CRYOCOR INC
Form 10-K
March 24, 2006
**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, 2005**

**OR**

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

**Commission file number 000-51410**

# CRYOCOR, INC.

**(Exact Name of Registrant as Specified in its Charter)**

| Delaware | 33-0922667 |
|---|---|
| (State 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:**

**None.**

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

**Common Stock, $0.001 par value**

**(Title of Class)**

---

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. x

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

As of March 1, 2006, the aggregate market value of the registrant s voting and nonvoting common stock held by non-affiliates of the registrant was approximately $8,723,285, based on the closing price of CryoCor s common stock on the Nasdaq National Market on March 1, 2006, of $2.50 per share. The registrant has elected to use March 1, 2006 as the calculation date because the registrant was a privately held concern on June 30, 2005 (the last business date of the registrant s second fiscal quarter).

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. YES x NO ¨

The number of shares of registrant s common stock outstanding on March 1, 2006 was 10,689,868.

**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 2006 Annual Meeting of Stockholders to be held on May 3, 2006 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, 2005.

**Table of Contents**

**CRYOCOR, INC.**

**ANNUAL REPORT ON FORM 10-K**

**For the Year Ended December 31, 2005**

**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 and ability to amend our PMA for AFL, statements related our restructuring, 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 add additional clinical sites for and complete enrollment in our AF pivotal trial and submit a PMA for AF, risks involved with our estimates of the size, make-up and costs involved with the Company s restructuring, risks involved with our ability to reduce our cash burn, risks associated with our ability to amend our PMA for AFL and 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, risks associated with our ability to obtain additional financing as necessary, and the other risks and uncertainties identified in the section of this Form 10-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 control and maintain 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 can lead to, and often coexists with, AF. As more fully discussed in Clinical Status in the United States page 15, in January 2006, we were notified by the United States Food and Drug Administration, or FDA, that our Premarket Approval, or PMA, for the treatment of AFL was not approvable as submitted at present. The FDA stated that the data presented did not meet the FDA s chronic efficacy criteria. We are evaluating whether we should amend our PMA for the treatment of AFL in 2006 based on a different analysis of chronic efficacy. There can be no assurance that we will decide to amend our

Table of Contents

PMA for the treatment of AFL, or if we do, that the FDA will accept our analysis or approve the PMA. We believe, and the FDA has informally indicated to us, that its decision not to approve our cryoablation system for the treatment of AFL based on the data we submitted does not impact our ongoing AF pivotal trial.

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 normal population. 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 and AFL 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, or they lack efficacy.

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

Table of Contents

***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 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.

***Heart Rate and Rhythm Disorders***

Heart rate and rhythm disorders, called cardiac arrhythmias, occur when abnormal heart tissue causes a disruption in the heart s normal electrical activation sequence that results in inappropriate generation or conduction of electrical impulses. This abnormal electrical activity can result in a lack of coordination of the pumping of blood between chambers of the heart. Arrhythmias can be classified based on whether the abnormal heart tissue drives the start of the arrhythmia, known as initiation, or abnormal tissue allows the arrhythmia to continue, known as perpetuation, and by whether the heart rate is slower or faster than normal. Bradycardia describes a slow heartbeat. 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.

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.

*Simple or complex*. Simple arrhythmias involve a limited area or fiber tract of the heart where the electrical disturbance occurs, while complex arrhythmias involve more heart tissue than simple arrhythmias.

Table of Contents

*Disorganized or organized*. Disorganized arrhythmias occur when the electrical disturbance follows an irregular and unpredictable pathway in the heart, while in organized arrhythmias the electrical disturbance follows a distinct pathway.

***Supraventricular Tachycardias***

Simple SVTs include Atrioventricular Nodal Reentrant Tachycardia, known as AVNRT, and Wolff-Parkinson White syndrome, known as WPW. The most common complex SVTs are AF and AFL. Complex SVTs have a higher incidence, or occur more frequently, and have a higher prevalence, or exist in the population to a greater extent, than simple SVTs. Complex SVTs are more difficult to treat than simple SVTs.

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, 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 some other medications.

*Atrial Fibrillation* AF is the most prevalent SVT. It is a 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. As AF progresses, individual episodes tend to increase in frequency, duration and severity as follows:

*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 a complex, 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.

**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.

Table of Contents

***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 complex 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 complex SVTs 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 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 AF and AFL and their symptoms are heart rhythm control drugs, heart rate control drugs and blood thinners. Rhythm control drugs can be used to either prevent

Table of Contents

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 use 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, reporting 23.8% mortality at five years for individuals on rhythm control drugs versus 21.3% for individuals on rate control drugs.

