CRYOCOR INC
Form 10-K
March 30, 2007
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS

PURSUANT TO SECTION 13 OR 15(d) OF THE

SECURITIES EXCHANGE ACT OF 1934

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2006

OR

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

Commission file number 000-51410

CRYOCOR, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	33-0922667
(State of Incorporation)	(I.R.S. Employer Identification No.)

9717 Pacific Heights Boulevard

San Diego, California 92121

(Address of Principal Executive Offices, including Zip Code)

(858) 909-2200

(Registrant s Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Common Stock, $0.001 par value

(Title of Class)

Securities registered pursuant to Section 12(g) of the Act:

None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ¨ NO x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES ¨ NO x

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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

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

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

The aggregate market value of the registrant s voting and nonvoting common stock held by non-affiliates of the registrant was $15,069,492 based on the closing sales price on June 30, 2006 as reported on the Nasdaq Stock Market.

The number of shares of registrant s common stock outstanding on March 1, 2007 was 11,030,366.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive Proxy Statement to be filed with the Securities and Exchange Commission, or SEC, pursuant to Regulation 14A in connection with the 2007 Annual Meeting of Stockholders to be held on May 14, 2007 are incorporated by reference into Part III of this report. Such Proxy Statement will be filed with the SEC within 120 days after the registrant s fiscal year ended December 31, 2006.

Table of Contents

CRYOCOR, INC.

ANNUAL REPORT ON FORM 10-K

For the Year Ended December 31, 2006

TABLE OF CONTENTS

Table of Contents

PART I

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

ITEM 1. BUSINESS

As used in this report, the terms we, our, ours and us refer to CryoCor, Inc., a Delaware corporation, and its subsidiaries, unless the context suggests otherwise. We were incorporated in Delaware in August 2000.

Overview

We have developed and manufacture a minimally invasive system based on our proprietary cryoablation technology for the treatment of cardiac arrhythmias. Cardiac arrhythmias are dysfunctions in the electrical activity of the heart that normally controls and maintains the highly coordinated contractions of the heart. Arrhythmias cause the heart to pump blood less efficiently, cause potentially debilitating symptoms and can result in life threatening events such as stroke. We have focused our initial development efforts on designing a system for treating atrial fibrillation, or AF, and atrial flutter, or AFL, the two most common and difficult to treat arrhythmias. AF is the most prevalent arrhythmia. AFL is the second most prevalent arrhythmia, and can lead to, and often coexists 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, during 2006, we reevaluated the chronic effectiveness

Table of Contents

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 greater than 80%. We met with the FDA in February 2007 to discuss the status of their review of our PMA amendment, and were notified that the FDA accepted the process by which our data was analyzed and that the FDA intended to convene an Advisory Panel meeting to advise the FDA on the evaluation of chronic effectiveness in our PMA. In subsequent discussions with the FDA, we provided additional information that we believe supports our basis for approval, and that has resulted in a higher computation of chronic effectiveness than previously submitted. The FDA decided to postpone the Advisory Panel meeting for CryoCor while they evaluate the additional information, and the FDA has indicated that it may no longer be necessary to convene an Advisory Panel meeting. We anticipate that the FDA will render a 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 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 second quarter of 2007. As of March 28, 2007, we need to enroll nine to 16 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, and 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. We believe our pivotal trial for the treatment of AF is significantly further along than any competing ablation catheter trial, and we estimate our lead time in enrolling our clinical trial is between 12-18 months ahead of the enrollment pace of the next most advanced AF pivotal trial. 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 mid-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.

AF afflicts more than 2.3 million people in the United States, where it has been estimated to account for more than $9 billion annually in disease-related healthcare costs including drug-based therapy. Our cryoablation system, if approved by the FDA, will address that portion of the patient population for whom drug therapy has not proven effective. Because we anticipate that our cryoablation system, if approved, is likely to be approved for use in patients for whom drug therapy has failed, we are not able to estimate the size of the potential market for our cryoablation system, and the $9 billion currently spent annually in treating AF is not necessarily a relevant indicator of the size of our potential market. It is estimated that each year approximately 500,000 new cases of AF occur in the United States. AF is the leading cause of stroke among the elderly, and people afflicted with this condition are at six times greater risk of stroke and two times greater risk of death as compared to the population without AF. AFL is the second most common arrhythmia. In 2000, it was estimated that more than 200,000 new cases of AFL occur annually in the United States.

The current standard of care for treating AF is chronic drug therapy, which is costly, often ineffective and can have serious side effects. Other existing treatments for AF include surgical procedures and the off-label use of catheter-based ablation devices. We believe these procedures have failed to gain broad market adoption because they require major surgery, can cause serious complications including death, are not approved for the treatment of AF or they lack effectiveness.

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

Table of Contents

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.

The Normal Heart

The human heart, which consists of four chambers, is responsible for the continuous pumping and circulation of blood throughout the body. The upper two chambers are the atria, and the lower two chambers are the ventricles. Blood returning to the heart from the body flows to the right atrium and then into the adjacent right ventricle. The right ventricle contracts and pumps blood to the lungs where blood takes up oxygen. Blood flows back to the heart from the lungs through the pulmonary veins to the left atrium and on into the adjacent left ventricle. When the left ventricle contracts, oxygenated blood is pumped to the rest of the body.

Each beat of the heart is initiated and coordinated via an electrical impulse that passes through the heart s electrical conduction system. The spread of the electrical impulse causes the muscle of the atria and ventricles to contract and pump blood. The electrical system of the heart consists of the sinoatrial, or SA, node, the atrioventricular, or AV, node and special pathways in the ventricles that conduct the electrical impulse. The SA node is the heart s natural, electrical pacemaker, responsible for initiating the impulse that sets the heart s rate and its regularity, or rhythm. The electrical impulse spreads throughout the atria, causing them to contract and pump blood into the ventricles. When the electrical impulse reaches the AV node, a signal transmission center, the AV node channels the impulse into the ventricles, causing them to contract. In a healthy resting heart, this cycle is repeated approximately 60 to 80 times per minute while the body is at rest.

Heart Rate and Rhythm Disorders

Heart rate and rhythm disorders, called cardiac arrhythmias, occur when abnormal heart tissue results in a disruption in the heart s normal electrical activation sequence that may result in inappropriate generation or conduction of electrical impulses. This abnormal electrical activity can produce a lack of coordination of the pumping of blood between chambers of the heart. Arrhythmias can be classified based on whether the heart rate is slower or faster than normal. Bradycardia describes a slower than normal heart rate. Typically, abnormal bradycardia is treated with an implanted artificial pacemaker. Tachycardia describes a fast heartbeat. Tachycardia can occur normally, such as during exercise, or as a result of a pathological disruption of the heart s electrical system, in which case it is known as an arrhythmia.

Table of Contents

Abnormal tachycardias can be characterized in the following ways:

Supraventricular or ventricular. Supraventricular tachycardia, or SVT, is a cardiac arrhythmia in which the electrical disturbance initiates and/or perpetuates in the atria or the AV node. In ventricular tachycardia, the electrical disturbance initiates and/or perpetuates in the ventricles.

Amount of affected heart tissue. Certain arrhythmias involve a limited area or fiber tract of the heart where the electrical disturbance occurs, while more complex arrhythmias involve more heart tissue.

Disorganized or organized. Disorganized arrhythmias occur when the electrical disturbance follows an irregular and unpredictable pathway in the heart such as typical AF, while in organized arrhythmias the electrical disturbance follows a distinct pathway such as AFL.

Supraventricular Tachycardias

The most common SVTs are AF and AFL which occur with a higher incidence, or occur more frequently, and have a higher prevalence, or exist in the population to a greater extent, than simple SVTs. These more complex SVTs are more difficult to treat than other SVTs such as Atrioventrical Nodal Reentrant Tachycardia, or AVNRT and Wolff-Parkinson White syndrome, or WPW.

Patients with SVTs can experience symptoms that range from mild to severe and which include fainting, fatigue, chest pain, shortness of breath and palpitations. The complications of SVTs can be fatal. The primary risk factors for SVTs include advanced age, obesity, heart valve disease or congenital heart disease, high blood pressure, chronic pulmonary disease and diabetes. Additional risk factors may include stress, excessive use of alcohol, caffeine, illicit drugs, tobacco, diet pills as well as certain other medications.

Atrial Fibrillation AF is the most prevalent SVT. It is a very complex, disorganized, supraventricular arrhythmia typically initiated in the left atrium or specifically in and around the pulmonary veins, which are the veins that lead into the left atrium from the lungs. AF is characterized by inappropriate electrical impulses that are so rapid, at more than 300 impulses per minute, and disorganized that the atria remain in a state of quiver and cannot contract and push blood into the ventricles. In some cases, a portion of the erratic atrial electrical impulses reaches the ventricles, resulting in an irregular, rapid beating, which reduces the overall efficiency of the heart s pumping action. During an AF episode, blood can pool within the atria, increasing the risk that a blood clot may form, be carried to the brain and cause a stroke. AF causes approximately 80,000 strokes each year in the United States.

Over time, if AF is not successfully treated, the abnormal initiation of the electrical impulses can modify the heart cells such that the arrhythmia continues indefinitely. The progression of AF tends to result in the following progression of increasing frequency, duration and severity:

Paroxysmal AF. Initial condition in which the initiation of the AF episode is unpredictable and subject to spontaneous termination without medical intervention.

Persistent AF. Initiating and perpetuating episode of AF that persists until terminated by drugs or electrical shock therapy.

Permanent AF. Perpetuating episode of AF that cannot be terminated by drugs or electrical shock therapy.

Atrial Flutter AFL is an organized, supraventricular arrhythmia that typically occurs in the right atrium. AFL is a disease of arrhythmia perpetuation. AFL shares some features with AF in that it causes similar symptoms and increases the risk of stroke as a result of increasing the likelihood of blood clot formation in the heart. In some cases, AFL may convert to AF, or conversely, AF can convert to AFL.

6

Table of Contents

Market Overview

According to an article in the January 2005 issue of *Current Opinion in Cardiology*, there are an estimated 800,000 new cases of SVT each year in the United States. The same publication also indicates that AF and AFL together represent approximately 89% of newly diagnosed SVTs.

Atrial Fibrillation

According to the Centers for Disease Control and Prevention, or CDC, AF is the most common sustained cardiac arrhythmia and increases the risk for additional types of heart disease and stroke, both leading causes of death in the United States. As reported in the January 2005 issue of *Current Opinion in Cardiology*, each year, there are approximately 500,000 new cases of AF in the United States. Approximately 2.3 million people in the United States and six million people worldwide currently have AF, according to Medscape. The incidence of AF is expected to double over the next 20 years.

Generally, AF is a progressive disease, and a significant number of AF patients will advance from paroxysmal AF to persistent AF or permanent AF, the more serious forms of the disease. At the time of initial diagnosis, approximately 90% of AF patients are classified as paroxysmal. However, a February 1996 issue of *Archives of Internal Medicine* reported studies of various populations of AF patients that indicate, depending on the population, between 35% to 66% of the cases studied had paroxysmal AF, with the remaining patients having progressed to persistent or permanent AF.

AF becomes more prevalent with increasing age. AF afflicts approximately 2.3% of the general population over the age of 40 years, approximately 6% of the population over the age of 65 years, and approximately 10% of the population in their 80s. AF is the leading cause of stroke among the elderly. Stroke is the third leading cause of death in the United States and the leading cause of adult disability. Individuals with AF have a six-fold greater risk of stroke than the normal population.

According to a May 2003 issue of *Circulation*, the rate of hospitalization due to AF in patients over the age of 35 years increased between two and three times from 1985 to 1999. Each year, billions of dollars are spent in the United States for healthcare expenditures related to AF, including costs associated with AF-related hospitalizations, AF drug therapy and its complications, life-long clinical follow-up, and AF-related stroke.

Atrial Flutter

AFL is the second most common SVT. According to the July 2000 issue of the *Journal of the American College of Cardiology*, there are estimated to be 200,000 new cases of AFL reported each year in the United States. This journal also reports that, like AF, AFL becomes more common with age.

Conventional Treatments and Their Limitations

The three primary objectives for managing patients with AF are to restore and maintain normal heart rhythm, control the heart rate, and prevent stroke. Treatment options include cardioversion, drug therapy and cardiac ablation, either individually or in combination. Each of these treatments has varying degrees of safety and effectiveness.

Cardioversion

Cardioversion is typically a hospital-based procedure performed to terminate an individual episode of sustained AF or AFL through the delivery of drugs or an external electrical shock across the chest. Drugs used to terminate an episode of AF or AFL are often ineffective and may cause life threatening ventricular arrhythmias. External electrical shocks are delivered when the patient is anesthetized or sedated. Cardioversion may be

Table of Contents

effective at terminating an individual episode of AF or AFL, but the treatment is not curative and does not prevent the initiation of future episodes.

Drug Therapy

The three primary categories of drugs used to treat the symptoms of AF and AFL and their complications or risks are heart rhythm control drugs, heart rate control drugs and blood thinners. Rhythm control drugs or anti-arrhythmics can be used to either prevent initiation or terminate perpetuation of an arrhythmia. Rhythm control drugs treat patients with AF and AFL by attempting to restore normal rhythm or prevent future episodes of the arrhythmia. Rate control drugs attempt to slow the frequency of the electrical signals that cause the ventricles to contract abnormally, thereby attempting to reduce symptoms by maintaining coordinated electrical activity between the atria and the ventricles. Blood thinners are prescribed in order to reduce the risk of blood clotting that may lead to stroke. Rhythm control drugs, rate control drugs and blood thinners are prescribed either alone or in combination to the majority of patients exhibiting the symptoms of AF or AFL.

For patients with AF or AFL, drugs are often used as life-long therapy. Amiodarone, the most widely prescribed rhythm control drug used to treat AF and AFL, has reported efficacy of 55% after five years of therapy, according to the *American Journal of Cardiology.* However, for patients with paroxysmal arrhythmias, this journal reported an efficacy of 43% after five years of therapy. According to the Medscape website, rhythm control drugs used for AF and AFL, excluding amiodarone, have efficacy estimated at 30% to 50%, respectively, at one to two years of follow-up and have a significant risk of side effects that can range from minor to life threatening. The AFFIRM study published in a December 2002 issue of the *New England Journal of Medicine* assessed the overall mortality for patients on rhythm control and rate control drugs to attempt to identify the best pharmacologic management of AF. The publication reported no significant difference in the mortality rate among individuals on the two different treatment strategies.

Although amiodarone is the most widely prescribed rhythm control drug, it has serious side effects, including lung toxicity, thyroid dysfunction, corneal opacities, liver damage and skin discoloration. Due to amiodarone s serious side effects, the FDA added a black box warning to its labeling, intended to notify physicians of these risks. Since December 2004, the FDA has required that patients receive a document which describes the side effects of amiodarone each time a prescription is filled. Furthermore, if the rhythm control drugs are ineffective at treating a patient, individual episodes of AF in the patient may continue to progress toward a state of permanent AF. Rate control drugs also have side effects that include reduction in blood pressure, hypoglycemia in diabetic patients, depression, sexual dysfunction and constipation.

Warfarin is the most widely prescribed oral anticoagulant, or blood thinning drug. Approximately 40% of paroxysmal AF patients receive warfarin oral anticoagulation therapy. In order for warfarin to be used safely, a patient s blood coagulation function must be maintained within a specified therapeutic range in order to reduce the risk of blood clots or bleeding from under or over anticoagulation, respectively. This therapeutic range is quite narrow and subject to a number of extrinsic factors, requiring patients to frequently test their blood coagulation function at a clinic or physician s office. Such frequent testing can be costly and inconvenient to the patient and may result in patient noncompliance.

Cardiac Ablation

Cardiac ablation is the process of disrupting or killing specifically targeted cardiac cells to create a lesion that blocks the origination or transmission of abnormal electrical activity. This lesion is intended to prevent the initiation or perpetuation, or both, of the abnormal electrical impulses associated with cardiac arrhythmias.

Surgical Ablation

The most effective surgical ablation technique for AF is the Cox-MAZE procedure whereby the surgeon makes patterned incisions through the atrial wall of the heart and then sews the heart tissue together to create an

Table of Contents

electrical maze that traps the abnormal electrical impulses. The Cox-MAZE procedure is highly-invasive and requires open heart surgery, yet is effective in over 90% of patients at preventing the initiation and perpetuation of AF, according to the February 2004 issue of *Pacing and Clinical Electrophysiology*. Notwithstanding its effectiveness, over the 13-year period ending in July 2000, the Cox-MAZE procedure was used to treat only approximately 350 patients. Dr. James Cox, the inventor of the Cox-MAZE procedure believes that the procedure has never been widely adopted by surgeons because of its complexity and invasiveness. We believe that surgical ablation procedures tend to be conducted only when the surgeon is already performing an open heart procedure, such as a bypass graft or a heart valve replacement or repair. Clinicians have begun to use RF, microwave, ultrasound or cryoenergy ablation devices to create lesions that resemble the surgical incisions created in traditional Cox-MAZE procedures, but in somewhat less complex surgical operations. Surgical techniques are not commonly used to treat AFL.

New techniques have recently been introduced for use in less invasive surgical procedures. These approaches still require surgery, but they access the heart through multiple small incisions in the chest to create ablation lines from the outer surface of the heart. As these procedures are still surgical in nature, they require patients to remain in the hospital for approximately six days following such procedures.

Minimally Invasive, Catheter-Based Ablation

In minimally invasive, catheter-based ablation procedures, a physician, typically an electrophysiologist, guides a catheter through a vein or artery into the heart and the physician places the tip of the catheter on the heart tissue responsible for initiating or perpetuating the arrhythmia. The physicians use fluoroscopy, or continuous X-ray imaging, to aid in positioning the catheters. The physician then delivers energy through the catheter to create a lesion and kill the target tissue. The number of lesions required to prevent the initiation or perpetuation of the arrhythmia depends on the type of SVT and its complexity. In order to safely and effectively treat AF, we believe that a physician needs to be able to safely create multiple, selectively large, permanent lesions within the heart tissue of the left atrium. The form of the energy can be RF, laser, ultrasound, microwave, or extreme cold (cryo). The degree of safety varies between energy sources. Currently, RF energy catheter systems and cryoenergy catheter systems are the only products that have been approved by the FDA for use in minimally invasive cardiac tissue ablation.

RF Ablation

RF energy uses heat to ablate tissue cells and create lesions and is commonly used to cut tissue or coagulate blood during surgery. It is also widely used by physicians in the treatment of various conditions, including prostate cancer, incontinence and gastro-intestinal disorders. RF cardiac tissue ablation is used as the primary treatment for some arrhythmias and as a secondary treatment for more complex arrhythmias, including AF. Although RF energy can ablate the cells that cause the arrhythmia within heart tissue, it can also destroy or significantly alter the extracellular material that binds cells together to form tissue. During cardiac tissue RF ablation procedures, physicians closely monitor the position of the catheter tip using fluoroscopy in order to attempt to ensure it does not drift and damage adjacent tissue or structures.

RF ablation is generally considered to be a safe and effective treatment for the less prevalent SVTs, such as AVNRT or WPW, with efficacy rates above 90% and complication rates of less than 5%. RF ablation also is currently used as a minimally invasive technique for the treatment of AFL and is approved by the FDA for this indication. This procedure is typically successful in treating AFL, with reported efficacy rates of approximately 90% and complication rates of less than 5%.

The FDA has not approved RF ablation for the treatment of AF, and we believe that as a result of the risk of serious and life threatening complications, RF ablation may have difficulty obtaining broad market adoption even if approved for this indication. Two articles published in the *New England Journal of Medicine* (from September 1998 and March 2006) reported effectiveness rates of 62%-74% for the treatment of AF using RF ablation. In

Table of Contents

addition, various published studies have reported serious complications, including creation of atrio-esophageal fistulas, or channels, through the atrial wall into the esophagus. Physicians have modified the techniques used when treating atrial fibrillation with RF ablation in seeking to reduce or eliminate complications. We believe that, while RF can be delivered safely in many areas of the heart during the treatment of atrial fibrillation, certain areas of the heart remain unsafe for the delivery of RF, and that cryoablation may be a safer ablation energy for those areas of the heart during the treatment of atrial fibrillation. Complications associated with RF ablation primarily result from the coagulation of blood and the alteration or destruction of the extracellular material that binds cells together to form tissue. Serious complications of RF ablation for the treatment of AF include the following:

Atrio-esophageal fistulas. Due to the left atrium s position next to the esophagus, the high level of heat generated during RF ablation can result in an injury that results in the formation of fistulas through the atrial wall into the esophagus, which can cause potentially fatal excessive bleeding or infection;

Blood clots. Heat generated by the RF energy can coagulate blood into clots that can travel to the brain and result in a stroke;

Pulmonary vein stenosis. Heat applied to tissue at the pulmonary vein can cause scarring which constricts the vein, potentially leading to reduced lung function;

Excessive bleeding. Heat generated by the RF energy can perforate the heart wall and lead to fluid around the heart constricting blood flow;

Phrenic nerve damage. RF energy can cause permanent nerve damage, resulting in diminished lung function; and

Pain. Due to the electrical stimulation of heart nerve fibers by the RF energy, patients can experience pain and discomfort during the procedure if they are not adequately sedated or anesthetized.

