOCOR INC - Form 424B3

Under the rules of the SEC, any person engaged in the distribution of our common stock may not simultaneously buy, bid for or attempt to induce any other person to buy or bid for our common stock in the open

Table of Contents

market for a period of two business days prior to the beginning of the distribution. The rules and regulations under the Exchange Act may also limit the timing of purchases and sales of shares of our common stock by the selling stockholders. We have notified the selling stockholders they should not begin any distribution of common stock unless they have stopped purchasing and bidding for common stock in the open market as provided in applicable securities regulations, including Regulation M promulgated under the Exchange Act.

We have informed the selling stockholders that the anti-manipulation provisions of Regulation M may apply to the sales of their shares. We have advised the selling stockholders that they will be subject to the prospectus delivery requirements under the Securities Act.

LEGAL MATTERS

Certain legal matters with respect to the validity of the common stock offered hereby will be passed upon for us by Cooley Godward Kronish LLP.

EXPERTS

The consolidated financial statements of CryoCor, Inc. appearing in CryoCor's Annual Report (Form 10-K) for the year ended December 31, 2006 have been audited by Ernst & Young LLP, an independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements), and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy these reports, proxy statements and other information at the SEC's public reference room at 100 F Street, N.E., Washington, D.C. 20549 or at the SEC's other public reference facilities. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference rooms. You can request copies of these documents by writing to the SEC and paying a fee for the copying costs. Our SEC filings are also available at the SEC's website at <http://www.sec.gov>. We maintain a website at www.cryocor.com. Information contained in or accessible through our website does not constitute part of this registration statement and should not be relied upon in connection with this prospectus unless that information is also in or is specifically incorporated by reference in this prospectus.

This prospectus is part of a registration statement that we filed with the SEC. The registration statement contains more information than this prospectus regarding us and our common stock, including certain exhibits. You can obtain a copy of the registration statement from the SEC at the address listed above or from the SEC's internet website.

Table of Contents

INFORMATION INCORPORATED BY REFERENCE

We are allowed to incorporate by reference information contained in documents that we file with the SEC. This means that we can disclose important information to you by referring you to those documents and that the information in this prospectus is not complete and you should read the information incorporated by reference for more detail. The information incorporated by reference is considered to be a part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. Any statement contained in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded, for purposes of this prospectus, to the extent that a statement contained in or omitted from this prospectus, or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein, modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We incorporate by reference the documents listed below and any future filings we will make with the SEC pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act from the date of this prospectus but prior to the termination of the offering:

Annual report on Form 10-K for the year ended December 31, 2006, filed with the SEC on March 30, 2007;

Quarterly report on Form 10-Q for the quarter ended March 31, 2007, filed with the SEC on May 15, 2007;

Current report on Form 8-K filed with the SEC on January 11, 2007;

Current report on Form 8-K filed with the SEC on February 12, 2007;

Current report on Form 8-K filed with the SEC on March 15, 2007;

Current report on Form 8-K filed with the SEC on April 9, 2007;

Current report on Form 8-K filed with the SEC on April 25, 2007;

Current report on Form 8-K filed with the SEC on May 7, 2007; and

The description of our common stock contained in our registration statement on Form 8-A, registering our common stock under Section 12 of the Exchange Act, filed with the SEC on July 1, 2005.

You may request a copy of these filings at no cost, by writing or telephoning us at the following address or telephone number:

CryoCor, Inc.

9717 Pacific Heights Blvd.

San Diego, CA 92121

Attn: Investor Relations

(858) 909-2200

Edgar Filing: CRYOCOR INC - Form 424B3

You should rely only on the information incorporated by reference or provided in this prospectus or any supplement. We have not authorized anyone else to provide you with different information. The selling stockholders will not make an offer of these shares in any state where the offer is not permitted. You should not assume that the information in this prospectus or any supplement is accurate as of any date other than the date on the front of these documents.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but not always, made through the use of words or phrases such as anticipate, estimate, plan, project, continuing, ongoing, expect, management believes, we believe, we intend and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed in this prospectus or incorporated by reference.

Because the factors discussed in this prospectus or incorporated by reference and even factors of which we are not yet aware, could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on behalf of CryoCor, you should not place undue reliance on any such forward-looking statements. These statements are subject to risks and uncertainties, known and unknown, which could cause actual results and developments to differ materially from those expressed or implied in such statements. We have included important factors in the cautionary statements included or incorporated in this prospectus, particularly under the heading **RISK FACTORS**, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. These and other risks are detailed in our reports filed from time to time under the Securities Act and/or the Exchange Act. You are encouraged to read these filings as they are made.

Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.