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 serious 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 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,

Table of Contents

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 kill the target tissue and create a lesion. 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 and other complex arrhythmias, 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 and these have only been approved for simple arrhythmias.

*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 simple arrhythmias and as a secondary treatment for other 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 simple 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 80% 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 will fail to obtain broad market adoption even if approved for this indication. While a September 1998 issue of the *New England Journal of Medicine* reported efficacy rates of 62% for the treatment of AF using RF ablation, various published studies have reported serious complications, including pulmonary vein stenosis, or narrowing of the pulmonary veins. A December 2003 issue of *Circulation* reported that pulmonary vein stenosis occurred in 15.6% of 608 consecutive patients treated for AF with RF ablation at five hospital centers. Complications associated with RF ablation are 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:

*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, or holes, through the atrial wall into the esophagus, which can cause potentially fatal excessive bleeding or infection;

Table of Contents

*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 that is serious and potentially fatal;

*Excessive bleeding.* Heat generated by the RF energy can perforate the heart wall and lead to excessive bleeding;

*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 creates lesions 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 complications associated 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, a simple cardiac arrhythmia. There is currently no cryoablation system available that is approved by the FDA for the treatment of complex arrhythmias, such as AF and AFL. In order to be able to treat complex 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 can become the new standard of care for the safe and effective treatment of AF and may provide clinical advantages in the treatment of AFL and other complex arrhythmias. As more fully discussed in Clinical Status in the United States page 15, our PMA for the treatment of AFL using our cryoablation system was not approved by the FDA. The FDA advised us that the data we submitted demonstrated that the cryoablation system s success rate for the treatment of AFL did not meet the FDA s chronic efficacy criteria. We are evaluating whether we should amend our PMA in 2006 based on a different analysis of chronic efficacy. We believe, and the FDA has informally indicated to us, that its decision not to approve our cryoablation system for the treatment of AFL based on the data we submitted does not impact our ongoing AF pivotal trial. 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, selectively 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.

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 50 medical centers, including approximately 30 medical centers in the United States where it has been used on approximately 350 subjects during our clinical trials, and approximately 20 medical centers in Europe, where it has been used on approximately 165 subjects during our clinical trials and approximately 1,000 patients. To date, we have not received any reports of esophageal fistulas, blood

Table of Contents

clots, stroke 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 complex arrhythmias, including 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 22 patients showed that 71% and 82% 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 efficacy 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 will not move from the intended lesion site during the ablation application, as is possible with heat-based ablation techniques. In addition, this adherence significantly reduces physician and patient exposure to X-ray radiation because it eliminates the need for extended fluoroscopy to monitor catheter tip position. Catheter tip-to-tissue adherence is a benefit frequently noted by physicians who use our cryoablation system.

*Familiar physician procedure.* Our cryoablation system employs catheter techniques and interfaces 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, thereby reducing or eliminating the need to sedate the patient. Pain is commonly reported by patients during RF ablation procedures, which is an important concern in Europe where general anesthesia or conscious sedation is typically not used during catheter-based procedures.

*Outpatient procedure.* Patients are typically treated with our cryoablation system on an outpatient basis. This abbreviates hospital stays, which may reduce or eliminate certain costs associated with more invasive surgical treatments.

**Our Strategy**

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

*Demonstrating the safety and efficacy of our cryoablation system through our clinical trials.* We believe our cryoablation system provides a safer and more effective treatment for AF than drug therapy, surgical ablation and RF or other heat-based ablation alternatives. 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. We completed enrollment and treatment of patients in our pivotal trial for AFL in November 2004, and submitted our PMA in July 2005. Our initial PMA submission for AFL was not approved by the FDA based on its analysis of chronic efficacy, and we are analyzing our clinical data to determine whether we can present chronic efficacy in a manner that is acceptable to the FDA. In AF, we are currently enrolling patients in a pivotal clinical trial and plan to submit a PMA in the second half of 2007.

*Commercializing our products through a direct sales force, a direct-to-consumer marketing effort, and third party distributors.* Within the United States, 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 of 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.

*Leveraging the influence of industry opinion leaders and major medical centers to accelerate physician 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. Under these collaborations, we plan to establish best practices and develop certification programs for these physicians. We also expect to continue 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. Medical technologies are often adopted first by leading United States medical centers, and then by European centers.

*Expanding our product line and acquiring complementary products.* We are currently developing our next generation cryoablation catheter, Quantum, that we believe will enable interventional cardiologists to adopt our cryoablation system to treat AF. We expect our Quantum catheter, once developed and if approved by the FDA, to enable physicians to perform AF cryoablation procedures in 1.5 hours or less, 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 allow 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 complex arrhythmias than competing cryoablation technologies.