Cryoablation

Cryoablation is the use of cryoenergy, or extreme cold, to ablate cardiac cells. Cryoablation ablates the tissue by freezing cells, which subsequently rupture and die when they thaw. Unlike RF and other heat-based ablation technologies, which can destroy both the cells and the extracellular material that binds the cells together, cryoablation leaves the material surrounding the cells fully intact. As a result, cryoablation may reduce the potential complications which have been observed with heat-based ablation technologies.

Currently, the only FDA approved cryoablation system for the treatment of cardiac arrhythmias is marketed by Cryocath Technologies Inc., a Canada-based medical device company. This system is indicated only for the treatment of AVNRT. There is currently no cryoablation system available that is approved by the FDA for the treatment of the more complex arrhythmias, such as AF and AFL. In order to be able to treat these arrhythmias, we believe that a cryoablation system must have adequate power to create multiple, selectively large, permanent lesions. The power required to create such lesions demands that a cryoablation system be able to achieve and maintain extremely low temperatures across a relatively large contact area throughout the entire procedure, with minimal temperature fluctuations.

We believe that our cryoablation system may provide clinical advantages in the treatment of AF and AFL. A safe and effective cryoablation procedure would reduce or eliminate a patient s dependence on chronic drug therapy, which is costly, frequently ineffective and often has serious side effects. We believe that our cryoablation system has the critical features necessary to deliver adequate power to quickly and effectively produce multiple, large, permanent lesions. Our cryoablation system uses proprietary technologies that enable our catheter tip to rapidly achieve and maintain the target freezing temperature throughout an ablation procedure.

Table of Contents

We believe the principal benefits of our cryoablation system are:

Safety. We believe that safety is one of the critical requirements for broad physician adoption of a treatment for AF. Clinical studies support our belief that cryoenergy is a safe energy source for the treatment of cardiac arrhythmias. To date, our cryoablation system has been used in approximately 55 medical centers, including approximately 30 medical centers in the United States where it has been used on approximately 400 subjects during our clinical trials, and approximately 25 medical centers in Europe, where it has been used on approximately 165 subjects during our clinical trials and approximately 1,500 patients. To date, we have not received any reports of esophageal fistulas, blood clots, strokes or pulmonary vein stenoses, which are risks associated with heat-based ablation procedures. We are conducting ongoing clinical trials to demonstrate the safety of our cryoablation system.

Acute and chronic efficacy. We believe that our cryoablation system may provide an effective treatment for AF and AFL based on the multiple clinical studies and trials completed to date. Clinical data from the two published AF studies conducted using our cryoablation system and covering 52 patients and 29 patients showed that 71% and 62% respectively of those patients reported relief from clinical symptoms of AF at follow-up intervals between six and 12 months. We are conducting ongoing clinical trials to demonstrate the effectiveness of our cryoablation system.

Secure catheter tip-to-tissue adherence. The extreme cold delivered by our cryoablation system causes the tip of the catheter to adhere to the heart tissue. As a result, the catheter tip does not move from the intended lesion site during the ablation application.

Familiar physician procedure. Our cryoablation system employs catheter techniques and controls similar to those commonly used by electrophysiologists in other catheter-based procedures.

Patient comfort. Cryoablation of cardiac tissue causes little or no pain during the procedure, potentially reducing or eliminating the need to sedate the patient. Pain is commonly reported by patients during RF ablation procedures, which is an important consideration in Europe where general anesthesia or conscious sedation is typically not used during catheter-based procedures.

Our Strategy

Our goal is to be the leading provider of minimally invasive, catheter-based treatments for the more complex arrhythmias, like AF and AFL. The key elements of our strategy include:

Demonstrating the safety and effectiveness of our cryoablation system through our clinical trials. We believe our cryoablation system provides an effective treatment that is a safer alternative for the treatment of AF than drug therapy, surgical ablation and RF or other heat-based ablation options. Our goal is to be the first company to obtain FDA approvals for the use of cryoablation in the minimally invasive treatment of AF and AFL.

Commercializing our products through a direct sales force, a direct-to-consumer marketing effort, and third party distributors. Within the United States, if approved for AF, we intend to market our cryoablation system through a specialized direct sales force that will target medical centers that perform high volumes of cardiac RF ablation procedures. We believe that a small sales force can sufficiently service the electrophysiology market in the United States because the market is highly concentrated, with the 300 most active medical centers accounting for 80% of cardiac RF ablations. We also plan to build patient awareness and support for our cryoablation system through the use of direct-to-consumer marketing. We believe there is significant interest on the part of AF patients to seek out and support a safe and effective treatment option. Internationally, we plan to offer our products through third party distributors located in specific geographic areas. Due to our limited cash resources, we do not plan to broadly commercialize our product for the treatment of AFL until our financial condition has improved.

Leveraging the influence of opinion leaders and major medical centers to accelerate adoption and market acceptance of our cryoablation system. We intend to utilize the support of leading

Table of Contents

electrophysiologists to communicate the merits of our cryoablation system as a treatment for AF and AFL to their peers and other members of the clinical community. We also intend to continue collaborating with leading medical centers to educate physicians about the use of our cryoablation system. We plan to use the centers to establish best practices and develop certification programs for these physicians. We also expect to support small, focused, physician-sponsored studies, such as physician preference studies and post-market analyses, to expand the clinical data available regarding the safety and effectiveness of our cryoablation system. Medical technologies are often broadly adopted first by leading United States medical centers, and then more extensively by European centers.

Expanding our product line and acquiring complementary products. We are currently developing our next generation cryoablation catheter, Quantum. We expect our Quantum catheter, once developed and if approved by the FDA, to enable physicians to perform AF cryoablation procedures in a shorter procedure time, making it a more attractive procedure for them. We may acquire complementary products and technologies.

Expanding and protecting our intellectual property position. We believe that our intellectual property position will assist us in maintaining our competitive position in cardiac cryoablation. We intend to continue to focus and expand our broad portfolio of owned or licensed United States and international patents and patent applications to protect the design and use of our products, principally in the areas of cryoablation and the treatment of arrhythmias.

CryoCor Cardiac Cryoablation System

Our cryoablation system consists of our Model 2020 Console, including its CryoArm Pre-Cooler and our disposable CryoBlator catheters. We also offer introducer sheaths to facilitate catheter placement in the atria for both AF and AFL ablation procedures. Our cryoablation system s components are designed to provide simple set up and minimize procedure time. Our cryoablation system utilizes proprietary technology embedded in the console, the pre-cooler and the disposable catheters that allows it to generate, deliver and transfer high levels of cryoenergy enabling selectively large lesion sizes, shorter procedure times and enhanced system versatility. We believe these advantages provide better therapeutic efficacy and a greater ability to treat more complex arrhythmias such as AF and AFL than competing cryoablation technologies.

Our cryoablation system operates by boiling, liquid nitrous oxide in the tip of the catheter under carefully controlled conditions. This results in stable catheter tip temperatures of approximately -90º Celsius. Our cryoablation system uses a microprocessor-controlled, two-stage cooling process to control the flow and boiling of the nitrous oxide. In the first cooling stage, gaseous nitrous oxide is delivered from the console to the pre-cooler. The pre-cooler reduces the nitrous oxide temperature to -35º Celsius, converting the nitrous oxide from a gas to a liquid. After the liquid nitrous oxide is delivered to the catheter s tip, the second cooling stage occurs as the liquid nitrous oxide boils, converting back into a gas. Our console dynamically adjusts the refrigeration power to changes in heat load associated with blood flow and the tissue that is in contact with the catheter tip.

Our CryoBlator catheter is critical in controlling the nitrous oxide boiling process and provides the means for the console to accurately monitor tip pressure, a parameter vital to pressure feedback loop in our cryoablation system. The size of the catheter is designed to facilitate efficient passage of spent, gaseous nitrous oxide out of the catheter and back into the console. This feature not only maintains optimal boiling pressure but also allows for the dynamic adjustment of refrigeration power without causing excess nitrous oxide to gather at the tip of the catheter. Significantly, the ability of our cryoablation system to maintain appropriate catheter tip pressure helps to ensure patient safety. Lastly, the catheter is designed to boil nitrous oxide only at its tip so that concentrated cryoenergy is delivered directly to the targeted heart tissue.

Table of Contents

Console and Pre-Cooler

Model 2020 Console. Our console is the command center of our cryoablation system. It is comprised of advanced control electronics, proprietary software, and refrigeration components. The console is operated through a simple user interface. A screen displays command prompts and continual updates on system performance, including catheter tip temperature during the procedure. Our console houses a primary and reserve source of nitrous oxide and the components to transport the nitrous oxide to the pre-cooler. A pre-ablation safety check to ensure the integrity of our catheter is performed before any nitrous oxide is delivered to our catheter.

CryoArm Pre-Cooler. Our CryoArm Pre-Cooler utilizes patented technology that we believe is an important innovation in the delivery of cryoenergy. This enables the catheter tip to reach and maintain extremely low temperatures. The pre-cooler is located on a movable arm attached to the console. The height of the arm can be adjusted to permit convenient location and manipulation of the catheter. The arm houses hardware that measures tip pressure and temperature in the catheter. The pre-cooler is separated from the console in order to eliminate the influence of any heat generated from the console components and places the location for the generation of chilled -35° Celsius nitrous oxide near the patient enabling the efficient delivery of nitrous oxide liquid to the tip of the catheter in a liquid state.

Disposables

CryoBlator Disposable Catheters. Our CryoBlator family of disposable catheters are 10-French, or approximately 3.3 millimeters, in diameter, providing sufficient internal dimensions in order to rapidly deliver and remove the volumes of nitrous oxide required to produce and sustain extremely low temperatures at the catheter tip. Our 10-French catheters have flow capacity that is 46% greater than that of a 9-French catheter and 400% greater than that of a 7-French catheter. We believe this greater flow capacity permits our cryoablation system to process substantially greater volumes of nitrous oxide than other competing cryoablation systems. There are six catheters in the CryoBlator family, which consists of catheters with available tip reaches of five centimeters or seven centimeters and three electrode tip sizes of 6.5 millimeters, 10 millimeters, or 15 millimeters. One of our catheters is currently being tested in clinical trials in the United States. The reach of the various tips provides the physician with the ability to manipulate the catheter effectively, taking into account individual anatomic variations. Our different catheter tip sizes enable the physician to create appropriate-sized lesions. Our catheters are similar to conventional electrophysiology catheters and include a standard handle that enables physicians to remotely manipulate the tip of the catheter through 180º and position it within the heart.

Model 3110 and 3130 Sheath Dilators. Our sheath dilators are long, plastic tubular devices that enable the catheter to enter the body and be delivered into the heart. Our sheath dilators have received 510(k) clearance by the FDA and are CE marked in Europe.

Quantum Catheter

We are currently developing our next generation disposable catheter, our Quantum catheter, which we envision will enable physicians to create larger lesions in both linear and curvilinear shapes, thereby reducing the total number of lesions required in an AF ablation procedure. Our Quantum catheter is being designed to permit delivery of therapeutic cryoenergy pursuant to an anatomical pattern rather than complex cardiac electrical activity mapping. We believe that this reduction in the number of lesions may reduce the average time for an AF cryoablation procedure. We also believe that Quantum may be used in AF ablation procedures combining RF and cryoablation where cryoablation is performed in regions of the heart where heat-based ablation presents an unreasonable risk. We have performed substantial research in our laboratories and have successfully completed several animal studies of the Quantum catheter. We are currently making modest design modifications to optimize the product and intend to begin clinical use by the end of 2007.

Table of Contents

The CryoCor Cryoablation Procedure

Our cryoablation procedure is typically performed in an electrophysiology lab and involves the following steps:

Introducing and placing the catheter. Similar to RF procedures, the physician guides a catheter into the heart under fluoroscopy, or continuous X-ray imaging, placing the tip of the catheter on the heart tissue responsible for initiating or perpetuating the arrhythmia. Physicians often use a mapping catheter, which identifies the location of abnormal electrical pathways or initiation sites, to guide the position of the cryoablation catheter.

Cryoablating the diseased heart tissue. Once the catheter is placed on the target site, the physician sets the ablation time and initiates the cooling of the catheter tip. Within seconds, the catheter tip reaches a freezing temperature and adheres to the target tissue at which time the physician can turn off the fluoroscopy. The physician continues to freeze the target site for approximately two minutes depending on the desired size of lesion.

Repositioning the catheter. After the specified time, and the creation of the desired lesion, the flow of nitrous oxide is turned off, the catheter begins to warm, releasing the tip from the lesion site. The physician then repositions the tip at the next target lesion site and repeats the procedure.

AF Cryoablation Procedure

AF is often initiated by electrical activity that emanates from abnormal tissue in and around the four pulmonary veins. One ablation procedure often performed in AF patients is referred to as pulmonary vein isolation, or PVI. During PVI procedures, the catheter is guided through the right atrium, across the septum, and into the left atrium. Multiple lesions are created in the left atrium near the pulmonary veins to electrically isolate one or more of the veins from the left atrium. PVI is used to stop the initiation of AF episodes by preventing the abnormal electrical activity emanating from the pulmonary vein from reaching the atrial tissue. Some clinicians have modified the PVI approach in a procedure referred to as anatomic ablation, which was developed in part to mimic the Cox-MAZE procedure and also to avoid the complication of pulmonary vein stenosis that has been associated with RF-based PVI. This procedure is completed using ablation lesions in a fixed anatomic pattern, often using a sophisticated mapping system that shows the location of the lesions in reference to the anatomy of the heart. Both anatomic ablation and PVI techniques have been performed with our cryoablation system.

While these procedures initially required approximately eight to ten hours to complete with our cryoablation system, current clinical practice using our cryoablation system requires approximately 2.5 to four hours as a result of improvements in our technology, additional data on the time required for an effective ablation, and increased physician experience.

AFL Cryoablation Procedure

AFL is caused by a looping electrical disturbance in the right atrium. The most common form of AFL involves an electrical impulse that travels toward the center of the heart across a narrow neck of tissue between the tricuspid valve and the inferior vena cava, called an isthmus. This isthmus is a common target for AFL ablation. To treat AFL, the catheter is initially positioned in the right atrium at the far end of the isthmus and cryoenergy is delivered. The catheter is then stepped across the isthmus in short increments creating individual lesions at each point. These successive freezes create a lesion line along the isthmus to block abnormal electrical conduction, which prevents perpetuation of the arrhythmia. While this procedure initially required approximately four to six hours to complete with our cryoablation system, current clinical practice requires approximately 45 minutes to two hours as a result of improvements in our technology, additional data on the time required for an effective ablation and increased physician experience.

Table of Contents

CryoCor s Clinical Development Program and Status

Overview

In Europe, our clinical strategy was to obtain CE Mark approval by successfully demonstrating the safety of our cryoablation system and then to collect additional effectiveness data through further clinical studies. Our CE Mark approval includes a broad cardiac arrhythmia ablation indication for the treatment of patients with AF, AFL and other SVTs. Subsequent to our approval, we limited the commercial distribution of our system to medical centers where physicians continued their use and investigation of our system. These investigations refined the cryoablation procedures and techniques, provided additional clinical experience, and aided in the evaluation of the function and reliability of our system. The results generated articles for peer-reviewed medical journals. We currently sell our cryoablation system through distributors in the United Kingdom and Italy, and our cryoablation system is used by physicians in the United Kingdom, Germany, Denmark, Belgium, the Netherlands, and Italy. We do not currently intend to sign any additional distribution agreements for the distribution of our cryoablation system in Europe.

Clinical Status in the United States

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, during 2006, 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 greater than 80%. We met with the FDA in February 2007 to discuss the status of their review of our PMA amendment, and were notified that the FDA accepted the process by which our data was analyzed and that the FDA intended to convene an Advisory Panel meeting to advise the FDA on the evaluation of chronic effectiveness in our PMA. In subsequent discussions with the FDA, we provided additional information that we believe supports our basis for approval, and that has resulted in a higher computation of chronic effectiveness than previously submitted. The FDA decided to postpone the Advisory Panel meeting for CryoCor while they evaluate the additional information, and the FDA has indicated that it may no longer be necessary to convene an Advisory Panel meeting. We anticipate that the FDA will render a 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 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 second quarter of 2007. As of March 28, 2007, we need to enroll nine to 16 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, and 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. We believe our pivotal trial for the treatment of AF is significantly further along than any competing ablation catheter trial, and we estimate our lead time in enrolling our clinical trial at between 12-18 months ahead of the enrollment pace of the next most advanced AF pivotal trial. 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 mid-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

AFL-02 Pivotal Trial

The AFL-02 pivotal trial was a single arm trial, which measured the device s clinical performance against certain predefined objective performance criteria, or OPCs, that have been used for RF-based devices studied in other single arm studies and have served as a basis for FDA marketing approval for such devices. The primary efficacy endpoint of this trial was acute success, defined as creation of bi-directional block, or blocking of the abnormal electrical impulses that perpetuate AFL, with cryoablation at the time of the procedure. The success in achieving such block was evaluated in the electrophysiology laboratory by the clinical investigators. Subsequent to the cryoablation procedure, cardiac electrical event recording was used by the subject at the time of symptoms and on a weekly basis to assist in the evaluation of chronic efficacy, defined as freedom from recurrence of AFL for six-months for subjects in whom acute efficacy was demonstrated. The primary safety endpoint was defined as the rate of all serious adverse effects, or SAEs, that occurred during the 7 days following the ablation procedure. An SAE was defined as death, a life-threatening complication, or a persistent or significant disability or incapacity requiring inpatient hospitalization or prolonged hospitalization or requiring intervention to prevent a permanent impairment of a body function or damage to a body structure.

Enrollment in this trial was completed in November 2004 and subjects were followed for six months following the ablation procedure. Preliminary safety and acute effectiveness data are shown in the following table:

AFL Pivotal Trial (AFL-02)

Trial Result	Observed Event Rate	Confidence Limit (CL)	Objective Performance Criteria (OPC)
7 Day SAEs	6.3%	10.3% (upper)	7%
7 Day SAEs (device or procedure related)	2.5%	5.6% (upper)	N/A
Acute Effectiveness	87.5%	81.6% (lower)	80%

The observed seven day rate for all SAEs was 10 out of 160 subjects, or 6.3% with an upper confidence limit, or CL, of 10.3% which does not meet the predefined OPC CL of 7%. Of the 10 SAEs, six were reported by the investigator as not being device or procedure related, resulting in an observed event rate of 2.5% with a CL of 5.6%. In the discussions we have held with the FDA during 2006, the FDA has not had any concerns or comments on the safety of our system.

Although we did not prospectively define a primary endpoint for chronic efficacy in our protocol, we collected chronic efficacy data throughout the six-month follow-up which we analyzed and submitted to the FDA as part of the PMA. The FDA had previously advised us that it would treat our chronic efficacy data as an important factor for marketing approval and that it would be assessed against the chronic efficacy OPC established by the FDA for RF ablation. In January 2006, we were notified by the FDA that our cryoablation system for the treatment of AFL 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, during 2006, 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 analysis of chronic effectiveness. We met with the FDA in February 2007 to discuss the status of their review of our PMA amendment, and were notified that the FDA accepted the process by which our data was analyzed and that the FDA intended to convene an Advisory Panel meeting to advise the FDA on the evaluation of chronic effectiveness in our PMA. In subsequent discussions with the FDA, we provided additional information that we believe supports our basis for approval, and that has resulted in a higher computation of chronic effectiveness than previously submitted. The FDA decided to postpone the Advisory Panel meeting for CryoCor while they evaluate the additional information, and the FDA has indicated that it may no longer be necessary to convene an Advisory Panel meeting. We anticipate that the FDA will render a decision on the approval of our PMA by August 2007. Although we believe our clinical data demonstrate

Table of Contents

adequate safety and effectiveness to support FDA approval, there can be no assurance that our product will be approved by the FDA for the treatment of AFL.