Our cryoablation system operates by vaporizing, or 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, the boiling point of nitrous oxide. Our cryoablation system uses a microprocessor-controlled, two-stage cooling process. 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 sense 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.

***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

Table of Contents

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. It 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 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 of the generation of chilled -35° Celsius nitrous oxide near the patient enabling the efficient delivery of nitrous oxide 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. Two of our catheters are currently being tested in clinical trials. 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 a procedure. Our Quantum catheter is being designed to permit delivery of therapeutic cryoenergy pursuant to a 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 to 1.5 hours or less. We believe that these features would make our cryoablation system appeal commercially to physicians other than electrophysiologists, such as interventional cardiologists. We have performed substantial research in our laboratories that has enabled us to perform early testing of the Quantum catheter in animals. We intend to begin clinical use by the beginning of 2007.

**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

Table of Contents

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 to three 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 can be 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, through the septum, and into the left atrium. Multiple lesions are created in the back wall of 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 initiating in the pulmonary vein from reaching the atrial tissue. Some clinicians have modified the PVI approach to stop both the initiation of AF as well as to prevent the perpetuation of AF. This technique, referred to as anatomic ablation, 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, called the isthmus. The 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 narrow isthmus and cryoenergy is delivered. The catheter is then stepped across the narrow isthmus in short increments creating individual lesions at each point. These successive freezes create a lesion line along the narrow isthmus to block abnormal 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 and increased physician experience.

**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 efficacy 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

Table of Contents

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 may seek additional distributors to help us market our product more broadly in Germany, Belgium, the Netherlands and Italy, but our recent restructuring is expected to delay any commercial expansion in Europe and we may not sign any additional distribution agreements.

In the United States, our clinical strategy is to obtain FDA approval to market our cryoablation system for two separate indications, AF and AFL, by conducting two pivotal trials in parallel. As more fully discussed below, in January 2006, the FDA notified us that our PMA for the treatment of AFL using our cryoablation system was not approvable as submitted at present. The FDA advised us that the data we submitted demonstrated that the cryoablation system s success rate for the treatment of AFL did not meet the FDA s chronic efficacy criteria. We are evaluating whether we should amend our PMA in 2006 based on a different analysis of chronic efficacy. We believe, and the FDA has informally indicated to us, that its decision not to approve our cryoablation system for the treatment of AFL based on the data we submitted does not impact our ongoing AF pivotal trial.

***Clinical Status in the United States***

In July 2005, we submitted the final module of our PMA for AFL to the FDA, which included the safety and effectiveness results of our clinical trial. During 2005, our San Diego facility was inspected by the FDA, and we had routine discussions with the FDA about the information included in our PMA. In January 2006, the FDA advised us that the data we submitted did not meet the FDA s chronic efficacy requirements to permit the approval of our system for the treatment of AFL. We are further analyzing our clinical data and evaluating whether we should amend our PMA for AFL based on a different analysis of chronic efficacy. There can be no assurance that we will decide to amend our PMA for the treatment of AFL, or if we do, that the FDA will accept our analysis or approve the PMA.

We are continuing to enroll patients for our pivotal trial for AF, which enrolled the first patient in December 2004, and have enrolled 112 patients as of March 22, 2006. We currently have 21 clinical sites that are open for patient enrollment and do not expect to open additional centers. At our expected patient enrollment rate of between 7-10 patients per month, we believe we will complete enrollment in our AF pivotal trial in the second half of 2006, with an expected PMA submission to the FDA in the second half of 2007.

*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 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.

Table of Contents

Enrollment in this trial was completed in November 2004 and subjects were followed for six months following the ablation procedure. Preliminary safety and acute efficacy 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% |
| Acute Efficacy | 86.9% | 81.6% (lower) | 80% |

All of the investigator-reported safety results were reviewed by an independent body prior to inclusion in the PMA submission to the FDA. 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 letter received from the FDA in January 2006, in which the FDA computed a chronic efficacy that did not meet their requirements for approval, the FDA did not have any 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. The FDA did not accept our analysis of chronic efficacy. The FDA conducted its own analysis of chronic efficacy, and the FDA s analysis did not meet the required OPC. Accordingly, in a letter received in January 2006, the FDA indicated that our PMA submission did not demonstrate sufficient effectiveness to permit approval, and accordingly, we received a non-approvable letter from the FDA. We are evaluating our clinical data and depending on the outcome of our evaluation, may amend our PMA for AFL in 2006. There can be no assurance that we will amend our PMA for the treatment of AFL, or if we do, that it will be approved by the FDA.

*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. 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.