AF-02 Pivotal Trial

Our AF-02 pivotal trial is a prospective, randomized, controlled multi-center trial to evaluate the safety and effectiveness of our cryoablation system in treating AF. The primary safety endpoint as defined in the protocol is the occurrence of SAEs during the 12-month period following the cryoablation procedure, when compared to the medical management group. The protocol also specifies a secondary safety endpoint as the occurrence of PV stenosis. The protocol defines the primary efficacy endpoint as the recurrence of symptomatic AF between three months and 12 months following cryoablation. There can be no assurance that the trial will be adequate to support marketing approval for this indication.

We believe that our enrollment, which is expected to be completed in the second quarter of 2007, has enrolled more patients than any other AF pivotal trial. As of March 28, 2007, we need to enroll nine to 16 additional patients to allow us to have the required population of evaluable patients. We are aware of two other companies, CryoCath and Johnson & Johnson, which are conducting pivotal trials for the treatment of AF, and we believe we are 12-18 months ahead of the rate of patient enrollment in those clinical studies. We believe pivotal trials for the treatment of AF are difficult and time consuming to enroll due to the requirement that a percentage of the potential patients be randomized to drug therapy, and the difficulty some patients experience in obtaining insurance reimbursement for the procedure. We understand the FDA is considering changing its guidance and permitting different enrollment and randomization criteria, which could permit other companies to increase the rate of patient enrollment and decrease the time advantage we believe we currently have in terms of being able to file a PMA for the treatment of AF before our competitors. However, even if the FDA does change its guidance and pivotal trial criteria, we believe we will be the first company to submit a PMA for the treatment of AF, and we anticipate filing a PMA for the treatment of AF in mid-2008.

Sales and Marketing

In the United States, we plan to market our cryoablation system through a specialized direct sales force or in combination with a marketing partner. Due to our limited cash resources, we do not plan to broadly commercialize our product for the treatment of AFL until our financial condition has improved. Once we begin broadly commercializing our cryoablation system, we intend to focus on the segment of the 2,000 electrophysiologists currently performing the highest volume RF based cardiac tissue ablation procedures. According to Verispan, in 2001, 300 medical centers performed 80% of all cardiac ablation procedures in the United States. We believe that a focused sales force of approximately 20 professionals would service these customers and cover much of the potential market for our cryoablation system in the United States. We will begin recruiting our sales force once we are closer to possibly receiving FDA approval for the treatment of either AFL or AF. In support of these efforts, we intend to build patient awareness through direct-to-consumer marketing for AF and AFL. We also expect to support smaller, more focused physician-sponsored studies, such as physician preference studies and post-market analyses to expand the clinical data available regarding the safety and efficacy of our cryoablation system.

Outside of the United States, we may expand our current network of distributors if we receive approval for AF. However, we do not currently intend to sign any additional distribution agreements for distribution of our cryoablation system in Europe. In 2005, we decided to close our German operation, CryoCor GmbH, and to begin selling our products exclusively through distributors. We currently sell our cryoablation system through distributors in the United Kingdom and Italy. Our current agreement with our distributors will continue until January 1, 2009 at which time it may be renewed for additional one year periods.

Table of Contents

Competition

The medical device industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products, designs and processes. Any products that we commercialize will be subject to 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 engineers and management personnel, establishing clinical trial sites and patient participation for clinical trials, as well as acquiring technology and technology licenses complementary to our programs or advantageous to our business.

There are a number of companies developing or marketing medical devices for the treatment of AFL and AF that are directly competitive with our product candidates. CryoCath Technologies has developed a minimally invasive, catheter-based system that uses cryoenergy to treat cardiac arrhythmias. In the United States, CryoCath has obtained marketing approval for its catheter-based cryoablation treatment of AVNRT and 510(k) clearance for its surgical probe to treat AF. In Europe, CryoCath has obtained the CE Mark for its catheter-based products for the treatment of SVTs. CryoCath has begun enrolling a pivotal trial in the United States for its catheter-based treatment of AF. We are not aware of any other competitors conducting clinical trials that utilize cryoenergy as their energy source for a minimally invasive catheter-based system for cardiac tissue ablation. We have requested that the United States Patent and Trademark Office, or USPTO, institute interference proceedings involving two patents owned by CryoCath and two of our applications relating to pre-cooling technologies. If we fail to prevail in these proceedings, we may not attain rights to certain patent claims. In addition, CryoCath may assert that the manufacture, use or sale of our cryoablation system infringes one or more claims of their patents. Statements attributed to CryoCath suggest that CryoCath may believe that aspects of our cryoablation system may be covered by one or more CryoCath patents or other intellectual property rights.

St. Jude Medical has been actively investing in or acquiring companies that are developing treatments and/or diagnostic tools for AF. Recent acquisitions include Epicor Medical, Irvine Biomedical, and Endocardial Solutions. In addition, St. Jude Medical invested in ProRhythm, and has the opportunity to purchase the company. Other medical device manufacturers and potential competitors include Johnson & Johnson and Boston Scientific, who have developed RF catheters that we believe are being used for the off-label treatment of AF. In additional, Johnson & Johnson is conducting a randomized trial to evaluate the safety and effectiveness of its cooled-RF catheter for the treatment of atrial fibrillation. Finally, a number of companies, including Medtronic, AtriCure, Boston Scientific and Guidant, which acquired AFx in 2004, have developed surgical probes for the treatment of AF. In January 2006, ProRhythm received approval from the FDA to conduct a pivotal trial of its ultrasound balloon for the treatment of AF. During 2006, the pivotal trial was placed on clinical hold due to patient complications, and we are not aware of the status of reinitiating the clinical trial.

There are a number of drugs that are routinely prescribed for the treatment of complex cardiac arrhythmias, and drugs are currently the primary therapy for AF. Patients who fail with one drug are typically prescribed additional drugs until the symptoms are reduced or the drugs are determined to be ineffective or inadvisable due to complications. We expect to compete with drugs to the extent they remain the treatment of choice for AF. There are several new drugs under development for the treatment of AF, including Dronedarone by Sanofi-Aventis and CVT-510 from CV Therapeutics.

Due to the size of the potential market, we anticipate that competitors will continue to dedicate significant resources to developing additional drugs and competing medical devices for the treatment of AF and AFL. Successful clinical results, regulatory approval and commercialization of any of these additional drugs and competing medical devices could have a material adverse impact on our business. Our ability to compete successfully will depend on our ability to develop proprietary products that reach the market in a timely manner and are more efficacious and safer than the alternatives available for the same condition. Our cryoablation system

Table of Contents

may be rendered obsolete or uneconomical by a technological advance or an entirely different approach developed by one or more of our competitors.

Manufacturing

Our San Diego facility provides space for our console manufacturing operations, sterile products manufacturing, packaging, storage and shipping, as well as for our research and development labs and general administrative facilities. We believe that our manufacturing facilities will be sufficient to meet our manufacturing needs for the foreseeable future.

In March 2006, we restructured our workforce and reduced our staffing levels across most departments. This has impacted our ability to manufacture consoles and catheters at the same production levels as 2005; however we have retained sufficient manufacturing capabilities to continue to manufacture our products in 2007 and 2008. If we receive approval for the treatment of either AF or AFL using our cryoablation system, we may have to increase our staffing levels to provide greater manufacturing capabilities to support a commercial launch in the United States. We may never receive approval for the treatment of AF or AFL using our cryoablation system. We have retained a staffing level that will be sufficient to maintain our compliance with the European and FDA quality standards.

We believe our manufacturing operations are in compliance with regulations mandated by the FDA and the European Union. We have previously been inspected by the Food and Drug branch of the California Department of Health Services. We have been FDA-registered since March 2004 and a California-licensed medical device manufacturer since May 2001. We obtained our CE Mark in March 2002, and our facility is ISO 13485 certified. In September 2005, we were inspected by the FDA in conjunction with our PMA filing for AFL. The FDA had several findings as a result of their inspection, and we have responded to these findings, and the inspection has been completed. In connection with our CE mark approval and compliance with European quality standards, our facility was originally inspected in November 2001 and in January 2006, was certified to be in compliance with ISO 13485.

Our sterile products, which are our CryoBlator catheters and our sheaths, are manufactured in a controlled environment in our San Diego facility that provides for protection of the products from contamination. Our catheter production group consists of five skilled employees and can produce approximately 3,250 catheters per year and our console manufacturing group can produce up to 24 consoles per year. We believe these production levels are sufficient to support our clinical trials and our existing commercial activity, but we will have to hire additional personnel, primarily in console manufacturing, if we receive approval for the treatment of AF or AFL.

There are a number of critical components and sub-assemblies in the sterile products and the console. The vendors for these materials are qualified through stringent initial evaluation and monitoring of their performance over time. We audit our critical component manufacturers on a regular basis and at varied intervals based on the nature and complexity of the components they provide and the risk associated with the components failure.

Most of the materials and components which are used in our cryoablation system are purchased from single sources due to quality considerations, costs or constraints resulting from regulatory requirements. Agreements with certain of our suppliers can be terminated by either party upon relatively short notice. These agreements will terminate earlier in the event of a material breach by us that remains uncured. We cannot quickly establish additional or replacement suppliers for certain components or materials, largely due to the FDA approval process and the complex nature of the manufacturing processes employed by our suppliers. Production issues or capacity constraints affecting our facilities, or those of our suppliers, would affect our ability to complete our clinical trials and to bring our cryoablation system to market.

Table of Contents

Third Party Reimbursement

Medicare, Medicaid and Other Third Party Reimbursement

Healthcare providers that purchase medical devices generally rely on third party payers, including the Medicare and Medicaid programs and private payers, such as indemnity insurers, employer group health insurance programs and managed care plans, to reimburse all or part of the cost of products. If approved by the FDA, our cryoablation system is expected to be sold principally to hospitals, medical centers and clinics that receive reimbursement from these third party payers. As a result, demand for our products is and will continue to be dependent in part on the coverage and reimbursement policies of these payers. The manner in which reimbursement is sought and obtained varies based upon the type of payer involved and the setting in which the product is furnished and utilized.

Payments from Medicare, Medicaid and other third party payers are subject to legislative and regulatory changes and are susceptible to budgetary pressures. Our customers revenues and ability to purchase our products are therefore subject to the effect of those changes and to possible reductions in coverage or payment rates by third party payers. Any changes in the healthcare regulatory, payment or enforcement landscape relative to our customers healthcare services has the potential to significantly affect our operations and revenues.

Medicare

Medicare is a federal program administered by the Centers for Medicare and Medicaid Services, or CMS, through fiscal intermediaries and carriers. Available to individuals age 65 or over, and certain other individuals, the Medicare program provides, among other things, healthcare benefits that cover, within prescribed limits, the major costs of most medically necessary care for such individuals, subject to certain deductibles and co-payments. There are three components to the Medicare program relevant to our business: Part A, which covers inpatient hospital services, Part B, which covers physician services, other healthcare professional services and outpatient services, and Part C, or Medicare Advantage, which is a program for managed care plans.

The Medicare program has established guidelines for the coverage and reimbursement of certain equipment, supplies and services. In general, in order to be reimbursed by Medicare, a healthcare item or service furnished to a Medicare beneficiary must be reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body part. The methodology for determining coverage status and the amount of Medicare reimbursement varies based upon, among other factors, the setting in which a Medicare beneficiary received healthcare items and services. Any changes in federal legislation, regulations and policy affecting Medicare coverage and reimbursement relative to our cryoablation system could have a material effect on our performance.

Inpatient Hospital Setting

If our cryoablation system is approved by the FDA, a significant portion of our revenues may be derived from our customers operating inpatient hospital facilities. Acute care hospitals are generally reimbursed by Medicare for inpatient operating costs based upon prospectively determined rates. Under the Prospective Payment System, or PPS, acute care hospitals receive a predetermined payment rate based upon the Diagnosis-Related Group, or DRG, into which each Medicare beneficiary stay is assigned, regardless of the actual cost of the services provided. Certain additional or outlier payments may be made to a hospital for cases involving unusually high costs. Accordingly, acute care hospitals generally do not receive direct Medicare reimbursement under PPS for the specific costs incurred in purchasing medical equipment. Rather, reimbursement for these costs is deemed to be included within the DRG-based payments made to hospitals for the services furnished to Medicare- eligible inpatients in which the equipment is utilized. Because PPS payments are based on predetermined rates and may be less than a hospital s actual costs in furnishing care, acute care hospitals have incentives to lower their inpatient operating costs by utilizing equipment, devices and supplies, including equipment sold by us, that will reduce the length of inpatient stays, decrease labor or otherwise lower their costs.

Table of Contents

Our product sales could be affected negatively if acute care hospitals reduce or discontinue use of our products due to insufficient reimbursement, or if other treatment options are perceived to be more profitable.

Outpatient Hospital Setting

CMS implemented the hospital Outpatient Prospective Payment System, or OPPS, effective August 1, 2000. OPPS is the current payment methodology for hospital outpatient services. Services paid under the OPPS are classified into groups called Ambulatory Payment Classifications, or APCs. Services grouped within each APC generally are similar clinically and in terms of the resources they require. A payment rate is established for most APCs through the application of a conversion factor that CMS updates on an annual basis. CMS may assign a qualifying service to a new technology APC for which the payment rate is based on a cost range rather than through the application of a conversion factor. In addition, under OPPS, CMS may authorize separate payments for new categories of devices, with payment amounts varying by hospital. OPPS may cause providers of outpatient services with costs above the payment rate to incur losses on such services provided to Medicare beneficiaries.

CMS proposes, and after consideration of public comment, implements changes to OPPS and payment rates on an annual basis. The OPPS methodology determines the amount hospitals will be reimbursed for procedures performed on an outpatient basis and determines the profitability of certain procedures for the hospital and may impact hospital purchasing decisions. We cannot predict the final effect that any change in OPPS regulations, including future annual updates, will have on customers of our cryoablation system. Any such effect, however, could be negative if APC groupings become less advantageous, reimbursement allowables decline, or if the OPPS is modified in any other manner detrimental to our business.

Physician Services

Medicare payment for physician and other practitioner services is based on a fee schedule. The fee schedule payment for almost all physician/practitioner service is based on the product of the relative value units, or RVUs, assigned to the service, a conversion factor, and a geographic adjustment factor based on regional costs. The RVU consists of a work and complexity component, a practice expense component and a malpractice expense component. The more time, effort, and expense involved in providing a particular service results in a higher RVU and thus a higher payment. The fee schedule calculations are applied to most medical services outlined in the American Medical Association s Current Procedural Terminology, or CPT, and some services described by alphanumeric Healthcare Common Procedure Coding System, or HCPCS, codes. CPT codes currently exist that cover electrophysiology mapping and ablation procedures and are used by physicians to submit claims for payment for the mapping and ablation procedures using our cryoablation system.

Medicaid

The Medicaid program is a cooperative federal/state program that provides medical assistance benefits to qualifying low income and medically needy persons. State participation in Medicaid is optional, and each state is given discretion in developing and administering its own Medicaid program, subject to certain federal requirements pertaining to payment levels, eligibility criteria and minimum categories of services. The coverage, method and level of reimbursement varies from state to state and is subject to each state s budget restraints. Changes to the coverage, method or level of reimbursement for our products may affect future revenue negatively if reimbursement amounts are decreased or discontinued.

Private Payers

Many third party private payers, including indemnity insurers, employer group health insurance programs and managed care plans, presently provide coverage for the purchase of medical equipment and supplies which may include our cryoabalation system. The scope of coverage and payment policies varies among third party

Table of Contents

private payers. Furthermore, many such payers are investigating or implementing methods for reducing healthcare costs, such as the establishment of capitated or prospective payment systems. Cost containment pressures have led to an increased emphasis on the use of cost-effective technologies and products by healthcare providers. Future changes in reimbursement methods and cost control strategies may limit or discontinue reimbursement for our products and could have a negative effect on revenues and results of operations.

Healthcare Fraud and Abuse

In the United States, there are federal and state anti-kickback laws that generally prohibit the payment or receipt of kickbacks, bribes or other remuneration in exchange for the referral of patients or other healthcare-related business. For example, the Federal Healthcare Programs Anti-Kickback Law prohibits anyone from, among other things, knowingly and willfully offering, paying, soliciting or receiving any bribe, kickback or other remuneration intended to induce the referral of patients for, or the purchase, order or recommendation of, healthcare products and services reimbursed by a federal healthcare program (including Medicare and Medicaid). Some states have anti-kickback laws which establish similar prohibitions, although these state laws may apply regardless of whether federal healthcare program payment is involved. If we are able to commercialize our products in the United States, anti-kickback laws will constrain our sales, marketing and promotional activities by limiting the kinds of financial arrangements we may have with physicians, medical centers, and others in a position to purchase, recommend or refer patients for our cryoablation system or other products we may develop and commercialize. Due to the breadth of some of these laws, it is possible that some of our current or future practices might be challenged under one or more of these laws. Furthermore, federal and state false claims laws prohibit anyone from presenting, or causing to be presented, claims for payment to third party payers that are false or fraudulent. For example, the federal Civil False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program (including Medicaid and Medicare). Although medical device manufacturers like us do not typically submit claims to third party payers, some of these false claims laws can potentially be used by government enforcement officials or private qui tam relators against a manufacturer which provides incorrect coding or billing advice about its products to customers that file claims, or which engages in kickback arrangements with customers that file claims. Violations of anti-kickback and false claims laws can lead to civil and criminal penalties, including imprisonment, fines and exclusion from participation in federal healthcare programs. Any such violations could have a material adverse effect on our business, financial condition and results of operations.

Research and Development

Our research and development team currently consists of eight people and focuses on product line extensions and improvements to our existing product line. We are working on enhancements to our products to shorten procedure times, increase ease-of-use, and improve patient outcomes. For example, we are developing our next-generation catheter, the Quantum catheter, with the goal of reducing cryoablation procedure times. We have historically spent a significant portion of our capital resources on research and development, incurring $5.8 million in 2006, $7.5 million in 2005 and $7.6 million in 2004 on research and development.

Intellectual Property

Our Patents

We rely on intellectual property rights for the protection of our current products and plan to rely on these rights to protect any other products that we may develop in the future. We own or have licensed a number of issued patents and pending patent applications in the United States and in foreign countries and plan to file additional patent applications on inventions that are important to our business and that we believe are patentable. We intend to aggressively pursue and defend patent protection on our proprietary technologies.

Table of Contents

As of March 1, 2007, we held 15 United States patents and have a number of pending United States patent applications and foreign patent applications in jurisdictions such as Australia, Canada and Europe. The 15 issued United States patents we own expire between 2021 and 2024.

On August 31, 2000, we entered into a license agreement with CryoGen, Inc. (now owned by American Medical Systems, or AMS) pursuant to which CryoCor was granted an exclusive, irrevocable, worldwide, non-transferable, royalty-free, fully paid license to 21 issued United States patents, 18 foreign patents and 33 foreign patent applications for the field of cardiac and vascular ablation to treat arrhythmias. The United States patents in this portfolio expire between 2012 and 2021. Pursuant to our license agreement, we granted a license to certain modifications, improvements and enhancements to the inventions encompassed in the patents licensed to us pursuant to the agreement back to AMS. AMS is obligated to maintain, enforce and prosecute the patents licensed to us pursuant to the agreement at its own cost and we are obligated to do the same with respect to any patents resulting from modifications, improvements and enhancements to the inventions encompassed in the patents licensed to us pursuant to the agreement. Both we and AMS have continuing confidentiality obligations under the license agreement.

We own or have licensed United States patents and patent applications that relate to a number of technologies that are employed by our cryoablation system as well as technologies which could be used by us in future product innovations or by competitors attempting to design around our patents. Patents that may issue from our most recent patent applications will expire in 2025. A brief description of these technologies is included below.

Model 2020 Console

We own or have licensed patents and patent applications relating to control systems which utilize various sensor arrangements, a control system that varies refrigerant pressure to maintain efficient cooling power and catheter tip temperature, and a method of performing pre-operational checks on a cooling system for leaks or blockages. Applications have also been filed on methods for assessing ice ball formation and methods for selecting cooling and warming rates to maximize cell death.

CryoArm Pre-Cooler

We own or have licensed a number of patents and patent applications covering various pre-cooler designs and pre-cooling concepts which enable the delivery of greater and more efficient cooling power to the tip of a catheter.