**Sales and Marketing**

In the United States, if we receive approval, we plan to market our cryoablation system through a specialized direct sales force or in combination with a marketing partner. Although there are approximately 2,000 electrophysiologists in the United States, we intend to focus on the 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. Over time, we intend to expand our sales force to service a broader group of potential customers, primarily interventional cardiologists. In support of these efforts, we intend to build patient awareness through direct-to-consumer marketing for AF and AFL. We also

Table of Contents

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. However, our recent restructuring is expected to delay our commercial expansion in Europe and we may never sign additional distribution agreements. In 2005, we decided to close our German operation, CryoCor GmbH, and to begin selling our products exclusively through distributors. Our current agreement with our distributor for the United Kingdom will continue until January 1, 2009 at which time it may be renewed for additional one year periods.

**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 simple SVTs. CryoCath is currently conducting feasibility studies in the United States for its catheter-based treatment of AF. We are not aware of any other competitors 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 prior to March 2007. St. Jude s acquisitions have predominantly focused on ultrasound as their ablation energy source. Ultrasound uses focused, high frequency sound waves to generate heat to ablate the tissue. 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. Finally, a number of companies, including Medtronic, Atricure, Boston Scientific and Guidant, which recently acquired AFx, 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.

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 and AFL. 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

Table of Contents

choice for AF and AFL. 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 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 2006 and 2007. If we receive approval for the treatment of either AF or AFL using our cryoablation system, we would 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 9001/EN 46001 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 8 consoles per year. We believe these production levels are sufficient to support our clinical trials and our anticipated commercial activity in Europe for 2006 and 2007.

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.

All 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

Table of Contents

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.

In April 2005, during our quality control testing of a lot of Model 1200 catheters, the predecessor catheter to our CryoBlator catheter, we identified several instances of inadequate seals in the joint where the articulation section is welded to the catheter shaft. We initiated an investigation to identify the source of the catheter integrity breaches in the Model 1200, but were not able to find a specific root cause. Accordingly, we were unable to guarantee that Model 1200 catheters previously released for use might not leak, and therefore initiated a voluntary recall in Europe of all of the remaining catheters from eight lots of our Model 1200 catheter. No Model 1200 catheters remain outstanding in Europe or the United States. We notified the FDA of the recall and informed them that we had withdrawn all Model 1200 catheters from use under our IDE. At the time of the discovery, we were phasing out the Model 1200 catheter and replacing it with our CryoBlator catheter, however the transition had not been completed and production of our CryoBlator catheter had not been increased adequately for United States trial use or European launch. As described in two previously filed modules of the PMA filing for AFL, our CryoBlator catheter contained modifications in its internal structural elements from the catheters that were used during the AFL pivotal trial. In February 2005, the FDA approved an IDE supplement to include our CryoBlator catheter in our ongoing AF pivotal clinical trial. While the FDA accepted these changes to the IDE, when the data from this trial are submitted with our AF PMA for marketing approval, the FDA may not allow us to pool the study results data from subjects treated with the two different models, or may cause us to enroll additional patients or could delay or deny our application for approval.

Our CryoBlator catheter, although similar in form and function to our Model 1200 catheter, is engineered differently at the joint where the potential for poor seals in the Model 1200 catheter occurred. Previous design testing of the CryoBlator catheter showed no catheter integrity breaches with associated gas leaks during normal product verification and validation. This earlier design testing was performed in February 2005 on CryoBlator product produced in late 2004. In part, as a result of the Model 1200 investigation, we conducted additional testing of our CryoBlator catheter in May 2005 to confirm that it met our product specifications. We have modified our product inspection with additional inspector training and enhanced criteria for acceptable radiofrequency welds of our CryoBlator catheter during production, based on the preliminary findings of our Model 1200 catheter product investigation. Because our CryoBlator catheter had engineering changes to its internal structural elements, we do not believe it has or will have the same potential issues that led to our voluntary recall of the Model 1200 catheter. However, we cannot assure you that our CryoBlator catheter will not experience similar problems as those experienced with the Model 1200 catheter, or other problems, or that our CryoBlator catheter will not be subject to a product recall in the future.

In 2005, we incurred costs of approximately $93,000, to recall our Model 1200 out of Europe and to withdraw the use of the Model 1200 from our IDE. These costs covered the return of the affected Model 1200 catheters, the costs to manufacture and issue replacement CryoBlator catheters and related shipping costs. Consistent with our revenue recognition policies, no revenue had been recognized related to any of the Model 1200 catheters that were returned.

**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

Table of Contents

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. 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

Table of Contents

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 annually 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 which may include our cryoabalation system. The scope of coverage and payment policies varies among third party 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.