CryoBlator Disposable Catheters

We have filed patent applications to cover various heat transfer element designs, methods for selecting capillary tube design dimensions to enhance cryocatheter performance, and designs that enable the articulation of catheters into various shapes without compromising the refrigerant flow therein.

Model 3110 and 3130 Sheath Dilators

We have filed a patent application on a device to minimize the introduction of air into a patient during insertion of a catheter which includes a flexible sheath and an air trap. Certain patents we have under the AMS licensed (now American Medical Systems) also cover sheaths including heat-transfer tips.

Other

We either own or have licensed additional patents or patent applications which cover technologies such as refrigerants which enable catheter tip temperatures below -90° Celsius, and the use of a balloon to anchor a

Table of Contents

catheter s heat transfer element. Finally, we have filed applications to cover catheters with elongated heat transfer elements and designs which enable the articulation of such catheters.

The patent position of companies like ours is generally uncertain and involves complex legal and factual questions. Our ability to maintain and solidify a proprietary position for our technology will depend on our past and future success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our pending patent applications will result in the issuance of patents or whether the rights granted under any issued patents that we own or have licensed will provide us with proprietary protection or competitive advantages against competitors with similar technology.

In 2004, we requested that the USPTO institute interference proceedings between two patents owned by CryoCath Technologies and two of our applications relating to certain primary and pre-cooling refrigeration system designs, and certain heat exchanger designs. One of our two applications that is involved in this interference proceeding is a reissue application stemming from a CryoGen-licensed patent. During 2006, the USPTO agreed to reissue this patent licensed from CryoGen that we consider to be important to our efforts to invoke interference proceedings. If the USPTO determines we are claiming rights to the same technology claimed by CryoCath Technologies, interference proceedings will commence to determine which company was the first to invent, and therefore has the rights to, the interfering subject matter. We believe we have an earlier date of invention, however, if we are not successful in these proceedings, if and when commenced, we could fail to gain rights to certain patent claims.

Patents issued or licensed to us may be infringed by the products or processes of others. The cost of enforcing our patent rights against infringers, if such enforcement is required, could be significant, and the time demands could interfere with our normal operations. In addition, our patents, or those licensed to us, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing our product.

Our Trade Secrets

We rely, in some circumstances, on trade secrets to protect our technology. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors and other contractors, however, these agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our Trademarks

We have registered trademarks for the CryoCor name and logo in Europe, Japan, Australia and New Zealand. We have also applied for registered trademarks for CryoCor, the CryoCor logo and CryoBlator in the United States and Canada.

Third Party Intellectual Property Rights

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. Our commercial success will depend, in part, on our ability to make and sell our cryoablation system without infringing the patents or proprietary rights of third parties.

We are aware of numerous patents issued to third parties in areas of technology related to our cryoablation system. Owners and/or licensees of these patents may assert that the manufacture, use or sale of the current or future versions of our cryoablation system infringe one or more claims of their patents. Some of the patents that

Table of Contents

may pose a material litigation risk to us, and some of the owners of such patents, are described below. The fact that we describe certain patents and patent owners below does not mean that we consider such patents to be valid, enforceable or infringed by any of our products or product candidates or that any party having rights under one or more of such patents intends to sue us for patent infringement.

We are aware of certain United States patents owned by CryoCath Technologies which contain claims relating to devices and methods of using devices for cryoablation. CryoCath may assert that the manufacture, use or sale of our cryoablation system infringes one or more claims of its patents. We believe that the development and marketing of our cryoablation system for the treatment of AFL and AF will not infringe any valid and enforceable claim of any of these CryoCath United States patents and, in certain circumstances, we have obtained written opinions from outside patent counsels regarding the validity of these patents and/or their potential infringement by our cryoablation system.

We are also aware of certain United States patents owned or licensed by Johnson & Johnson or the Regents of the University of California that encompass devices and methods for treating arrhythmias using circumferential ablation. We believe that the development and marketing of our cryoablation system for the treatment of AFL and AF will not infringe any valid and enforceable claim of any of these United States patents.

We are also aware of a United States patent owned by Spembly Medical Limited which encompasses cryosurgical probe systems. We believe that the development and marketing of our cryoablation system for the treatment of AFL and AF will not infringe any valid and enforceable claim of this United States patent.

We have taken reasonable steps with respect to these and other third party patents of which we are aware to ensure that our products do not and will not infringe on the valid patent rights of others. In some instances these steps include obtaining a written opinion of patent counsel regarding the validity of such patents and/or their potential infringement by our cryoablation system. While we currently believe we have freedom to operate with respect to third party patents or other intellectual property rights of which we are aware, others may challenge our position in the future. We believe that we have meritorious defenses to any infringement suit brought against us based on the patents and other intellectual property of which we are currently aware. Nonetheless, there has been, and we believe there will continue to be, significant litigation in the medical device industry regarding patent and other intellectual property rights. The possibility of litigation filed against us based on one or more of these or other patents or other intellectual property is a significant risk. For example, 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 by our cryoablation system.

There is also the risk that there may be issued patents or other intellectual property rights of which we are not aware in areas of technology related to our products. Should these intellectual property rights exist and should a third party successfully assert them against us, our business may be materially and adversely affected. Moreover, because patent applications can take many years to issue, there may be currently pending applications of which we are not yet aware and whose ultimate scope is as yet unknown which may later result in issued patents that if successfully asserted against us would materially and adversely affect our business.

Consequences of Infringement

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 to 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. Investors should consider the possibility of a patent

Table of Contents

infringement suit a significant risk. If any such patent is successfully asserted against us, it would materially and adversely affect our business.

If any patents held by third parties are ultimately determined to contain one or more valid claims that we infringe, 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;
- 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;
- discontinue manufacturing or other processes incorporating infringing technology; and/or
- obtain licenses to the infringed intellectual property, which may not be available to us on acceptable terms, or at all.

In addition, litigation with any patent owner, even if the allegations are without merit, would likely be expensive, time-consuming and would likely divert management s attention from our core business.

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 by 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 commercialization or shipment of our cryoablation system.

Employees and Consultants

As of December 31, 2006, we had 36 full-time employees and two part-time employees, all of whom are employed at-will. Of these employees, eight are engaged in research and development, 10 in manufacturing, 12 in clinical, regulatory affairs and quality assurance and eight in administration, finance, management, information systems, corporate development and human resources. Three of our employees have a Ph.D. degree and/or an M.D. degree and are engaged in activities relating to clinical and regulatory areas and executive management. None of our employees is subject to a collective bargaining agreement. We believe our relations with our employees are good.

We have entered into an agreement with TriNet Employer Group, Inc., a professional employer organization, under which TriNet provides payroll and employee benefit services and acts as a co-employer of our employees.

Table of Contents

MANAGEMENT

Executive Officers, Directors and Other Key Employees

The following table sets forth our current directors, executive officers and other key employees and their ages as of March 1, 2007:

Name	Age	Position(s)
Executive Officers and Directors		
Edward F. Brennan, Ph.D.	55	President and Chief Executive Officer and Director
Gregory J. Tibbitts	39	Vice President, Finance and Chief Financial Officer
Helen S. Barold, M.D., MPH, FACC, FHRS	41	Chief Medical Officer
Robert Adelman, M.D.[(2)(3)]	44	Director
David J. Cooney[(1)(2)]	37	Director
Jerry C. Griffin, M.D.[(1)(3)]	62	Director
J. Mark Hattendorf[(1)]	56	Director
Arda M. Minocherhomjee, Ph.D.[(2)]	53	Director
Kurt C. Wheeler[(2)(3)]	54	Director

(1) Member of the Audit Committee.
(2) Member of the Compensation Committee.
(3) Member of the Nominating and Corporate Governance Committee.

Executive Officers and Directors

Edward F. Brennan, Ph.D. has served as our Chief Operating Officer since January 2005, our President since March 2005 and our Chief Executive Officer and a member of our board of directors since March 2006. During 2004, Dr. Brennan consulted for various technology companies. From January 2001 to December 2003, Dr. Brennan was Managing Director for Perennial Ventures, a venture fund focused on early-stage investing in technology companies. From January 2000 to December 2000, Dr. Brennan served as Vice President of Tredegar Investments, a venture capital investment company. Dr. Brennan was also Executive Vice President for CardioGenesis Corp., a medical device company, from June 1995 to December 1999, where he was responsible for domestic and international clinical programs, regulatory affairs, quality systems and scientific research activities. He is the Chairman of Hemosense, Inc., serves on the Board of Directors of Kilroy Realty Inc., and serves or has served on the boards of a number of privately-held technology companies. Dr. Brennan received a B.A. in Chemistry and Biology and a Ph.D. in Biology from the University of California, Santa Cruz.

Gregory J. Tibbitts has served as our Vice President, Finance and Chief Financial Officer since July 2004. From April 2000 to June 2004, he held various positions including Chief Financial Officer with Elitra Pharmaceuticals Inc., a biotechnology company. From December 1996 to March 2000, Mr. Tibbitts was a senior manager in the audit department of Ernst & Young LLP, specializing in the biotechnology, medical device and other high technology industries. He also worked with Ernst & Young LLP from September 1989 to April 1993 before joining the mortgage banking division of ITT Financial as their Controller. Mr. Tibbitts received a B.A. in Business Administration from the University of San Diego and an M.B.A. in Finance from San Diego State University. He is a Certified Public Accountant in the State of California.

Helen S. Barold, M.D., MPH, FACC, FHRS has served as our Chief Medical Officer since August 2006. From 2000 to 2002, Dr. Barold worked as a Medical Officer for the United States Food and Drug Administration, in the office of device evaluation of the Center for Devices and Radiological Health. From 2002 and until 2006, Dr. Barold practiced in cardiology and cardiac electrophysiology at the National Naval Medical Center in Bethesda, Maryland. She received her M.D. from the University of Rochester and her Masters in Public Health from Johns Hopkins University, completed her Internal Medicine residency at Johns Hopkins Hospital, and her Cardiology and Electrophysiology residency at Duke University.

Table of Contents

Robert Adelman, M.D. has been a member of our board of directors since June 2003. Since March 2002, Dr. Adelman has served as a principal for OrbiMed Advisors, LLC, an asset management fund that specializes in private equity investments and structured transactions of small-capitalization public equity companies, which together with its affiliates, is one of our principal stockholders. From November 2000 to August 2001, Dr. Adelman was Vice President of Business Development for NeoGenesis Pharmaceuticals, Inc., a pharmaceutical discovery company. In October 1999, Dr. Adelman founded Veritas Medicine, a healthcare clinical trials matching company, where he served as Chief Operating Officer until October 2000. He also co-founded Operon Technologies, Inc. a commercial producer of synthetic DNA. Dr. Adelman received a B.A. in Biochemistry from the University of California, Berkeley and an M.D. from Yale University School of Medicine. He trained as an orthopedic surgeon at the Hospital for Special Surgery at Cornell University.

David J. Cooney has been a member of our board of directors since January 2002. Since February 1997, Mr. Cooney has worked with, and is currently a Partner of, Beecken Petty O Keefe & Company, a private investment management firm focused exclusively on the healthcare industry which, together with Healthcare Equity QP Partners, L.P. and its affiliates, is one of our principal stockholders. From October 1995 to February 1997, Mr. Cooney worked in the Corporate Finance Department at Smith Barney in New York, specializing in public offerings and mergers and acquisitions for healthcare companies. Mr. Cooney serves on the boards of directors of a number of privately-held healthcare companies. He received a B.S. in History from the University of Illinois and an M.P.P. from Georgetown University with a specialization in Finance.

Jerry C. Griffin, M.D. has been a member of our board of directors since March 2001. Dr. Griffin currently is the President of Griffin & Schwartz Scientific Services Inc., a management consulting firm. From September 1999 to 2006, Dr. Griffin served as President, Chief Executive Officer and as a director of POINT Biomedical Corporation, a developer of pharmaceutical products for use with ultrasound imaging. From September 1992 to November 1998, Dr. Griffin was employed by InControl, Inc., where he served most recently as Executive Vice President and was responsible for worldwide regulatory affairs and clinical development activities. From July 1977 to August 1992, Dr. Griffin was a faculty member in the Department of Medicine, Division of Cardiology at several teaching institutions, including Professor of Medicine at the University of California at San Francisco, Assistant Professor at Baylor College of Medicine and Clinical Assistant Professor of Medicine at Stanford University. He also serves or has served on the boards of directors at one publicly held company, Scicle Pharma, Inc. and at several privately-held medical device and biotechnology companies. Dr. Griffin received a B.S. from the University of Southern Mississippi, an M.D. from the University of Mississippi.

J. Mark Hattendorf has been a member of our board of directors since July 2006. Mr. Hattendorf has over 30 years of experience in accounting, finance and business management, including as the senior financial officer for a number of publicly and privately-held companies. From April 2005 to October 2006, Mr. Hattendorf was Chief Financial Officer of EWI Holdings, a software company in San Diego. From July 2001 to April 2005 he was an independent financial and business consultant advising clients on acquisitions and due diligence, negotiation strategies and financing strategies. He has experience serving on the board of directors of publicly-held and not-for-profit entities. Mr. Hattendorf began his career with KPMG s predecessor firm, Peat Marwick Mitchell & Co. He is a Certified Public Accountant and holds an undergraduate degree in Accounting and an MBA in Finance from Loyola Marymount University in Los Angeles, California.

Arda M. Minocherhomjee, Ph.D. has served as a member of our board of directors since June 2003. He is currently a partner at Chicago Growth Partners. Since 1998, he has served as a managing director of William Blair Capital Partners and prior to that was a Principal and senior healthcare analyst at William Blair & Company. He currently serves on the board of directors of Favrille, Inc., a biopharmaceutical company, as well as several privately-held pharmaceutical and medical device companies. Dr. Minocherhomjee received a M. Sc. in Pharmacology from the University of Toronto and an M.B.A. from the University of British Columbia, and was a post-doctoral fellow in pharmacology at the University of Washington Medical School.

Kurt C. Wheeler is our Chairman and has been a member of our Board of Directors since September 2000. Mr. Wheeler is a Managing Director at Clarus Ventures LLC, a company he co-founded in 2005. Since 1999,

Table of Contents

Mr. Wheeler has been a General Partner of MPM Bioventures II-III funds. He currently serves on the board of directors of two publicly-held companies, Hemosense, Inc. and Somaxon Pharmaceuticals. In addition, Mr. Wheeler serves on the boards of a number of privately held life science companies. He holds a degree from Brigham Young University and an M.B.A. from Northwestern University, where he serves on the Kellogg Alumni Advisory Board.

Availability of Reports filed with the SEC

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.

ITEM 1A. RISK FACTORS

Except for the historical information contained herein, this Form 10-K contains forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those discussed here. Factors that could cause or contribute to differences in our actual results include those discussed in the following section, as well as those discussed in Part II, Item 7 entitled Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere throughout this Form 10-K. You should consider carefully the following risk factors, together with all of the other information included in this Form 10-K. 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 December 2007. These cash requirements include our planned payoff of our existing debt of $7.0 million, which is due in June 2007. However, our future funding requirements will depend on many factors, including but not limited to:

- our ability to obtain FDA approval or other regulatory approval for our products;
- the scope, rate of progress and cost of our clinical trials and other research and development activities;

Table of Contents

the costs and timing of seeking regulatory approvals;

clinical trial results;

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

the costs of 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.

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.

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. There can be no assurance that we will be able to obtain additional funds during 2007 on satisfactory terms, or at all. 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. Based upon the foregoing, our independent registered public accounting firm has 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.

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

Table of Contents

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 December 31, 2006, we had an accumulated deficit of $85.0 million. We have incurred net losses in each year since our inception in August 2000, including net losses of $15.1 million, $17.1 million, and $15.8 million for the years ended December 31, 2006, 2005, and 2004, respectively. We expect to continue to incur significant and increasing operating losses, in the aggregate and on a per share basis, for the next several years. These losses, among other things, have had and will continue to have an adverse effect on our stockholders equity, net current assets and working capital. Because of the risks and uncertainties associated with developing medical devices, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

We expect that our primary expenses for the next 24 months will be for conducting our clinical trial for AF, costs associated with preparing our PMA for AF, other costs associated with new product development and costs associated with our PMA for AFL. We expect that our general and administrative and legal costs will continue to increase due to the additional operational and regulatory burdens applicable to public companies. If we do not restructure or refinance our existing debt, we expect to pay off our existing debt of $7.0 million when due in June 2007. In addition, we anticipate that the interference we have filed with the USPTO will be declared in 2007 and substantial financial resources will be required to support this action. If we receive FDA marketing approval of our cryoablation system, 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. In February 2007, we announced that the FDA had notified us that our PMA would be taken to an Advisory Panel meeting, where the chronic effectiveness would be evaluated by an Advisory Panel to see if our PMA warrants approval. In subsequent discussions in February 2007 with the FDA, we presented additional information that we believe support our basis for approval, and the FDA decided to postpone and potentially cancel an Advisory Panel meeting for CryoCor while they evaluate the additional information. As a result of our additional information, the computed chronic effectiveness for our PMA for the treatment of atrial flutter is modestly higher than originally considered by the FDA, and the FDA has indicated that it may no longer be necessary to convene an Advisory Panel meeting. We anticipate that the FDA will render a decision on the approval of our PMA by August 2007. However there can be no assurance that the FDA will decide to approve our PMA for atrial flutter.

Table of Contents

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

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

32

Table of Contents

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. 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 completing the enrollment of our AF pivotal trial. If we do not meet our estimated milestones as publicly disclosed for both AF and AFL, we may be unable to commercialize our products in the United States, or any commercialization of our products in the United States may be delayed and, as a result, our business may be harmed and our stock price may decline. If our cryoablation system is not approved by the FDA for any indication for commercialization in the United States, we may be forced to cease operations.

We will need separate FDA approval supported by a separate clinical trial for each proposed indication for our cryoablation system. We intend to seek FDA approval of our cryoablation system to treat both AFL and AF, and will only be able to market our cryoablation system for an indication for which we receive FDA approval. If the FDA does not approve our cryoablation system for treating both AFL and AF, we intend to market our cryoablation system only for the indication for which we receive FDA approval. For each indication, the FDA s marketing approval process is expensive and the outcome is uncertain. To obtain FDA marketing approval, we are required to submit detailed and comprehensive scientific data demonstrating safety and effectiveness of our cryoablation system to the FDA s satisfaction. The marketing approval process also requires passing FDA inspection of our manufacturing facilities and of the clinical trial records for data integrity and compliance with regulatory requirements. The FDA s PMA approval review process generally takes one to three years after filing, but may take longer. The FDA has not approved any medical device for treating AF and has approved four devices for AFL, all of which use radiofrequency, or RF, energy.

As discussed above, in January 2006, the FDA informed us that our PMA for the treatment of AFL using the cryoablation system was not approvable at that time. After receipt of this FDA letter, we conducted an independent evaluation of chronic effectiveness for each subject that experienced acute effectiveness, and based upon the results of this evaluation, we met with the FDA in July 2006 to discuss the process around and results from our independent review of the AFL clinical data. We filed an amendment to our PMA in November 2006, and provided additional information to the FDA in February 2007. We anticipate that the FDA will render a decision on the approval of our PMA by August 2007. However there can be no assurance that the FDA will decide to approve our PMA for atrial flutter. There can be no assurance that the Advisory Panel meeting will result in a recommendation for approval, or the FDA will determine that the data presented in the amended PMA meets the FDA s chronic effectiveness criteria and there can be no assurance that we will receive approval for our amended PMA.

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

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

Table of Contents

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

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

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

- subjects do not enroll in our pivotal trial at the rate we currently expect;
- subjects withdraw from our pivotal trial at a higher withdrawal rate than we expected when designing the trial;
- the FDA places our pivotal trial on hold;
- insufficient capital to fund the pivotal trial;
- supply shortages of the catheters used in the pivotal trial;
- recalls of the catheters used in the pivotal trial;
- subjects are not followed-up at the rate we currently expect;
- subjects experience an unacceptable rate or severity of adverse side effects;
- third party clinical investigators do not perform our pivotal trial on our anticipated schedule or consistent with the clinical trial protocol, Good Clinical Practice and regulatory requirements, or other third party organizations do not perform data collection and analysis in a timely or accurate manner;
- inspections of our clinical trial sites by the FDA or Institutional Review Boards, or IRBs, find regulatory violations that require us to undertake corrective action, suspend or terminate one or more sites, or prohibit us from using some or all of the data in support of our PMA application;
- changes in laws, governmental regulations or administrative actions force us to modify the conduct of our trials or otherwise create unexpected burdens;

the reimbursement by governmental and other third party payers changes;

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

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

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

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

third parties, investigators and contract laboratories conducting our pivotal trial do not perform as contractually required or expected.

Table of Contents

Subject enrollment in clinical trials and successful completion of subject follow-up in clinical trials depend on many factors, including the size of the subject population, the nature of the trial protocol, the proximity of subjects to clinical sites, the eligibility criteria for the trial, and subject compliance. Subjects may be discouraged from enrolling or continuing to participate in our clinical trial if the trial protocol requires them to undergo extensive pre- and post-treatment procedures to assess the safety and effectiveness of our cryoablation system. For example, two of the 160 patients originally enrolled in our AFL trial withdrew from the trial prior to completing the trial. In addition, we have seen a higher withdrawal rate of patients than we originally anticipated in our AF clinical trial. Withdrawal rates may continue to increase as we conduct our AF clinical trial because the follow up period for the AF trial is 12 months as opposed to six months for the AFL trial. In addition, subjects participating in our clinical trial may die before completion of their follow-up. Moreover, it may be difficult to successfully follow our subjects for the required 12-month period. Although to date we have successfully followed all our subjects from our AF feasibility study for the required 12-month period, historical results may not be indicative of our future performance. Additionally, we may experience delays in the enrollment of our pivotal trial. For example, our enrollment for our AF pivotal trial has progressed more slowly than we expected. We have opened new centers and have taken efforts to stimulate enrollment, which has improved the pace of our enrollment. However, it may take us longer than we anticipate to complete the enrollment of our AF pivotal trial. Additionally, we have seen a higher withdrawal rate of patients than we originally anticipated, which required us to request from the FDA that we be able to enroll more than the 160 patients originally planned. In January 2007, the FDA approved our request to increase the size of our pivotal trial. 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, we have requested that the FDA permit us 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

Table of Contents

regulatory requirements, which often require significant resources and subject us and our suppliers to potential regulatory inspections and stoppages. We or our suppliers may not satisfy these requirements. If we or our suppliers do not achieve and maintain required regulatory approval for our manufacturing operations, including for any additional commercial-scale manufacturing facilities that we may obtain in the future, our commercialization efforts in the United States, if any, could be delayed, which could impair our business and financial condition and could require us to cease operations.

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

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

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

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:

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

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

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

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

- any patents issued to us, our collaborators or our licensors, may not provide a basis for a commercially viable product or provide us with any competitive advantage;
- any patents issued to us, our collaborators or our licensors may be challenged, circumvented or invalidated by third parties;

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

The outcome of patent litigation is subject to substantial uncertainties, especially in medical device-related patent cases that may, for example, turn on the interpretation of claim language by the court which may not be to our advantage and also the testimony of experts as to technical facts upon which experts may reasonably disagree. Our involvement in patent litigation could result in significant expense. Some of our competitors have considerable resources available to them and a strong economic incentive to undertake substantial efforts to stop

Table of Contents

or delay us from bringing our cryoablation system to market and achieving market acceptance. We, on the other hand, are an early stage company with comparatively few resources available to us to engage in costly and protracted litigation. Moreover, regardless of the outcome, patent litigation against or by us could significantly disrupt our development and commercialization efforts, divert our management s attention and quickly consume our financial resources.

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

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

Table of Contents

or otherwise, could delay the manufacture and delivery of our cryoablation system and prevent the possible commercialization of our cryoablation system in the United States and additional sales of our cryoablation system in Europe and adversely impact our business.

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

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

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

We currently manufacture our cryoablation system at our facilities in San Diego, California. If there was a disruption to our manufacturing operations, we would have no other means of manufacturing our cryoablation system until we have 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, or to meet demand for our cryoablation system in Europe. If we obtain regulatory approval from the FDA for our cryoablation system but are unable to manufacture a sufficient supply of our cryoablation systems, our revenues, business and financial prospects would be materially adversely affected. In addition, if we obtain regulatory approval for our cryoablation system, but the scaled up production process is not efficient or produces cryoablation systems that do not meet quality and other standards, our future gross margins, if any, will be adversely affected.

Table of Contents

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

Our Quantum catheter is more complicated to manufacture than our CryoBlator catheter, and our experience in manufacturing the initial prototypes indicate that it may take longer to manufacture a single Quantum catheter as required to manufacture a single CryoBlator catheter. This complexity may delay our ability to advance the Quantum catheter into human clinical trials. However, we believe we will develop efficiencies in manufacturing our Quantum catheter to permit us to manufacture it in a commercially viable amount of time. For example, the time required to initially manufacture the Model 1100 catheter, and time required to initially manufacture the Model 1200 catheter, were substantially longer than the time currently required to manufacture our CryoBlator catheter. In addition, after we have conducted 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.

Table of Contents

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

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

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

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

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

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

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

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

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

Table of Contents

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

We have signed distribution agreements with third parties in Europe to market and sell our cryoablation system in the United Kingdom and Italy. We do not intend to sign additional distribution agreements in Europe and we may never sign additional distribution agreements. If our relationships with our distributors do not progress as anticipated, if we are unable to identify alternative distributors, or if their sales and marketing strategies fail to generate sales of our products in the future, our business, financial condition and results of operations would be harmed. We are 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

Table of Contents

subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, the coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations.

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

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;

Table of Contents

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

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

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

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

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

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

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

Table of Contents

testing, we may identify deficiencies which we may not be able to remediate in time to meet our deadline for compliance with Section 404.

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

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

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

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

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

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

- results of our clinical trials;
- failure of any of our products to receive FDA or other regulatory approvals;
- success or failure to raise any additional capital on a timely basis or on acceptable terms;
- regulatory developments in the United States and foreign countries;
- developments, disputes or litigation concerning patents or other proprietary rights;
- failure of any of our product candidates, if approved for commercial sale, to achieve commercial success;
- ability to manufacture our products to commercial standards;
- 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,

Table of Contents

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

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

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

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

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

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

Our executive officers, current directors and holders of five percent or more of our common stock, as of March 1, 2007, beneficially owned approximately 62.0% of our common stock based on the SEC s rules for determining beneficial ownership. These stockholders will likely be able to determine the composition of our board of directors, retain the voting power to approve all matters requiring stockholder approval and continue to have significant influence over our operations. The interests of these stockholders may be different than the interests of other stockholders on these matters. This concentration of ownership could also have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could reduce the price of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease an approximately 18,500 square foot facility in San Diego, California for our headquarters and for our research and development, and manufacturing activities. This lease expires September 30, 2008. We have also leased a small facility in Cologne, Germany, which was the headquarters of our wholly-owned subsidiary, CryoCor GmbH which we have now closed. We have vacated this facility as of June 30, 2006,

and we in are discussions with the landlord about terminating this lease. We believe that our current United States facility will be sufficient to meet our needs for the foreseeable future.

Table of Contents

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be involved in litigation relating to claims arising out of our operations. Other than the interference proceedings described below, we are not currently involved in any material legal proceedings.

On March 24, 2004 and July 9, 2004, we requested that the USPTO institute interference proceedings involving two patents owned by CryoCath and two of our patent applications relating to certain primary and pre-cooling refrigeration system designs, and certain heat exchanger designs. During 2006, the USPTO agreed to reissue a patent licensed from CryoGen that we consider to be important to our efforts to invoke interference proceedings, however an interference proceeding has not yet been invoked. If the USPTO determines we are claiming rights to the same technology claimed by CryoCath, interference proceedings will commence to determine which company was the first to invent, and therefore has the rights to, the technology. Responses have been provided for each office action, but an official interference has not yet been declared. We believe we have an earlier date of invention, however, if we are not successful in these proceedings, we could fail to gain rights to certain patent claims.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of CryoCor s stockholders, through the solicitation of proxies or otherwise, during the quarter ended December 31, 2006.

Table of Contents

PART II

ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

We had our initial public offering on July 13, 2005, and sold 3,709,090 shares of common stock at $11 per share. Prior to such time there was no public market for our common stock. Our common stock is currently traded on the Nasdaq Stock Market, or Nasdaq, under the symbol CRYO .

The following table sets forth the high and low sales prices per share of our common stock for the quarterly periods indicated as reported on Nasdaq which correspond to our quarterly fiscal periods for financial reporting purposes.

	2006	
	High($)	Low($)
Common Stock		
First Quarter	5.99	2.10
Second Quarter	3.35	1.28
Third Quarter	3.44	1.25
Fourth Quarter	3.50	1.40

	2005	
	High($)	Low($)
Common Stock		
Third Quarter beginning July 13, 2005	11.10	6.00
Fourth Quarter	6.70	5.10

On March 16, 2007, the closing price of CryoCor s common stock on Nasdaq was $5.14 per share. As of March 16, 2007, there were 11,047,351 shares of common stock outstanding held by approximately 167 holders of record.

Dividends

CryoCor has never paid or declared any cash dividends on its common stock and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. The terms of our senior secured credit facilities entered into in March 2005 restrict our ability to declare or pay dividends. We intend to retain future earnings, if any, to fund our growth. Any future payment of dividends to our stockholders will depend on decisions that will be made by our board of directors and will depend on then existing conditions, including our financial condition, contractual restrictions, capital requirements and business prospects.

Use of Proceeds

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

We invested $35.4 million in proceeds from the offering, net of underwriting discounts and commissions and offering expenses, in money market funds, United States government or corporate bond securities, and asset-backed securities. Through December 31, 2006, we have used approximately $19.6 million of the proceeds from

Table of Contents

our initial public offering for research and development activities, clinical trial activities, expenses related to our facility, manufacturing and quality system operations, sales and marketing activities, and for working capital and general corporate purposes.

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

Equity Compensation Plan Information

The following table provides information as of December 31, 2006 with respect to compensation plans under which CryoCor s common stock is authorized for issuance.

Plan Category	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders	1,328,725	$ 2.33	301,953(1)
Total	1,328,725	$ 2.33	301,953

(1) Includes 151,678 shares of our common stock available for issuance under our Employee Stock Purchase Plan as of December 31, 2006. Excludes future increases in the number of shares reserved for issuance pursuant to the terms of the 2005 Equity Incentive Plan, the 2005 Non-Employee Directors Stock Option Plan and our 2005 Employee Stock Purchase Plan.

Performance Graph

The following performance graph illustrates a comparison of total cumulative stockholder return on our common stock since July 13, 2005, the date of out initial public offering, to two indices: (i) the Center for Research in Security Prices (CRSP) Total Return Index for the Nasdaq Stock Market and (ii) a peer group industry index based on the standard industrial code for surgical medical and dental instruments and supplies (Peer Group Index). The graph assumes an initial investment of $100 on July 13, 2005 and that all dividends have been reinvested. No cash dividends have been declared on our common stock. The comparisons in the graph are required by the Securities and Exchange Commission and are not intended to forecast or be indicative of possible future performance of our common stock.

Table of Contents

The information in this performance graph is being furnished and shall not be deemed filed for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this performance graph shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended.

Table of Contents

ITEM 6. SELECTED FINANCIAL DATA

The following consolidated financial data are only a summary and should be read together with our consolidated financial statements and the notes thereto, and the information under Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this report on Form 10-K. Our historical results are not necessarily indicative of the results that may be expected in the future.

	Years ended December 31,				
	2006	2005	2004	2003	2002
	(in thousands except per share amounts)				
Consolidated statement of operations data					
Product sales	$ 540	$ 843	$ 493	$ 342	$ 281
Operating expenses:					
Cost of sales[1]	2,468	3,101	2,854	2,649	2,844
Research and development[2]	5,835	7,536	7,586	6,387	4,336
Selling, general and administrative[3]	7,360	6,918	5,736	2,260	2,174
Total costs and expenses	15,663	17,555	16,176	11,296	9,354
Loss from operations	(15,123)	(16,712)	(15,683)	(10,954)	(9,073)
Interest and other income (expense), net	71	(384)	(83)	(218)	35
Net loss	(15,052)	(17,096)	(15,766)	(11,172)	(9,038)
Dividends and accretion to redemption value of redeemable convertible preferred stock		(2,662)	(4,308)	(1,641)	
Cumulative dividends on Series C preferred stock		(102)	(241)	(547)	(902)
Net loss attributable to common stockholders	$ (15,052)	$ (19,860)	$ (20,315)	$ (13,360)	$ (9,940)
Basic and diluted net loss per share common share[4]:	$ (1.40)	$ (3.96)	$ (769.77)	$ (635.43)	$ (530.11)
Shares used to compute basic and diluted net loss per common share:	10,773	5,010	26	21	19

	As of December 31,				
	2006	2005	2004	2003	2002
			(in thousands)		
Consolidated balance sheet data					
Cash, cash equivalents and short-term investments	$ 19,004	$ 30,946	$ 5,436	$ 7,923	$ 659
Total debt	6,857	6,570	1,084	2,175	374
Redeemable convertible preferred stock			33,149	16,594	
Accumulated deficit	(85,012)	(69,960)	(50,202)	(30,128)	(17,315)
Total stockholders equity (deficit)	11,822	24,243	(30,004)	(11,048)	1,613

(1) Cost of sales includes $411,000, $277,000 and $54,000 of non-cash stock-based compensation for the years ended December 31, 2006, 2005 and 2004, respectively.

(2) Research and development includes $497,000, $770,000 and $327,000 of non-cash stock-based compensation for the years ended December 31, 2006, 2005 and 2004, respectively.

(3) Selling, general and administrative includes $1,418,000, $1,047,000 and $668,000 of non-cash stock-based compensation for the years ended December 31, 2006, 2005 and 2004, respectively.

(4) See Note 2 to our consolidated financial statements for information regarding computation of basic and diluted net loss per share attributable to common stockholders and pro forma basic and diluted net loss per share attributable to common stockholders. The pro forma basic and diluted net loss per share attributable to common stockholders reflects the weighted average effect of the assumed conversion of our convertible preferred stock into shares of common stock at the conversion rates in effect for the period presented.

53

Table of Contents

ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the consolidated financial statements, including related notes, appearing elsewhere in the this Form 10-K for the year ended December 31, 2006.

Overview

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

We have filed an application for premarket approval, or PMA, with the United States Food and Drug Administration, or FDA, for the treatment of AFL with our CryoCor Cardiac Cryoablation System, or cryoablation system. Our PMA was filed initially in July 2005. In January 2006, we were notified by the FDA that the PMA was not approvable at that time as the data presented did not meet the FDA s chronic effectiveness criteria. Subsequent to receiving the non-approvable letter, we reevaluated the chronic effectiveness for each subject treated in the study and after meeting with the FDA, we amended our PMA for the treatment of AFL based on this different analysis of chronic effectiveness. In this analysis, we computed our chronic effectiveness to be greater than 80%. We met with the FDA in February 2007 to discuss the status of their review of our PMA amendment and were notified that the FDA accepted the process by which our data was analyzed, and that the FDA intended to convene an advisory panel meeting to advise the FDA on the evaluation of chronic effectiveness in our PMA. In subsequent discussions with the FDA, we provided additional information that we believe supports our basis for approval and that has resulted in a higher computation of chronic effectiveness than previously submitted. The FDA decided to postpone the Advisory Panel meeting for CryoCor while they evaluate the additional information and the FDA has indicated that it may no longer be necessary to convene an Advisory Panel meeting. We anticipate that the FDA will render a 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 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 second quarter of 2007. As of March 28, 2007, we need to enroll nine to 16 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. We believe our pivotal trial for the treatment of AF is significantly further along than any competing ablation catheter trial and we estimate our lead time in enrolling our clinical trial is between 12-18 months ahead of the enrollment pace of the next most advanced AF pivotal trial. 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 mid-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

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

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

Financial Operations

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

Research and Development Expenses. Our research and development expenses primarily consist of costs incurred to further our research and development activities and include salaries and related employee benefits, including non-cash share-based compensation, costs associated with clinical trials, pre-clinical activities, regulatory activities, research-related overhead expenses, fees paid to external service providers and fees paid under contracts with research organizations, which conduct certain research and development activities on our behalf. We expense research and development costs as they are incurred.

Selling, General and Administrative Expenses. Our selling, general and administrative expenses consist primarily of cash compensation and non-cash share-based compensation for executive, finance and administrative personnel. Other significant costs include professional fees for accounting and legal services, including legal services associated with our efforts to obtain and maintain protection for the intellectual property related to our cryoablation system.

Results of Operations

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

Years Ended December 31, 2006, 2005 and 2004

Product Sales. Our product sales were $540,000 in 2006, $843,000 in 2005 and $493,000 in 2004. These revenues were generated from the sale of our products in Europe. As of December 31, 2006, we had $78,000 of

Table of Contents

deferred revenue related to product shipped to European customers that has not yet met our revenue recognition criteria. The $303,000, or 36%, decrease in product sales from 2005 to 2006 was due to the closure of our European subsidiary and our decision to sell products only through our network of distributors, which is at a reduced margin than selling products directly. The $350,000, or 71% increase in product sales, from 2004 to 2005 was due to increased catheter orders from our distributors and medical centers in Europe.

Cost of Sales. Our cost of sales was $2.5 million in 2006, $3.1 million in 2005 and $2.9 million in 2004. Cost of sales primarily consists of materials, labor and overhead costs associated with the manufacturing and warranty of our products. The decrease in cost of sales from 2005 to 2006 was related to lower headcount costs due to our staff restructuring in March 2006 as well as reduced sales volumes in 2006. If our products are approved by the FDA and are successfully commercialized, we anticipate that our cost of sales as a percentage of revenues will decline as we achieve higher future volumes of product sales. Included in cost of sales for the years ended December 31, 2006, 2005 and 2004 were non-cash share-based compensation of $411,000, $277,000 and $54,000, respectively.

Research and Development Expenses. Our research and development expenses were $5.8 million in 2006, $7.5 million in 2005 and $7.6 million in 2004. The $1.7 million, or 23%, decrease from 2005 to 2006 was primarily due to slower patient enrollment in 2006 versus 2005 for the AF pivotal trial as well as costs incurred in 2005 associated with the filing of our PMA for atrial flutter. The $50,000 decrease from 2004 to 2005 was primarily due to lower payroll costs and lower clinical trial costs related to our AF pivotal trial as compared to higher costs incurred in 2004 associated with our fully enrolled AFL pivotal trial. These decreases were partially offset by an increase in non-cash share-based compensation expenses of $443,000. Included in research and development expenses for the years ended December 31, 2006, 2005 and 2004 were non-cash share-based compensation of $497,000, $770,000 and $327,000, respectively.

Selling, General and Administrative Expenses. Our selling, general and administrative expenses were $7.4 million in 2006, $6.9 million in 2005 and $5.7 million in 2004. The $442,000, or 6%, increase from 2005 to 2006 was primarily due to an increase in non-cash share-based compensation of $371,000. The $1.2 million, or 21%, increase from 2004 to 2005 was primarily due to an increase in non-cash share-based compensation of $379,000, an increase of $450,000 in other compensation-related costs and $550,000 in increased costs associated with being a public company, which are primarily legal, accounting and insurance costs. Included in selling, general and administrative expenses for the years ended December 31, 2006, 2005 and 2004 were non-cash share-based compensation of $1.4 million, $1.0 million and $668,000, respectively.

Interest Income. Our interest income was $1.1 million in 2006, $634,000 in 2005 and $109,000 in 2004. The fluctuation in interest income directly relates to the balance of short-term investments throughout those years. The short-term investment balance was affected by our mid-year initial public offering in 2005 and our private equity placement in 2004.

Interest Expense. Our interest expense was $1.1 million in 2006, $1.0 million in 2005 and $192,000 in 2004. Our 2006 and 2005 interest expense includes $788,000 and $621,000, respectively, related to our $7.0 million debt facility. In addition, our 2006 and 2005 interest expense also included $286,000 and $227,000, respectively, in non-cash interest expense from the amortization of the debt discount recorded on warrants issued in March 2005. In 2004, we incurred $110,000 of interest expense related to a term loan issued in mid-2003 that was paid off in March 2005, as well as interest expense on capital leases.