Table of Contents

**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 seven people and focuses on product line extensions and modest 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 substantially reducing cryoablation procedure times. As a result of the restructuring more fully discussed in Employees and Consultants page 26, we reduced our research and development capabilities which will delay or impact our ability to enhance existing products and may delay our ability to develop new products. We have historically spent a significant portion of our capital resources on research and development, incurring $8.1 million in 2005, $7.6 million in 2004 and $6.4 million in 2003 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.

As of March 1, 2006, we held 11 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 11 issued United States patents we own expire between 2021 and 2023.

Table of Contents

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 combined RF/cryoablation, refrigerants which enable catheter tip temperatures below -90° Celsius, and the use of a balloon to anchor a 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

Table of Contents

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. 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, 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, CryoArm 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 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. We are also aware of statements attributed to

Table of Contents

employees of CryoCath which suggest that CryoCath may believe that aspects of our cryoablation system may be covered by one or more United States patents owned by CryoCath. 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 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;

Table of Contents

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***

In February 2006, we announced that we will be reducing our staff levels as part of a restructuring, and as of March 15, 2006, we had 46 full-time employees. After the restructuring is completed in June 2006, we expect to have 35 full-time employees, all of whom will be employed at-will. Of these employees, seven will be engaged in research and development, nine in manufacturing, 10 in clinical, regulatory affairs and quality assurance and nine in administration, finance, management, information systems, corporate development and human resources. Three of our employees have a Ph.D. degree and/or M.D. degree and are engaged in activities relating to research and development, manufacturing, clinical quality assurance and business development. 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, 2006:

| Name | Age | Position(s) |
|---|---|---|
| *Executive Officers and Directors* | | |
| Edward F. Brennan, Ph.D. | 54 | President and Chief Executive Officer and Director |
| Gregory J. Tibbitts | 38 | Vice President, Finance and Chief Financial Officer |
| Gregory M. Ayers, M.D., Ph.D. | 44 | Director |
| Kurt C. Wheeler[2][3] | 53 | Director |
| Robert Adelman, M.D.[2][3] | 43 | Director |
| David Cooney[1][2] | 36 | Director |
| Jerry C. Griffin, M.D.[1][3] | 61 | Director |
| Arda M. Minocherhomjee, Ph.D.[1][2] | 52 | 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. 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., and serves on the boards of directors 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.

*Gregory M. Ayers, M.D., Ph.D.* has served as a member of our board of directors since August 2000. From July 2002 to March 2006, Dr. Ayers served as our Chief Executive Officer. Dr. Ayers also served as our President from August 2000 to March 2005. From February 2000 to July 2002, Dr. Ayers was a venture partner with MPM Capital LLC, a venture capital firm that invests primarily in biotechnology and medical technology companies and which, together with its affiliates, is one of our principal stockholders. He also acted as our interim Chief Executive Officer during that time. Dr. Ayers also served as interim Chief Executive Officer of Hemosense, Inc., a company specializing in anticoagulant testing, from April 2001 to July 2002, and he is currently a member of its board of directors. From December 1998 to May 2004, Dr. Ayers was a consultant for numerous organizations and was Vice President, Clinical and Regulatory, of Corvascular, Inc., a surgical company, from January 1999 to May 2004. In April 1992, Dr. Ayers joined InControl, Inc., a medical device company that developed implantable atrial defibrillators, initially as a clinical scientist, and from September

Table of Contents

1996 to December 1998, he served as its Vice President of Clinical Affairs. Dr. Ayers has also served on several university committees. He is a fellow of the American College of Cardiology and holds 18 United States patents in the area of defibrillation, cardiac arrhythmia management and cardiac temperature control. Dr. Ayers received a B.S. and Ph.D. in Biomedical Engineering from Purdue University and an M.D. from Indiana University.

*Kurt C. Wheeler* has been a member of our board of directors since September 2000 when MPM Capital invested in the Company. Mr. Wheeler is a Managing Director at Clarus Ventures LLC, a company he co-founded in 2005. Since 1999, Mr. Wheeler has been a General Partner of MPM BioVentures II III funds. Prior to joining MPM in 1999, Mr. Wheeler was Chairman and CEO of InControl, Inc., a publicly traded medical company that designed, developed, and marketed implantable medical devices to treat irregular heart rhythms. In September 1998, Mr. Wheeler negotiated the sale of InControl to Guidant Corporation. He serves on the board of directors of Cardiac Dimensions, CryoCor, CHF Solutions, Hemosense, Inc., Intraluminal Therapeutics, Scout Medical, Xoft, Neuromed Pharmaceuticals and Somaxon Pharmaceuticals. Previously, he was on the board of Heartstream, which was acquired by Hewlett Packard. Prior to InControl, Mr. Wheeler was a principal in the life science group at the Mayfield Fund, a venture capital partnership. He has participated in the early stage development of several biotechnology companies including Sungene Technologies, Affymax NV and Cell Genesys. He began his professional career at Eli Lilly & Co. He holds a B.A. degree from Brigham Young University and an M.B.A degree from Northwestern University, where he serves on the Kellogg Alumni Advisory Board.

*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 Cooney* has been a member of our board of directors since January 2002. Since February 1997, Mr. Cooney has served as Principal for 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.A. 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. Since September 1999, Dr. Griffin has served as President, Chief Executive Officer and 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 of 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, and was a Fellow in Cardiology from Stanford University.

Table of Contents

*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.

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

We have a limited operating history and no products in commercial distribution in the United States. Our product candidates are still being developed, and all but our cryoablation system are still in early stages of development. Our product candidates will require significant additional development, clinical trials, regulatory clearances or approvals by the FDA and additional investment before they can be commercialized in the United States. We anticipate that our cryoablation system will not be approved for commercialization in the United States by the FDA for any indication for several years, if at all.

As of December 31, 2005, we had an accumulated deficit of $70.0 million. We have incurred net losses in each year since our inception in August 2000, including net losses of $17.1 million, $15.8 million and $11.2 million for the years ended December 31, 2005, 2004 and 2003, respectively. We expect to continue to incur significant and increasing operating losses, in the aggregate and on a per share basis, for the next several years. These losses, among other things, have had and will continue to have an adverse effect on our stockholders equity, net current assets and working capital. Because of the risks and uncertainties associated with developing medical devices, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

We expect that our primary expenses for the next 24 months will be for conducting our clinical trial for AF, costs associated with preparing our PMA for AF, other costs associated with new product development and costs associated with analyzing the data associated with, and potentially amending, our PMA for AFL. We expect that our general and administrative and legal costs will increase due to the additional operational and regulatory burdens applicable to public companies. In addition, if we receive FDA marketing approval of our cryoablation system, we expect to incur increased sales, marketing, manufacturing and compliance expenses.

Table of Contents

We do not currently have the required approvals to market our cryoablation system in the United States and we may not receive them. We may not become profitable even if we obtain FDA approval and succeed in commercializing our cryoablation system in the United States. As a result, we cannot be sure when we will become profitable, if at all.

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

We may need to raise substantial additional capital to:

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

We believe that the net proceeds from our initial public offering, together with our existing cash, cash equivalents and short-term investment balances, will be sufficient to meet our anticipated cash requirements through 2007. However, our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- the costs and timing of seeking regulatory approvals, including costs associated with analyzing the data associated with, and potentially amending, our PMA for AFL as well as a potential FDA advisory panel review for AF;
- clinical trial results;
- acceptance by the FDA of our clinical trial design and data to support marketing approval for the desired indications;
- the costs of establishing sales, marketing and distribution capabilities;
- the costs of filing, prosecuting and maintaining our owned and licensed patent applications and patents, and defending and enforcing these patents and other intellectual property rights;
- the effect of competing products and technologies; and

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

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

Table of Contents

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

In late January 2006, we received a letter from the FDA informing us that our PMA for the treatment of AFL using the cryoablation system is not approvable at present. The FDA stated that its interpretation of the data presented by us from our trial did not meet the FDA s chronic efficacy criteria. We are further analyzing our clinical data and evaluating our ability to amend our PMA for AFL presenting chronic efficacy in a manner that is acceptable to the FDA. The timeline for filing an amendment, if at all, is not known. In addition, there can be no assurance that we will amend our PMA, or if we do, that it will be approved by the FDA. If we do not amend our PMA, or if we do amend it and it 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.

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

- the objective performance criteria, or 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 efficacy rather than chronic efficacy as the primary measure of product effectiveness in the AFL pivotal trial;
- interfering effects of medication; and
- protocol deviations by our clinical investigators.

Based on these concerns, we cannot be certain that the FDA will 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.

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

We have expended significant time, money and effort in the development of our cryoablation system, which is still in clinical testing, has not yet received FDA approval for any indication and may never be commercialized in the United States. In our public announcements, we have provided estimates for the timing of the accomplishment of various clinical, regulatory and other product development goals relating to our cryoablation system, which we sometimes refer to as milestones. These milestones include the enrollment of subjects in our clinical trials, the submission of data from our clinical trials to the FDA, the timing of FDA approval for our cryoablation system and other clinical and regulatory events. These estimates are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control, and we may never achieve some or all of these milestones. For example, in January 2006, the FDA informed us that our PMA for the treatment of AFL is not approvable based on the data we submitted. In response, we are analyzing our clinical data and evaluating our ability to amend our PMA for AFL in a manner that is acceptable to the FDA. The timeline for filing an amendment, if at all, is not known. In addition, there can be no assurance that we will determine to amend our PMA, or if we do, that it will be approved by the FDA. 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.