Liquidity and Capital Resources

We have incurred losses since our inception in August 2000. As of December 31, 2006, we had an accumulated deficit of $85.0 million. We have funded our operations to date from private placements of equity and debt securities for aggregate net cash proceeds of $51.2 million through December 31, 2006, as well as bank debt and the proceeds of our initial public offering, which was closed in July 2005 and raised aggregate net

Table of Contents

proceeds of $35.4 million after deducting underwriting expenses and commissions and offering costs. Concurrent with the closing of the initial public offering, all of our outstanding preferred shares converted into shares of common stock.

The audit report of our independent registered public accounting firm included in this Annual Report on Form 10-K contains an unqualified opinion with an explanatory paragraph, to the effect that there is substantial doubt about our ability to continue as a going concern. This opinion could itself have a material adverse effect on our business, financial condition, results of operations and cash flows.

As of December 31, 2006, we had no long-term debt outstanding, short-term debt outstanding of $7.0 million (excluding a debt discount for warrants of $143,000), working capital of $10.9 million and cash, cash equivalents and short-term investments totaling $19.0 million. We currently invest our cash in money market funds, United States government or corporate bond securities and asset-backed securities. In March 2005, we entered into a debt facility and borrowed $7.0 million thereunder. As part of that transaction, we repaid in full an outstanding term loan of $1.8 million. The new debt facility bears interest at a rate of 11.25% per year and requires interest-only payments through June 2007, at which time the principal is due and payable. Based upon our current planned level of expenditures, we believe the proceeds from our initial public offering, together with cash flows from operating activities will be adequate to permit us to repay our outstanding debt facility in June 2007 and to meet our anticipated cash requirements for working capital until December 2007.

Net Cash Used in Operating Activities. Net cash used in operating activities decreased $2.2 million to $12.2 million for the year ended December 31, 2006, compared to $14.5 million for the year ended December 31, 2005. The net cash used in both of these periods primarily reflects the net loss for each period, offset in part by depreciation and amortization, non-cash share-based compensation, amortization of debt discount and changes in operating assets and liabilities.

Net Cash Used in Investing Activities. Net cash provided by investing activities increased $25.2 million to $4.4 million for the year ended December 31, 2006, compared to $20.8 million used in investing activities for the year ended December 31, 2005. Cash provided by (used in) investing activities relates to purchases and maturities of short-term investments as well as purchases and disposals of property and equipment. The increase in net cash used in investing activities for the year ended December 31, 2006 is related to proceeds from the sales of short-term investments versus the purchases of short-term investments subsequent to our July 2005 initial public offering.

Net Cash Provided by Financing Activities. Net cash provided by financing activities decreased $40.1 million to $256,000 for the year ended December 31, 2006, compared to $40.4 million for the year ended December 31, 2005. Net cash provided by financing activities during the year ended December 31, 2006 was primarily attributable to proceeds from the issuance of common stock related to the exercise of stock options granted under our equity incentive plans. Net cash provided by financing activities during the year ended December 31, 2005 was primarily attributable to our initial public offering which had net proceeds of $35.4 million as well as borrowing under our new debt facility of $7.0 million, offset by the pay-off of an existing term loan and payments on existing capital leases.

Operating Capital and Capital Expenditure Requirements

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

Table of Contents

We do not expect to generate significant product revenues until we obtain marketing approval for and begin selling our cryoablation system in the United States. Based upon our current level of expenditures, we believe the proceeds from our initial public offering, together with cash flows from operating activities will be adequate to permit us to repay our outstanding debt facility in June 2007 and to meet our anticipated cash requirements for working capital until December 2007. We will need to seek additional financing and we expect to sell additional equity or debt securities or obtain an additional credit facility to increase our financial resources. The sale of additional equity and convertible debt securities will result in additional dilution to our stockholders. If we raise additional funds through the issuance of convertible debt securities, these securities would have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned clinical and commercial activities, and research and development efforts, or to cease operations.

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

The restructuring plan included:

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

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

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

At present, we have a wholly owned subsidiary in Cologne, Germany that previously sold our products in Germany, Belgium, and the Netherlands. We discontinued the activities of this subsidiary in 2006, and are currently pursuing the dissolution of this subsidiary. We incurred restructuring charges of $252,000 in conjunction with the closing of our subsidiary, of which $90,000 remains accrued at December 31, 2006. We have signed distribution agreements for the sale of our cryoablation system in the United Kingdom and Italy, and our United Kingdom distributor supports our customers in Germany, Belgium, Denmark and the Netherlands. At present, we do not currently expect to sign additional distribution agreements in Europe. If we obtain marketing approval from the FDA, we plan to commercialize in the United States with our own sales force or in combination with a marketing partner.

We anticipate spending at least $4.3 million in external costs during 2007 and 2008 for clinical trials and regulatory activities related to using our cryoablation system to treat AFL and AF, and an anticipated clinical trial

Table of Contents

for our next generation catheter, Quantum. We believe the total costs for our clinical trials for AFL and AF and the development of our existing product candidates will require approximately $11.9 million during 2007 and 2008, with our remaining cash and cash equivalents being used to prosecute and maintain our intellectual property portfolio, to fund our facility, manufacturing and quality system operations and to fund our working capital and general corporate requirements during this same period.

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

Our forecasts of the period of time through which our financial resources will be adequate to support our operations and the costs to complete development of products are forward-looking statements and involve risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed in the Risk Factors section of this Form 10-K, and in our other securities filings filed with the Securities and Exchange Commission. We have based these estimates on assumptions that may prove to be wrong, and we may be required to utilize our available capital resources sooner than we currently expect.

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

- our ability to obtain FDA approval or other regulatory approval for our products;
- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- the costs and timing of seeking regulatory approvals, including participation in FDA advisory panel meetings;
- clinical trial results;
- acceptance by the FDA of our clinical trial design and data to support applications for marketing approval of the desired indications;
- the costs of filing, prosecuting, and maintaining our owned and licensed patent applications and patents, and defending and enforcing these patents and other intellectual property rights;
- the costs of establishing sales, marketing and distribution capabilities;
- the extent and level of reimbursement for cryoablation;
- the commercial acceptance of our product following the initiation of our sales efforts in the United States;
- the effect of competing products and technologies; and

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

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

Table of Contents

Contractual Obligations. The following table summarized our outstanding contractual obligations as of December 31, 2006:

		Payments due in			
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating leases	$ 676,000	$ 392,000	$ 284,000	$	$
Debt facility	7,000,000	7,000,000			

The table above reflects only payment obligations that are fixed and determinable. Our commitments for operating leases primarily relate to the lease for our headquarters in San Diego, California. In November 2006, we renewed this lease through September 2008, and the table above includes the payments of approximately $27,000 per month that will be due pursuant to the terms of the lease.

At December 31, 2006, we had purchase commitments outstanding totaling $29,000 for console materials, $69,000 in deposits on console inventory components, and $518,000 in console inventory which is recorded within inventory on our balance sheet. This total inventory represents approximately nine consoles in finished goods, components to build an additional ten complete consoles, and components that could be used in the production of additional consoles. These materials are not expected to be obsolete in the time period anticipated for commercialization. At December 31, 2006, we had disposables inventory totaling $302,000, of which $273,000 is raw materials. This inventory level represents approximately 1,100 finished catheters. We anticipate that the existing inventory levels, including the open purchase commitments, will be needed in either 2007 or 2008 to the extent we are able to commercialize our products in the United States.

We also have service agreements with clinical sites, individuals and institutional research organizations for the conduct of our AF pivotal trial. We make payments to these sites and organizations based upon the actual number of patients enrolled and the period of follow-up in the trials, and we have accrued approximately $894,000 in fees and expenses through December 31, 2006 payable in connection with our AF pivotal trial. We do not have minimum payment obligations under these agreements and the amount to be paid to each center and the timing of those payments will vary based on the negotiated amount paid for each patient to be treated and for each patient screened who fails to or declines to participate in the clinical trial. We anticipate that the external cash outlay of completing our AF pivotal trial and submitting a PMA for the treatment of AF with our cryoablation system will be approximately $3.5 million during 2007 and 2008. However, due to the variability associated with these agreements and the timing of patient enrollment, we are unable to estimate with certainty the future patient enrollment costs we will incur. We expect to incur additional expenses in connection with the preparation of our regulatory filings, including costs associated with employees and consultants and related legal expenses.

We have agreed to cover the treatment costs for certain patients in our AF pivotal trial who are either not insured, or who are insured but were declined coverage by their insurance company for the costs associated with this procedure. As of December 31, 2006, we have agreed to cover the treatment costs for one patient, at an estimated cost of approximately $25,000. We anticipate that there may be additional patients for whom we agree to pay the treatment costs, and project that the total number of patients for which we could cover the cost of the treatment could be between 5-10 patients, at an estimated cost of $15,000 $35,000 each, the total cost for which is included in our estimated total payments during 2007 and 2008 of $3.5 million.

Critical Accounting Policies and Significant Judgments and Estimates

Our management s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and

Table of Contents

liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

Revenue Recognition

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

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

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

Clinical Trial Expenses

Clinical trial costs are a component of research and development expenses and include fees paid to participating hospitals and other service providers which conduct clinical trial activities with patients on our behalf. The various costs of the trial are contractually based on the nature of the service and we accrue the costs as the services to the patient are provided.

Share-Based Payments

We have four share-based compensation plans consisting of three stock option programs and an employee stock purchase plan. Prior to January 1, 2006, we accounted for these plans under the recognition and measurement provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB 25, and related guidance, as permitted by Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation,* or SFAS 123. Effective January 1, 2006, we adopted the fair value recognition provisions of the Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment,* or SFAS 123(R), as interpreted by the SEC s Staff Accounting Bulletin No. 107, or SAB 107, using the prospective method and the modified prospective method. Therefore, we have not restated our financial results for prior periods.

Table of Contents

In accordance with SFAS 123(R), we utilized the prospective method for stock options granted prior to our initial public offering as we had used the minimum value method of measuring the fair value of these options for pro forma disclosure purposes under SFAS 123. Therefore, unless modified in the future, these options are excluded from the adoption of SFAS 123(R). We utilized the modified prospective method for stock options granted subsequent to our initial public offering as we had used the fair-value-based method of measuring the fair value of these options for pro forma disclosure purposes under SFAS 123. Under these transition methods, compensation cost recognized during the year ended December 31, 2006 included the following: (a) share-based compensation cost associated with options granted prior to our initial public offering with exercise prices less than the deemed fair value of the common stock at the date of grant, (b) compensation cost related to any share-based payments granted subsequent to the date of our initial public offering through, but not vested as of, December 31, 2005, and (c) compensation cost for any share-based payments granted subsequent to December 31, 2005, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R).

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

As a result of adopting SFAS 123(R), we recognized additional share-based employee compensation expense of $510,000 during the year ended December 31, 2006 in addition to $1.8 million in compensation expense recorded as required under APB 25. We calculated this expense based on the fair values of the share-based compensation awards as estimated using the Black-Scholes option valuation model. Use of this model requires us to make assumptions about expected future volatility of our stock price and the expected term of the options that we grant. Calculating share-based compensation expense under SFAS 123(R) also requires us to make assumptions about expected future forfeiture rates for our option awards. As of December 31, 2006, total unrecognized compensation expense related to unvested share-based compensation arrangements already granted under our various plans was $3.2 million, which we expect will be recognized over a weighted-average period of 1.9 years. However, it is difficult to predict the actual amount of share-based compensation expense that we will recognize in future periods because that expense can be affected by changes in the amount or terms of our share-based compensation awards issued in the future, changes in the assumptions used in our model to value those future awards, changes in our stock price, and changes in interest rates, among other factors.

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

Inventory

As of December 31, 2006, we had raw materials, work-in-process and finished goods console inventory totaling $518,000. In addition, we had open purchase commitments totaling $29,000 for console components ordered that will be received and paid for during 2007 as well as $69,000 in deposits on console inventory components. This total inventory represents approximately nine consoles in finished goods, components to build an additional ten complete consoles, and raw materials that could be used in the production of additional consoles. Further, at December 31, 2006, we had disposables inventory totaling $302,000, of which $273,000 is raw materials. This inventory level represents approximately 1,100 finished catheters. We evaluated whether these levels of console and catheter inventory was excessive based upon the January 2006 communication from

Table of Contents

the FDA indicating that our cryoablation system was not approvable at that time for the treatment of AFL. We concluded that the existing inventory levels, including the open purchase commitments, were not excessive for the following reasons:

Consoles

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

Disposables

- we anticipate the sale of approximately 300-600 catheters in Europe during 2007;
- we believe we will receive approval to sell our product in the United States in either 2007, 2008 or 2009; and
- the catheter raw materials are not subject to obsolescence in the time period contemplated for commercialization.

Based on the above, we concluded that no reserves were needed at December 31, 2006 for either the existing console and catheter inventory or the materials on order, to be delivered in 2007. We will continue to evaluate these inventory levels based on the progress of our trials and regulatory approvals.

Recent Accounting Pronouncements

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109*, or FIN 48. FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing the recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006 and we are required to adopt it in 2007. We do not expect the adoption of FIN 48 to have a material impact on our consolidated results of operations and financial condition.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including commercial paper, money market funds, government and corporate debt securities and asset-backed securities. Our cash, cash equivalents and short-term investments as of December 31, 2006 included liquid money market accounts, commercial paper, corporate debt securities and asset-backed securities. Due to the short-term nature of our investments, we believe that there is no material exposure to interest rate risk.

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

63

Table of Contents

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See the list of financial statements filed with this report under Item 15 below.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Regulations under the Securities Exchange Act of 1934, or the Exchange Act, require public companies to maintain disclosure controls and procedures which are defined to mean a company s controls and other procedures that are designed to ensure that information required to be disclosed in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission s rules and forms. CryoCor s management, including our Chief Executive Officer, who is our principal executive officer, and our Chief Financial Officer, who is our principal financial officer, conducted an evaluation as of the end of the period covered by this report of the effectiveness of our disclosure controls and procedures. Based on their evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective for this purpose.

Changes in Internal Control over Financial Reporting

Our Chief Executive Officer and our Chief Financial Officer have determined that there were no changes in our internal controls over financial reporting during our most recent fiscal year that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitation on Effectiveness of Controls

It should be noted that any system of controls, however well designed and operated, can provide only reasonable and not absolute assurance that the objectives of the system are met. The design of any control system is based, in part, upon the benefits of the control system relative to its cost. Control systems can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. In addition, over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

ITEM 9B. OTHER INFORMATION

None.

Table of Contents

PART III

ITEM 10. DIRECTORS EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item 10 is incorporated herein by reference to our definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after December 31, 2006 for our Annual Meeting of Stockholders to be held on May 14, 2007.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 is incorporated herein by reference to our definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after December 31, 2006 for our Annual Meeting of Stockholders to be held on May 14, 2007.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item 12 is incorporated herein by reference to our definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after December 31, 2006 for our Annual Meeting of Stockholders to be held on May 14, 2007.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this Item 13 is incorporated herein by reference to our definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after December 31, 2006 for our Annual Meeting of Stockholders to be held on May 14, 2007.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item 14 is incorporated herein by reference to our definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after December 31, 2006 for our Annual Meeting of Stockholders to be held on May 14, 2007.

Table of Contents

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Financial Statements and Financial Statement Schedules.

Documents filed as part of this report:

1. Financial Statements:

The financial statements of CryoCor listed below are set forth in Item 8 of this report for the year ended December 31, 2006

2. Financial Statement Schedules:

All other schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or notes thereto.

(b) Exhibit Index

Number	Description of Document
3.1(1)	Registrant s Amended and Restated Certificate of Incorporation.
3.2(1)	Registrant s Amended and Restated Bylaws.
4.1(1)	Form of Common Stock Certificate of Registrant.
4.2(1)	Amended and Restated Investor Rights Agreement dated June 4, 2003 between the Registrant and certain of its stockholders.
10.1(1)(2)	Form of Indemnity Agreement by and between Registrant and its directors and executive officers.
10.2(1)(2)	2000 Stock Option Plan and Forms of Stock Option Agreement and Form of Notice of Grant of Stock Option thereunder.
10.3(1)(2)	2005 Equity Incentive Plan and Forms of Stock Option Agreement and Form of Stock Option Grant Notice thereunder.
10.4(1)(2)	2005 Non-Employee Directors Stock Option Plan and Form of Stock Option Agreement and Forms of Stock Option Grant Notice thereunder.
10.5(1)(2)	2005 Employee Stock Purchase Plan and Form of Offering Document thereunder.
10.6(1)(2)	Fourth Amended and Restated Executive Employment Agreement made effective as of November 30, 2002, between the Registrant and Gregory M. Ayers, as amended.
10.7(1)(2)	Employment Agreement made effective as of January 17, 2005, by and between the Registrant and Edward F. Brennan.
10.8(1)(2)	Executive Employment Agreement made effective as of July 1, 2004, by and between the Registrant and Gregory J. Tibbitts.

Table of Contents

Number	Description of Document
10.9(1)(2)	Employment Offer Letter Agreement dated September 27, 2000, between the Registrant and Russell Olson.
10.110(1)(3)	Lease made as of November 1, 2000 between the Registrant and The Irvine Company, as amended.
10.11(1)(3)	Contribution Agreement entered into as of August 31, 2000, by and between the Registrant and CryoGen, Inc.
10.12(1)	License Agreement entered into as of August 31, 2000, by and between the Registrant and CryoGen, Inc.
10.13(1)	Venture Loan and Security Agreement dated as of March 18, 2005, by and between the Registrant and Horizon Technology Funding Company LLC.
10.14(1)	Commitment Agreement entered into as of March 24, 2005 among the Registrant and certain of its stockholders.
10.15(1)	Research and Development Agreement entered into as of August 31, 2000, by and between the Registrant and CryoGen, Inc.
10.16(4)(2)	Letter Amendment Agreement dated March 21, 2006 between the Registrant and Gregory M. Ayers.
10.17(5)(2)	Employment Offer Letter dated August 3, 2006 between the Registrant and Dr. Helen S. Barold.
10.18(6)(2)	Letter Amendment Agreement dated November 1, 2006 between the Registrant and Gregory M. Ayers.
10.19(7)	Second Amendment to Lease dated November 8, 2006, between the Registrant and the Irvine Company LLC
21.1(1)	List of Subsidiaries.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney. Reference is made to the signature page of this report.
31.1	Certification of principal executive officer required by Rule 13a-14(a) or Rule 15d-14(a).
31.2	Certification of principal accounting officer required by Rule 13a-14(a) or Rule 15d-14(a).
32.1	Certification by the Chief Executive Officer and the Chief Financial Officer of CryoCor, Inc., as required by Rule 13a-14(b) or 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C.1350).

(1) Incorporated by reference to the Registrant s Registration Statement on Form S-1 (File No. 333-123841), filed with the Securities and Exchange Commission on April 5, 2005, as amended.

(2) Indicates management contract or compensatory plan.

(3) Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

(4) Incorporated by reference to the Registrant s report on Form 8-K filed with the Securities and Exchange Commission on March 22, 2006.

(5) Incorporated by reference to the Registrant s report on Form 10-Q filed with the Securities and Exchange Commission on November 8, 2006

(6) Incorporated by reference to the Registrant s report on Form 8-K filed with the Securities and Exchange Commission on November 3, 2006

(7) Incorporated by reference to the Registrant s report on Form 8-K filed with the Securities and Exchange Commission on November14, 2006

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CryoCor, Inc.

By: /s/ Edward F. Brennan, Ph.D.
Edward F. Brennan, Ph.D.

Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Edward F. Brennan, and Gregory J. Tibbitts, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and re-substitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them or their or his substitute or substituted, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Edward F. Brennan, Ph.D. **Edward F. Brennan, Ph.D.**	President and Chief Executive Officer and Director *(Principal Executive Officer)*	March 30, 2007
/s/ Gregory J. Tibbitts **Gregory J. Tibbitts**	Vice President, Finance and Chief Financial Officer (*Principal Financial and Accounting Officer*)	March 30, 2007
/s/ Robert Adelman, M.D. **Robert Adelman, M.D.**	Director	March 30, 2007
/s/ David J. Cooney **David J. Cooney**	Director	March 30, 2007
/s/ Jerry C. Griffin, M.D., FACC **Jerry C. Griffin, M.D., FACC**	Director	March 30, 2007
/s/ J. Mark Hattendorf **J. Mark Hattendorf**	Director	March 30, 2007

/s/ ARDA MINOCHERHOMJEE, PH.D. **Arda Minocherhomjee, Ph.D.**	Director	March 30, 2007
/s/ KURT C. WHEELER **Kurt C. Wheeler**	Director	March 30, 2007

Table of Contents

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders

CryoCor, Inc.