Table of Contents

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

As discussed above, in January 2006, the FDA informed us that our PMA for the treatment of AFL using the cryoablation system is not approvable at present. We are analyzing our clinical data and evaluating our ability to amend our PMA for AFL presenting chronic efficacy in a manner that is acceptable to the FDA. Our current timeline for amending our PMA for AFL, if at all, is uncertain. In addition, there can be no assurance that we will amend our PMA, or if we do, that it will be approved by the FDA. If we do not amend our PMA or the 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 cannot assure you that we will obtain FDA approval to market our cryoablation system in the United States for either AFL or AF in a timely manner or at all. In addition, even if we obtain approval for one indication, we may never obtain approval for the other indication. If we fail to obtain FDA approval for at least one indication, we will not be permitted to market our cryoablation system in the United States and may be forced to cease our operations. In addition, if we do not receive FDA approval for the AF indication, we may never become profitable.

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

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

Table of Contents

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

To obtain FDA approval for marketing, our pivotal trials must generate data demonstrating that our cryoablation system is safe and effective for each indication for which approval is sought. The FDA s grant of permission to proceed with the AFL and AF pivotal trials does not constitute a binding commitment that the FDA will consider either trial design adequate to support approval for our cryoablation system. In addition, there can be no assurance that the data generated during the pivotal trials will meet our chosen safety and effectiveness endpoints or otherwise produce results that will lead the FDA to grant marketing approval. For example, although we believed the efficacy data in the AFL pivotal trial would meet the predefined objective performance criterion, or OPC, in January 2006, the FDA informed us that our PMA for the treatment of AFL using the cryoablation system is not approvable at present based on their analysis of chronic efficacy. We are further analyzing our clinical data and evaluating our ability to amend our PMA for AFL presenting chronic efficacy in a manner that is acceptable to the FDA. Our current timeline for amending our PMA for AFL, if at all, is uncertain. In addition, there can be no assurance that we will amend our PMA, or if we do, that it will be approved by the FDA. If our PMA is not approved by the FDA, we will not be able to market our cryoablation system for the treatment of AFL in the United States. If the FDA concludes that the AFL or AF trials have failed to demonstrate safety and effectiveness, we will not receive FDA approval to market our cryoablation system in the United States for those indications.

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

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

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

the reimbursement by governmental and other third party payers changes;

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

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

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

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

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 dropped out of the trial prior to completing the trial. Drop out rates may increase as we conduct our AF clinical trial because the follow up period for the AF trial is 12 months as opposed to six months for the AFL trial. In addition, subjects participating in our clinical trial may die before completion of their follow-up. Moreover, it may be difficult to successfully follow our subjects for the required 12-month period. Although to date we have successfully followed all our subjects from our AF feasibility study for the required 12-month period, historical results may not be indicative of our future performance. Delays in subject enrollment or failure of subjects to continue to participate in a trial may cause an increase in costs and delays in our clinical trial or result in the failure of the trial, which could cause us to fail to secure FDA marketing approval of our cryoablation system in a timely manner, if at all.

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

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

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

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

Our cryoablation system works by utilizing a pressurized system that delivers nitrous oxide to cool the tip of a catheter to freeze cardiac tissue in contact with the catheter tip while the catheter is in contact with the patient s heart. Although our cryoablation system is designed to prevent leaks in the catheter and to prevent the flow of nitrous oxide into the catheter if the catheter has been ruptured, nitrous oxide could enter the blood stream if the catheter developed a leak, which could result in serious injury to a patient, or even death. In April 2005, during routine quality control testing of a lot of Model 1200 catheters, we identified several instances of inadequate seals in the joint where the articulation section is welded to the catheter shaft, which could allow a leak of nitrous oxide into a patient. We initiated an investigation which covered several weeks to identify the source of the catheter integrity breaches, but were unable to find a specific root cause. In May 2005, we initiated a voluntary recall in Europe of all eight of the outstanding lots of our Model 1200 catheter and removed the Model 1200 from clinical trial use. Although no adverse events in patients have been reported associated with a leak of a Model 1200 catheter, we cannot assure you that none will occur.