We have audited the accompanying consolidated balance sheets of CryoCor, Inc. as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2006. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

The accompanying financial statements have been prepared assuming that CryoCor, Inc. will continue as a going concern. As more fully described in Note 1, CryoCor, Inc. has incurred recurring operating losses and cash flow deficits and has limited working capital. These conditions raise substantial doubt about the Company s ability to continue as a going concern. Management s plans in regard to these matters also are described in Note 1. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

As described in Note 1 of the notes to consolidated financial statements, effective January 1, 2006 the Company changed its method of accounting for share-based payments as required by the provisions of Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of CryoCor, Inc. at December 31, 2006 and 2005, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

San Diego, California

February 21, 2007

Table of Contents

CryoCor, Inc.

Consolidated Balance Sheets

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

	December 31, 2006	2005
Assets		
Current Assets:		
Cash and cash equivalents	$ 3,025	$ 10,583
Short-term investments	15,979	20,363
Accounts receivable, net	56	100
Inventories, net	820	718
Prepaid expenses and other current assets	555	756
Total current assets	20,435	32,520
Property and equipment, net	610	680
Other assets	297	244
Total assets	$ 21,342	$ 33,444
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 212	$ 488
Accrued compensation	1,002	758
Accrued clinical development liabilities	942	751
Accrued liabilities	429	427
Deferred revenue	78	205
Capital lease obligation, current portion		2
Current portion of long-term debt	6,857	
Total current liabilities	9,520	2,631
Long-term debt, less current portion		6,570
Stockholders equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized at December 31, 2006 and 2005, respectively; zero shares outstanding at December 31, 2006 or 2005		
Common stock, $0.001 par value, 75,000,000 shares authorized at December 31, 2006 and 2005, respectively; 11,030,366 and 10,643,999 shares issued and outstanding at December 31, 2006 and 2005, respectively	11	11
Additional paid-in capital	96,709	99,089
Deferred stock compensation		(4,964)
Accumulated comprehensive income	114	67
Accumulated deficit	(85,012)	(69,960)
Total stockholders equity	11,822	24,243
Total liabilities and stockholders equity	$ 21,342	$ 33,444

See accompanying notes.

Table of Contents

CryoCor, Inc.

Consolidated Statements of Operations

(in thousands except per share amounts)

	Years ended December 31,		
	2006	**2005**	**2004**
Product sales	$ 540	$ 843	$ 493
Operating expenses:			
Cost of sales	2,468	3,101	2,854
Research and development	5,835	7,536	7,586
Selling, general and administrative	7,360	6,918	5,736
Total costs and expenses	15,663	17,555	16,176
Loss from operations	(15,123)	(16,712)	(15,683)
Interest income	1,147	634	109
Interest expense	(1,076)	(1,018)	(192)
Net loss	(15,052)	(17,096)	(15,766)
Dividends and accretion to redemption value of redeemable convertible preferred stock		(2,662)	(4,308)
Cumulative dividends on Series C preferred stock		(102)	(241)
Net loss attributable to common stockholders	$ (15,052)	$ (19,860)	$ (20,315)
Basic and diluted net loss per common share	$ (1.40)	$ (3.96)	$ (769.77)
Shares used to compute basic and diluted net loss per common share	10,773	5,010	26

See accompanying notes.

Table of Contents

CryoCor, Inc.

Consolidated Statements of Stockholders Equity

(in thousands except for the number of shares)

	Common stock		Additional paid-in	Deferred stock	Accumulated comprehensive	Accumulated	Total stockholders
	Shares	Amount	in capital	compensation	income	deficit	equity (deficit)
Balance at December 31, 2003	22,253	$	$ 18,979	$	$ 95	$ (30,128)	$ (11,048)
Dividends and accretion to redemption value of Series D redeemable convertible preferred stock						(4,308)	(4,308)
Deferred stock compensation related to employee stock option grants			5,215	(5,215)			
Amortization of deferred stock compensation				622			622
Cancellation of stock options issued to employees and related deferred compensation			(25)	25			
Compensation related to stock options issued to non-employees			83				83
Compensation related to modification of employee stock option			40				40
Issuance of common stock under stock plans, net	3,945		3				3
Issuance of common stock for cash of $10 and services rendered from former executive	16,425		197				197
Issuance of common stock to consultant for services rendered	8,709		117				117
Comprehensive loss:							
Foreign currency translation adjustment					56		56
Net loss						(15,766)	(15,766)
Comprehensive loss							(15,710)
Balance at December 31, 2004	51,332	$	$ 24,609	$ (4,568)	$ 151	$ (50,202)	$ (30,004)

Table of Contents

CryoCor, Inc.

Consolidated Statements of Stockholders Equity (Continued)

(in thousands except for the number of shares)

	Common stock		Additional paid-in	Deferred stock	Accumulated comprehensive	Accumulated	Total stockholders
	Shares	Amount	in capital	compensation	income	deficit	equity (deficit)
Balance at December 31, 2004	51,332	$	$ 24,609	$ (4,568)	$ 151	$ (50,202)	$ (30,004)
Issuance of common stock in initial public offering in July 2005 for cash of $11.00 per share, net of issuance costs of $5,421	3,709,090	4	35,379				35,383
Conversion of 6,367,834 shares of convertible preferred stock into common stock	1,574,302	2	4				
Conversion of redeemable convertible preferred stock into common stock	5,040,932	5	35,806				35,811
Issuance of common stock related to exercise of warrants	34,978						
Dividends and accretion to redemption value of Series D redeemable convertible preferred stock						(2,662)	(2,662)
Deferred stock compensation related to employee stock option grants			2,956	(2,956)			
Amortization of deferred stock compensation				1,954			1,954
Cancellation of stock options issued to employees and related deferred compensation			(606)	606			
Compensation related to stock options granted to non-employees			130				130
Compensation related to modification of an employee stock option			10				10
Issuance of common stock under stock plans, net	233,365		144				144
Warrants issued in connection with debt facility			657				657
Comprehensive loss:							
Foreign currency translation adjustment					(28)		(28)
Unrealized loss on available-for-sale securities					(56)		(56)
Net loss						(17,096)	(17,096)
Comprehensive loss							(17,180)
Balance at December 31, 2005	10,643,999	$ 11	$ 99,089	$ (4,964)	$ 67	$ (69,960)	$ 24,243

Table of Contents

CryoCor, Inc.

Consolidated Statements of Stockholders Equity (Continued)

(in thousands except for the number of shares)

	Common stock		Additional paid-in	Deferred stock	Accumulated comprehensive	Accumulated	Total stockholders
	Shares	Amount	in capital	compensation	income	deficit	equity (deficit)
Balance at December 31, 2005	10,643,999	$ 11	$ 99,089	$ (4,964)	$ 67	$ (69,960)	$ 24,243
Share-based compensation			2,270				2,270
Elimination of deferred stock compensation upon adoption of SFAS 123(R)			(4,964)	4,964			
Compensation related to stock options granted to non-employees			56				56
Issuance of common stock under stock plans, net	386,367		258				258
Comprehensive loss:							
Foreign currency translation adjustment					(15)		(15)
Unrealized loss on available-for-sale securities					62		62
Net loss						(15,052)	(15,052)
Comprehensive loss							(15,005)
Balance at December 31, 2006	11,030,366	$ 11	$ 96,709	$	$ 114	$ (85,012)	$ 11,822

See accompanying notes.

Table of Contents

CryoCor, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Years ended December 31,		
	2006	**2005**	**2004**
Operating activities			
Net loss	$ (15,052)	$ (17,096)	$ (15,766)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	295	489	532
Non-cash share-based compensation	2,326	2,094	1,049
Amortization of debt discount	287	227	
Amortization of premium/discount on short-term investments	(276)	10	
Loss on disposition of property and equipment	51		18
Changes in operating assets and liabilities:			
Accounts receivable	52	(49)	(26)
Inventories	(89)	(95)	75
Prepaid expenses and other assets	155	(506)	34
Accounts payable	(280)	37	138
Deferred revenue	(140)	(55)	267
Accrued liabilities	429	490	362
Net cash used in operating activities	(12,242)	(14,454)	(13,317)
Investing activities			
Purchases of property and equipment	(275)	(322)	(271)
Proceeds from sale of property and equipment			2
Purchases of short-term investments	(27,928)	(22,429)	
Proceeds from sales of short-term investments	32,650	2,000	
Net cash provided by (used in) investing activities	4,447	(20,751)	(269)
Financing activities			
Net proceeds from issuance of preferred stock			12,246
Net proceeds from issuance of common stock		35,383	10
Proceeds from issuance of common stock under stock plans, net	258	144	3
Proceeds from long-term debt		7,000	
Principal payments on capital lease	(2)	(80)	(293)
Principal payments on long-term debt		(2,083)	(916)
Net cash provided by financing activities	256	40,364	11,050
Effect of exchange rate changes on cash	(19)	(12)	49
Net (decrease) increase in cash and cash equivalents	(7,558)	5,147	(2,487)
Cash and cash equivalents at beginning of period	10,583	5,436	7,923
Cash and cash equivalents at end of period	$ 3,025	$ 10,583	$ 5,436
Supplemental disclosures of cash flow information:			
Cash payments for interest	$ 788	$ 788	$ 134

See accompanying notes.

Table of Contents

CryoCor, Inc.

Notes to Consolidated Financial Statements

Note 1. Organization and Summary of Significant Accounting Policies

Organization

CryoCor, Inc. (CryoCor or the Company or we), a Delaware corporation, is a medical technology company that has developed and manufactures a minimally invasive, disposable catheter system based on proprietary cryoablation technology for the treatment of cardiac arrhythmias.

In 2001, the Company established a wholly owned German subsidiary, CryoCor GmbH, in order to market and support the Company s products in the European community. In 2002, the Company received European regulatory approval for the commercial sale of the Company s products. At present, the majority of the Company s revenues relate to sales to European customers. In November 2005, the Company announced its intention to close CryoCor GmbH and sell its products in Europe solely through European distributors. See Note 3 for further details on the closure of the subsidiary.

Basis of Presentation

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. This basis of accounting contemplates the recovery of the Company s assets and the satisfaction of liabilities in the normal course of business. Successful completion of the Company s development program and its transition to attaining profitable operations is dependent upon obtaining additional financing adequate to fulfill its research and development activities and achieving a level of revenue adequate to support its cost structure. The Company believes that it can effectively manage its working capital to fund operations through December 2007; however, the Company does not anticipate having significant commercial operations until 2008, if at all; therefore, it is actively seeking additional debt or equity financing until it becomes cash flow positive. There can be no assurances that there will be adequate financing available to the Company and the consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

Reclassifications

Certain prior period expenses have been reclassified to conform to the current period presentation. These expense reclassifications primarily relate to properly classifying facility costs, quality assurance costs and share-based compensation expenses.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and CryoCor GmbH. All intercompany accounts and transactions have been eliminated in consolidation.

Foreign Currency Translation and Transactions

The financial statements of CryoCor GmbH are measured using the euro as the functional currency. For purposes of consolidation, the assets and liabilities of this subsidiary are translated at the rate of exchange at the balance sheet date. Income and expense items are translated at the average daily rate of exchange during the reporting period. Resulting measurement gains or losses are recognized as a component of other comprehensive income. With the exception of long-term advances from CryoCor, which are denominated in United States dollars and are considered long-term investments in nature, transactions denominated in currencies other than the

Table of Contents

CryoCor, Inc.

Notes to Consolidated Financial Statements (Continued)

local currency are recorded based on exchange rates at the time such transactions arise. Subsequent changes in exchange rates result in transaction gains and losses, which are reflected in income as unrealized (based on period-end translations) or realized upon settlement of the transaction. Transaction gains or losses were not material for the years ended December 31, 2006, 2005 and 2004.

Use of Estimates

The preparation of financial statements in conformity with United States generally accepted accounting principles requires management to make estimates and assumptions that affect the amount reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Impairment of Long-Lived Assets

In accordance with Financial Accounting Standard Board (FASB) Statement of Financial Accounting Standard (SFAS) No. 144, *Accounting for the Impairment of Disposable Long-Lived Assets*, the Company will record impairment losses on long-lived assets used in operations when events and circumstances indicate that assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. While the Company s current and historical operating losses and cash flows are indicators of impairment, the Company believes the future cash flows to be received support the carrying value of its long-lived assets and accordingly, the Company has not recognized any impairment losses through December 31, 2006.

Revenue Recognition

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

The Company has three principal products that can be sold to customers, specifically the console that generates the cryoenergy, a disposable catheter that delivers the cryoenergy to the target site, and a sheath that helps position the catheter. While the Company may sell consoles in the future, its current revenues are generated by the sales of catheters and sheaths, with catheters comprising approximately 95%, 93% and 94% of the 2006, 2005 and 2004 revenues, respectively. Currently, the Company s customers are solely European distributors who sell its products to European hospitals.

Historically, customers have had the right to return products until one month following expiration of the product, which has been six months after its production. Effective October 1, 2006, the catheter and sheath products now expire one year and two years after production, respectively. Therefore, the Company modified its return policy such that the Company will no longer grant a right to return products upon expiration of their product lives. As the Company has had limited sales of its products, it currently recognizes revenues when the customer has paid for the product and the right of return, if any, has expired.

The Company s current European customers do not typically purchase consoles and the Company s current business practice in Europe is to loan consoles free of charge to medical centers to stimulate sales of disposable

Table of Contents

CryoCor, Inc.

Notes to Consolidated Financial Statements (Continued)

products. The Company does not intend to reclaim the consoles, however, the Company retains the right to do so in the event it becomes dissatisfied with the medical center s use of the console. The Company has not modified the pricing of its disposable catheters to recover the cost of its consoles. Therefore, there is no revenue attributable to its consoles and, accordingly, the consoles are expensed upon shipment to the customer. In the event the Company elects to sell consoles in the future, the Company does not intend to offer a right of return on the consoles.

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

Research and Development

Research and development expenses primarily consist of costs incurred to further the Company s research and development activities and include salaries and related employee benefits, including non-cash share-based compensation, costs associated with clinical trials, pre-clinical activities, regulatory activities, research-related overhead expenses, fees paid to external service providers and fees paid under contracts with research organizations, which conduct certain research and development activities on behalf of the Company. Research and development costs are expensed as incurred.

Clinical Trial Expenses

Clinical trial costs are a component of research and development expenses and include fees paid to participating hospitals and other service providers which conduct clinical trial activities with patients on behalf of the Company. The various costs of the trial are contractually based on the nature of the service and the Company accrues the costs as the services to the patient are provided.

Inventories

Inventories are carried at the lower of cost or market using the first-in, first-out method. The Company began capitalizing inventory costs associated with the manufacture of medical equipment after receiving European regulatory approval to initiate the commercial sale of the Company s products in 2002. Costs capitalized include raw materials and subcontract conversion costs associated with the manufacture and assembly of the Company s medical products.

Property and Equipment

Property and equipment are stated at cost. Depreciation and amortization of the Company s assets are calculated using the straight-line method over an estimated useful life ranging from three to five years, or the lease term, as appropriate. Leasehold improvements are amortized over the estimated useful life or the lease term, whichever is shorter.

Share-Based Payments

Adoption of SFAS 123(R)

Effective January 1, 2006, the Company adopted the fair value recognition provisions of the SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)) as interpreted by the SEC s SAB No. 107 (SAB 107),

Table of Contents

CryoCor, Inc.

Notes to Consolidated Financial Statements (Continued)

using the prospective method and the modified prospective method. Therefore, the Company did not restate its financial results for prior periods. In accordance with SFAS 123(R), the Company utilized the prospective method for stock options granted prior to its initial public offering as the Company had used the minimum value method of measuring the fair value of these options for pro forma disclosure purposes under SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123). Therefore, unless modified in the future, these options are excluded from the adoption of SFAS 123(R). The Company utilized the modified prospective method for stock options granted subsequent to its initial public offering as the Company had used the fair-value-based method of measuring the fair value of these options for pro forma disclosure purposes under SFAS 123. Under these transition methods, compensation cost recognized during the year ended December 31, 2006 included the following: (a) share-based compensation cost associated with options granted prior to the Company s initial public offering with exercise prices less than the deemed fair value of the common stock at the date of grant, (b) compensation cost related to any share-based payments granted subsequent to the date of the Company s initial public offering through, but not vested as of, December 31, 2005, and (c) compensation cost for any share-based payments granted subsequent to December 31, 2005, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R).

During 2004 and the first half of 2005, prior to the completion of the Company s initial public offering, 1,194,366 stock options were granted to employees at exercise prices that were below the deemed fair value of the common stock on the date of grant. Accordingly, deferred stock compensation was recorded into stockholders equity during 2004 and 2005 in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations (APB 25). The deferred stock compensation was being amortized on a straight-line basis over the vesting period of the related awards, which is generally four years. During the years ended December 31, 2005 and 2004, amortization of deferred stock compensation was $2.0 million and $622,000, respectively. In accordance with SFAS 123(R), the Company eliminated the remaining $5.0 million balance of deferred compensation against paid in capital on the date of adoption of SFAS 123(R) but, as noted above, continues to recognize the related compensation cost in the statement of operations.

Share-Based Compensation Costs under FAS123(R) for the Year Ended December 31, 2006

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

	Year ended December 31, 2006
Share-based employee compensation costs included in:	
Cost of sales	$ 400
Research and development	492
Selling, general, and administrative	1,378
Total share-based employee compensation costs	2,270
Income tax benefit recognized	
Impact on net loss	$ 2,270

As a result of adopting SFAS 123(R), we recognized share-based employee compensation expense of $510,000 during the year ended December 31, 2006 in addition to $1.8 million in compensation expense recorded as required under APB 25. Both of these amounts are included in the table above.

Table of Contents

CryoCor, Inc.

Notes to Consolidated Financial Statements (Continued)

The amount of share-based compensation associated with the cost of production is not significant; therefore the Company did not capitalize any share-based compensation cost as part of inventory during the year ended December 31, 2006 or for any prior periods.

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

Pro Forma Information under FAS123 for the Years Ended December 31, 2005 and 2004

Prior to January 1, 2006, the Company accounted for its share-based compensation plans under the recognition and measurement provisions of APB 25, as permitted by SFAS 123, as amended by SFAS 148, *Accounting for Stock-Based Compensation*. Prior to the adoption of SFAS 123(R), the Company provided pro forma net loss and pro forma net loss per common share disclosures for share-based awards, as if the fair-value-based method defined in SFAS 123 had been applied. The table below illustrates the pro forma effect on net loss and net loss per share attributable to common stockholders if the Company had applied the fair value provisions of SFAS 123 to options granted under its share-based employee compensation arrangements during the year ended December 31, 2005 (in thousands, except per share amounts):

	Year ended December 31, 2005
Net loss attributable to common stockholders, as reported	$ (19,860)
Add: Share-based employee compensation expense included in loss from operations	1,954
Deduct: Share-based employee compensation expense determined under fair value method	(31)
Pro forma net loss attributable to common stockholders	$ (17,937)
Basic and diluted net loss per share attributable to common stockholders	$ (3.96)
Pro forma basic and diluted net loss per share attributable to common stockholders	$ (3.58)

For purposes of this pro forma disclosure, the Company estimated the value of the stock options using the Black-Scholes option valuation model and amortized that value to expense over the stock options vesting periods. The Company allocated this fair value to the pro forma compensation expense using the straight-line attribution method. Per the requirements of SFAS 123(R), the deduction of share-based compensation expense in the above table excludes all stock option grants historically valued using the minimum value method. Therefore, the table above does not include any information related to 2004 or the first half of 2005, as all options granted prior to the Company s July 2005 initial public offering were valued using the minimum value method.

Valuation of Stock Option Awards

Prior to the Company s initial public offering, the fair value for each option grant was determined using the minimum value method. Since the completion of the initial public offering in July 2005, the fair value of each option award is estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following table. Expected volatilities are based on historical volatility of the Company s stock as well as the stock of comparable medical device companies. As permitted by SAB 107, the Company utilized the shortcut approach to estimate the stock options expected term, which represents the period of time that options are expected to be outstanding. The Company utilized this approach as it believes its historical share option exercise experience does not provide a reasonable basis upon which to estimate an expected term. The

Table of Contents

CryoCor, Inc.

Notes to Consolidated Financial Statements (Continued)

risk-free interest rate for the expected term of the option is based on the United States Treasury yield curve in effect at the time of grant. No dividend yield was assumed as the Company has not paid dividends to date and has no intention to do so in the near future.

As share-based compensation expense recognized in the financial statements under SFAS 123(R) is based on awards that are ultimately expected to vest, it is reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated to be 4% for stock options granted for 2006 based upon historical forfeitures.

	Years ended December 31,		
	2006	2005	2004
Expected volatility	78%	0% 70%	0%
Expected term	5.72 years	6 years	6 years
Risk-free interest rate	4.75%	3.52%	3.25%
Expected dividends	0%	0%	0%

Comprehensive Loss

Comprehensive income is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources, including foreign currency translation adjustments and unrealized gains and losses on marketable securities. The Company presents comprehensive income in its consolidated statements of stockholders equity. Comprehensive loss does not have an impact on the Company s results of operations.

Income Taxes

In accordance with SFAS No. 109, *Accounting for Income Taxes,* a deferred tax asset or liability is determined based on the difference between the financial statement and tax basis of assets and liabilities as measured by the enacted tax rates that will be in effect when these differences reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized.

Fair Value of Financial Instruments

Financial instruments, including cash and cash equivalents, accounts payable and accrued liabilities are carried at cost, which management believes approximates fair value given their short-term nature. Based on the borrowing rates currently available to the Company for loans with similar terms, management believes the fair value of the long-term debt approximates its carrying value.

Recently Issued Accounting Standards

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109* (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing the recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006 and is required to be adopted by the Company in 2007. The Company does not expect the adoption of FIN 48 to have a material impact on its consolidated results of operations and financial condition.

Table of Contents

CryoCor, Inc.

Notes to Consolidated Financial Statements (Continued)

Note 2. Net Loss per Common Share

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

	Years ended December 31,		
	2006	2005	2004
	(in thousands, except per share amounts)		
Historical			
Numerator:			
Net loss attributable to common stockholders	$ (15,052)	$ (19,860)	$ (20,315)
Denominator:			
Weighted-average common shares outstanding	10,784	5,090	26
Weighted-average unvested common shares subject to repurchase	(11)	(80)	
Denominator for basic and diluted net loss per share attributable to common stockholders	10,773	5,010	26
Basic and diluted net loss per share attributable to common stockholders	$ (1.40)	$ (3.96)	$ (769.77)
Historical outstanding anti-dilutive securities not included in diluted net loss per share attributable to common stockholders calculation			
Redeemable convertible preferred stock (1)			4,892
Convertible preferred stock (1)			1,566
Options to purchase common stock	1,329	1,086	1,159
Warrants to purchase common and convertible preferred stock	83	83	166
	1,412	1,169	7,783

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

Note 3. Balance Sheet Information

Cash and Cash Equivalents

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

Investment Securities

Investment securities generally consist of high-grade auction rate securities, United States government debt securities, corporate debt securities and asset-backed securities. The Company classifies all securities as

Table of Contents

CryoCor, Inc.

Notes to Consolidated Financial Statements (Continued)

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

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

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

	December 31, 2006				December 31, 2005			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Corporate debt securities	12,735	6		12,741	15,924		(48)	15,876
Asset-backed securities	3,238			3,238				
U.S. government securities					4,495		(8)	4,487
	$ 15,973	$ 6	$	$ 15,979	$ 20,419	$	$ (56)	$ 20,363

Inventories

Inventories consist of the following (in thousands):

	December 31,	
	2006	2005
Raw materials	$ 612	$ 504
Work in process	38	94
Finished goods	208	170
	858	768
Reserves for excess and obsolete inventory	(38)	(50)
Inventory, net	$ 820	$ 718

At December 31, 2006, the Company had purchase commitments outstanding totaling approximately $29,000 for console materials, $69,000 in deposits on console inventory components, and $518,000 in console inventory which is recorded within inventory on our balance sheet. This total inventory represents approximately nine consoles in finished goods, components to build an additional ten complete consoles, and components that could be used in the production of additional consoles. These materials are not expected to become obsolete in the time period anticipated for commercialization. At December 31, 2006, the Company had disposables inventory totaling $302,000, of which $273,000 is raw materials. This inventory level represents approximately 1,100 finished catheters. The Company anticipates that the existing inventory levels,

including the open purchase

Table of Contents

CryoCor, Inc.

Notes to Consolidated Financial Statements (Continued)

commitments, will be needed in either 2007 or 2008 to the extent we are able to commercialize our products in the United States.

Property and Equipment

Property and equipment consist of the following (in thousands):

	December 31,	
	2006	2005
Manufacturing and laboratory equipment	$ 1,080	$ 1,022
Computers and software	835	792
Office furniture and equipment	562	535
Leasehold improvements	441	440
	2,918	2,789
Less accumulated depreciation and amortization	(2,308)	(2,109)
	$ 610	$ 680

Depreciation and amortization expense from operations related to property and equipment for the years ended December 31, 2006, 2005 and 2004 was $295,000, $489,000 and $532,000, respectively.

Restructuring Accrual

The Company has recorded restructuring charges of approximately $252,000 in connection with the closing of CryoCor GmbH as of December 31, 2006 and $90,000 remains accrued on the balance sheet at that date, primarily due to payments owed on the remaining term of the facility lease, which will run through June 2008. The Company has not incurred any additional restructuring costs in connection with the closing of CryoCor GmbH subsequent to June 30, 2006.

In January 2006, the Company received a non-approvable letter from the FDA related to its application for premarket approval (PMA) for the treatment of atrial flutter, a cardiac arrhythmia. As a result of that letter, the Company restructured its operations in early March 2006 whereby it reduced its staffing levels to reduce its monthly cash requirements. As of December 31, 2006, the Company had recorded severance expenses of $280,000 and sales and marketing contract termination expenses of $50,000 associated with the restructuring, all of which had been paid at that date. The Company s San Diego facilities were not impacted by the restructuring plan and all restructuring activities were substantially completed as of July 2006. In November 2006, after an analysis of the Company s clinical data and discussions with the FDA, the Company s amended its PMA which the FDA is currently reviewing.

Note 4. Commitments and Contingencies

Leases

The Company leases its facilities under a non-cancelable operating lease, which expires during 2008. The lease requires the Company to pay for all maintenance, insurance and property taxes. Under the terms of the Company s facility lease, the Company was required to execute a letter of credit in favor of the landlord for $100,000. The restricted cash of $100,000 that collateralizes the letter of credit is included in Other Assets on the balance sheet.

Table of Contents

CryoCor, Inc.

Notes to Consolidated Financial Statements (Continued)

The Company historically leased certain equipment under capital lease obligations. In July 2001, the Company executed a lease line of $850,000 with a financial institution and issued a warrant to purchase 218 shares of common stock. In May 2002, the Company issued an additional warrant to purchase 352 shares of common stock, in consideration with extension of the lease line to a total of $1.5 million. The lease line was intended to fund equipment acquisitions and leasehold improvements. The Company did not finance any equipment or leasehold improvements during 2006 and the capital leases have all been paid off as of December 31, 2006.

Annual future minimum obligations for operating leases as of December 31, 2006 are as follows (in thousands):

2007	392
2008	284
2009	
2010	
2011 and thereafter	
Total minimum lease payments	$ 676

Rent expense was $422,000, $398,000 and $411,000 for the years ended December 31, 2006, 2005 and 2004, respectively.

Long-Term and Short-Term Debt

In August 2003, the Company executed a Term Loan Agreement (the term loan) for $3.0 million with a financial institution and issued a warrant to purchase 14,633 shares of common stock (See Note 5).

In March 2005, the Company entered into an agreement whereby it borrowed $7.0 million from a financial institution (the facility). As part of this transaction, the Company paid off its existing term loan which had an outstanding balance of $1.8 million at the time of the pay off. The facility places restrictive covenants on the Company s operations, which preclude the Company from incurring new debt or placing liens on its assets, disposing of property, making dividend payments or distributions to stockholders, or entering into transactions that would result in a change of control. The facility bears interest at a rate of 11.25% per annum and requires monthly interest-only payments through June 2007, at which time all remaining principal is due and payable. In conjunction with the facility, the Company issued two warrants to purchase a total of 68,288 shares of common stock. The fair value of the warrants was $657,000 based upon an estimated fair value upon the date of grant of $13.43 per common share, an estimated life of six years, a volatility rate of 70% and a risk free interest rate of 4.34%. The fair value of the warrant was recorded as a discount to the facility and is being amortized to interest expense on a straight-line basis over the term of the loan. The remaining unamortized fair value of the warrants is $143,000 at December 31, 2006. The warrants are exercisable through 2015.

Long-term and short-term debt consisted of the following at December 31 (in thousands):

	2006	2005
Long-term debt	$	$ 7,000
Short-term debt	7,000	
Less: debt discount	(143)	(430)
	$ 6,857	$ 6,570

Table of Contents

CryoCor, Inc.

Notes to Consolidated Financial Statements (Continued)

License Agreement

In August 2000, the Company executed an exclusive, irrevocable, perpetual, worldwide, non-transferable, royalty-free, fully-paid up license agreement with CryoGen, Inc. (CryoGen) for the exclusive use of their intellectual property in the field of cardiac arrhythmias. The Company has the right to sublicense, make, have made, import, use, have used, offer to sell, sell or have sold licensed products and perform and have performed processes under certain CryoGen intellectual property rights, enhancements and joint enhancement interest, solely in the CryoCor field. The license expires concurrent with the last patent to expire.

Note 5. Stockholders Equity

Initial Public Offering

In July 2005, 3,709,090 shares of common stock were sold at $11.00 per share during the Company s initial public offering.

Preferred Stock

In conjunction with the initial public offering, all outstanding shares of preferred stock were converted to common stock. Prior to the conversion of the preferred stock to common stock, the Company recorded accretion to the redemption value of the preferred stock and cumulative dividends on certain series of preferred stock. In 2005 and 2004, the Company recorded $2,764,000 and $4,549,000 for dividends and accretion, respectively.

Common Stock

During November 2004, 16,425 shares of common stock were issued to a former executive in connection with a separation agreement in exchange for $0.62 per share. Compensation expense of $186,000 was recorded for the estimated fair value of shares issued less purchase price paid on the date of issuance.

During December 2004, 8,709 shares of common stock were issued to a consultant for services rendered. Compensation expense of $117,000 was recorded for the estimated fair value of shares issued on the date of issuance.

Warrants

In July 2001 and May 2002, the Company issued two warrants to purchase 218 and 352 shares of common stock, respectively, to a financial institution (see Note 4).

During 2003, upon executing the term loan agreement with a financial institution (the Holder), the Company issued a warrant to purchase 14,633 shares of common stock at $6.15 per share with an expiration date of August 4, 2013. The Holder of this warrant has the right (the Put Right) to require the Company to purchase the warrant from the Holder for total consideration of $90,000. The Holder may only exercise the Put Right during the first to occur of the following periods on or after January 15, 2005: (i) the twenty day period ending on the closing of an acquisition, or (ii) the twenty day period ending on the liquidation, dissolution or winding up of the Company.

In March 2005, the Company issued a warrant to purchase 68,288 shares of common stock (see Note 4).

As of December 31, 2006, the Company had outstanding warrants to purchase 83,491 shares of common stock.

Table of Contents

CryoCor, Inc.

Notes to Consolidated Financial Statements (Continued)

Note 6. Employee and Non-employee Stock Benefit Plans

Equity Compensation Plans

The Company currently has three active share-based compensation plans (collectively the Plans): the 2000 Stock Option Plan, the 2005 Equity Incentive Plan and the Non-Employee Director Plan. As of December 31, 2006, 1,328,725 shares of the Company s common stock were reserved for issuance upon exercise of options granted by the Company and 150,275 shares were available for future grant for issuance under the Plans. The Plans provide for the grant of incentive and non-statutory stock options to employees, non-employee directors and outside consultants.

The exercise price of incentive stock options must equal at least the fair market value on the date of grant and the exercise price of non-statutory stock options may be not less than 85% of the fair market value on the date of grant. Stock options granted under the Plans expire no later than ten years from the date of grant. Stock options generally vest over a period of four years. Unvested common shares obtained through early exercise of stock options are subject to repurchase by the Company at the original issue price. Since its initial public offering, the Company no longer permits the early exercise of stock options. During the years ended December 31, 2006 and 2005, 5,065 shares and 2,966 shares have been repurchased by the Company, respectively. At December 31, 2006 and 2005, 3,668 and 64,801 shares were subject to repurchase, respectively.

Information under FAS123(R) for the Year Ended December 31, 2006

A summary of stock options under the Plans as of December 31, 2006 and activity during the year then ended are as follows:

	Shares	Weighted-average exercise price	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Options outstanding at December 31, 2005	1,085,914	$ 1.32		
Options granted	866,176	$ 2.73		
Options exercised	(381,820)	$ 0.63		
Options forfeited	(241,545)	$ 1.87		
Options outstanding at December 31, 2006	1,328,725	$ 2.33	8.57	$ 1,086
Options vested and expected to vest at December 31, 2006	1,251,872	$ 2.33	8.55	$ 1,037
Options vested and exercisable at December 31, 2006	346,155	$ 2.29	7.72	$ 427

The weighted-average grant-date fair value of stock options granted during the year ended December 31, 2006 was $1.89. Aggregate intrinsic value is the sum of the amounts by which the quoted market price of the Company s stock exceeded the exercise price of the options at December 31, 2006 (in-the-money options). The total intrinsic value of options exercised during the year ended December 31, 2006 was $868,000.

As of December 31, 2006, $3.2 million of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under the Plans is expected to be recognized over a weighted-average period of 1.9 years.

Cash proceeds from the exercise of stock options were $240,000 and $147,000 for the years ended December 31, 2006 and 2005, respectively. Because of the Company s net operating losses, the Company did not

Table of Contents

CryoCor, Inc.

Notes to Consolidated Financial Statements (Continued)

realize any tax benefits for the tax deductions from share-based payment arrangements during the years ended December 31, 2006 and 2005.

Information under FAS123 for the Years Ended December 31, 2005 and 2004

A summary of activity under the Plans is as follows:

		Options Outstanding and Exercisable	
	Shares available	Number of shares	Weighted-average exercise price
Balance at December 31, 2003	1,041,973	203,548	$ 2.74
Granted	(982,144)	982,144	$ 0.62
Exercised		(3,945)	$ 0.71
Canceled	22,872	(22,872)	$ 3.00
Balance at December 31, 2004	82,701	1,158,875	$ 0.94
Authorized	528,224		
Granted	(337,791)	337,791	$ 1.83
Exercised		(236,331)	$ 0.62
Repurchased	2,966		$ 0.62
Canceled	174,421	(174,421)	$ 0.74
Balance at December 31, 2005	450,521	1,085,914	$ 1.32

The weighted-average fair value of options granted during 2005 and 2004 was $11.87 and $6.22 per share, respectively. At December 31, 2005 and 2004, the weighted-average remaining contractual life of outstanding options was 8.59 years and 9.36 years, respectively.

Stock Options Granted to Non-employees

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and Emerging Issues Task Force Issue (EITF) No. 96-18, *Accounting for Equity Instruments that Are Issued to other than Employees for Acquiring, or in conjunction with Selling Goods, or Services* (EITF 96-18) which require that such equity instruments are recorded at their fair value on the measurement date. The measurement of share-based compensation is subject to periodic adjustment as the underlying equity instruments vest. Non-employee stock-based compensation charges are amortized over the vesting period on a straight-line basis. The following table illustrates the weighted-average assumptions for the Black-Scholes valuation model used in determining the fair value of options granted to non-employees:

	Years Ended December 31,		
	2006	2005	2004
Expected volatility	81%	70%	70%
Expected term	10 years	10 years	10 years
Risk-free interest rate	4.51%	4.34%	4.34%
Expected dividends	0%	0%	0%

During the years ended December 31, 2005 and 2004, the Company granted options to purchase 4,838 and 50,258 shares, respectively, of common stock to consultants at a weighted-average exercise price of $0.62 per share. No options were granted to non-employees during 2006; however, three employees converted to

Table of Contents

CryoCor, Inc.

Notes to Consolidated Financial Statements (Continued)

consultants during the year. As part of their consultancy contracts, some of their option grants continued to vest and were therefore treated under EITF 96-18 subsequent to employment termination. All options generally vest over a four-year period and have a ten year life. The related stock-based compensation expense related to non-employees was $56,000, $130,000, and $83,000 for the years ended December 31, 2006, 2005 and 2004, respectively.

Employee Stock Purchase Plan

The Company has an Employee Stock Purchase Plan (ESPP) for all eligible employees to purchase its common stock through payroll deductions at 85% of the lower of the stock s fair market value on the first day of the offering or the last day of the purchase period. Purchases are limited to 15% of each employee s compensation. In addition, the Board of Directors has specified that the maximum number of shares of common stock that may be purchased by any participant on any purchase date during any offering is 483 shares. As of December 31, 2006, the Company had issued 9,612 shares over the life of the ESPP at an average price of $2.18. At December 31, 2006, 151,678 shares were reserved for future issuance under the ESPP.

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

	Year ended December 31, 2006	Year ended December 31, 2005
Expected volatility	78%	70%
Expected term	0.5 2 years	1.41 years
Risk-free interest rate	2.0% 5.1%	2.5%
Expected dividends	0%	0%

Cash received from ESPP contributions for the year ended December 31, 2006 and 2005 was $18,000 and $9,000, respectively. Because of the Company s net operating losses, the Company did not realize any tax benefits for the tax deductions from share-based payment arrangements during the years ended December 31, 2006 and 2005.

Table of Contents

CryoCor, Inc.

Notes to Consolidated Financial Statements (Continued)

Note 7. Income Taxes

Significant components of the Company s deferred tax assets as of December 31, 2006 and 2005 are shown below. Valuation allowances of $29,155,000 and $23,648,000 were established at December 31, 2006 and 2005, respectively, as realization of such assets is uncertain.

	December 31,	
	2006	2005
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 17,798	$ 13,879
Research and development credits	2,673	2,368
Capitalized research and development	8,072	7,007
Other, net	612	394
Total deferred tax assets	29,155	23,648
Valuation allowance	(29,155)	(23,648)
Net deferred tax assets	$	$

At December 31, 2006, the Company had federal and California tax net operating loss carryforwards of approximately $46.4 million and $27.6 million, respectively. The federal and California tax loss carryforwards will begin expiring in 2020 and 2012, respectively, unless previously utilized. The Company also had federal and California research and development tax credit carryforwards of approximately $1.7 million and $1.5 million, respectively. The federal research and development credit will begin expiring in 2020, unless previously utilized.

Pursuant to Internal Revenue Code Sections 382 and 383, use of the Company s net operating loss and credit carryforwards may be limited if a cumulative change in ownership of more than 50% occurs within a three-year period.

Note 8. 401(k) Defined Contribution Plan

During 2000, the Company adopted a 401(k) defined contribution plan (the 401(k) Plan) that covers substantially all full time employees, as defined, who meet certain age requirements. Employees may contribute up to a maximum of 25% of their annual compensation (subject to a maximum limit imposed by federal tax law). The Company may make qualified non-elective contributions to the Plan. The amount of such contribution for each plan year shall be an amount determined by the Company. The allocation of qualified non-elective contributions shall be made to the accounts of non-highly compensated participants only. Employer contributions begin vesting upon completion of two years of service and become fully vested upon six years of service. As of December 31, 2006, the Company had made no contributions to the 401(k) Plan.

Table of Contents

CryoCor, Inc.

Notes to Consolidated Financial Statements (Continued)

Note 9. Quarterly Financial Information (unaudited)

Summarized quarterly results of operations for the years ended December 31, 2006 and 2005 are as follows (in thousands, except per share amounts):

	Year ended December 31, 2006			
	First	Second	Third	Fourth
Product sales	$ 113	$ 159	$ 214	$ 54
Cost of sales	763	547	542	616
Research and development expenses	1,531	1,395	1,369	1,540
Net loss attributable to common stockholders	(4,271)	(3,570)	(3,363)	(3,848)
Basic and diluted net loss per common share	(0.40)	(0.33)	(0.31)	(0.36)

	Year ended December 31, 2005			
	First	Second	Third	Fourth
Product sales	$ 329	$ 201	$ 152	$ 161
Cost of sales	723	874	728	776
Research and development expenses	1,684	2,131	1,677	2,044
Net loss attributable to common stockholders	(5,027)	(6,129)	(4,092)	(4,612)
Basic and diluted net loss per common share	(71.12)	(41.27)	(0.45)	(0.44)