Table of Contents

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

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

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

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

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

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

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

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

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

- the perceived safety and effectiveness of the product;
- the prevalence and severity of any side effects;
- the procedure time associated with the use of the product;

Table of Contents

potential advantages over alternative treatments;

the strength of marketing and distribution support; and

sufficient third party coverage or reimbursement.

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

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

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

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

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

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

the FDA s general prohibition against promoting products for unapproved or off-label uses;

the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and

the Reports of Corrections and Removals regulation, which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act, or FDCA.

Even if our products are approved, stringent FDA conditions of approval may significantly impact our sales and earnings depending on the scope and complexity of such conditions.

36

Table of Contents

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 32 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 18 patents issued outside of the United States and have a number of pending patent applications outside the United States. Limitations on patent protection in some countries outside the United States, and the differences in what constitutes patentable subject matter in these countries, may limit the protection we have under patents issued to us outside of the United States. In addition, laws of foreign

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

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

We are aware of numerous United States patents owned or licensed by third parties in areas potentially related to the technology used in our cryoablation system. These third parties include CryoCath Technologies,

Table of Contents

Inc., Johnson & Johnson, the Regents of the University of California and Spembly Medical Ltd. These third parties or our other competitors may have issued patents that cover technologies that we use in producing our product candidates, or that we use in treating patients with our product candidates. Owners of these patents or their licensees may assert that the manufacture, use or sale of our cryoablation system infringes one or more claims of their patents.

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

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

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

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

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

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

In addition, if third parties file patent applications or are issued patents claiming technology also claimed by us in pending applications, we may be required to participate in interference proceedings with the USPTO or in other proceedings outside the United States, including oppositions, to determine priority of invention or patentability. For example, we have filed requests with the USPTO seeking to invoke an interference proceeding

Table of Contents

involving certain patents owned by CryoCath Technologies, Inc. If we are not successful in this proceeding, this proceeding could result in us failing to gain rights to certain patent claims. Even if we are successful, we may incur substantial costs and the time and attention of our management and scientific personnel will be diverted in pursuit of these proceedings.

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

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

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

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

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

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

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

If we receive FDA approval for our cryoablation system, we will need to rapidly expand our sales and marketing operations and grow our research and development, product development and administrative operations. This expansion would place a significant strain on our management and operational and financial resources. Our current and planned personnel, systems, procedures and controls may not be adequate to support

39

Table of Contents

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

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

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

Although we believe that our procedures for use, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources.

Table of Contents

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

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

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

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

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

Table of Contents

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

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

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

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

We do not have a sales organization in the United States and have limited experience as a company in the sales, marketing and distribution of medical devices. If our cryoablation system is approved by the FDA, we plan to establish our own sales force to market our cryoablation system in the United States. Developing a sales force is expensive and time consuming and could delay or limit the success of any product launch. We may not be able to develop this capacity on a timely basis or at all. We may choose to contract with third parties, including distributors or agents, to perform sales, marketing and distribution services in the United States. If we 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 Italy and the United Kingdom, although our distribution agreement in Italy is inactive. We may seek additional distribution agreements to sell our cryoablation system in other countries in Europe, however our recent restructuring will delay commercial expansion in Europe, and we may never sign additional distribution agreements. If our relationships with our distributors do not progress as anticipated, if we are unable to identify alternative distributors, or if their sales and marketing strategies fail to generate sales of our products in the future, our business, financial condition and results of operations would be harmed. We are closing our subsidiary in Germany through which we historically distributed our product in Belgium, the Netherlands and Germany and we may no longer sell our product in these geographic areas.

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

The medical device industry is characterized by rapidly advancing technologies and a strong emphasis on proprietary products, designs and processes and intense competition. Any products that we commercialize will face intense competition. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early stage companies may also prove to be

Table of Contents

significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified personnel, establishing clinical trial sites and patient registration for clinical trials, as well as acquiring technology and technology licenses complementary to our programs or advantageous to our business.

Our competitors may:

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

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

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

Our business exposes us to the risk of product liability claims that is inherent in the testing, manufacturing and marketing of medical devices. We may be subject to product liability claims, including frivolous lawsuits, if our cryoablation system causes, or appears to have caused, an injury. Claims may be made by consumers, healthcare providers, third party strategic collaborators or others selling our products. Although we have product liability and clinical trial liability insurance that we believe is appropriate for our company, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, the coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

If we obtain approval to market our products in the United States, we intend to also pursue marketing our products in a number of international markets. Although our cryoablation system has been approved for

Table of Contents

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

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

We expect that a key element of our strategy will be to discover, develop and commercialize new products for the treatment of AFL and AF as extensions of, or in addition to, our cryoablation system. For example, we are completing development of our next generation catheter, Quantum, which we expect to introduce into clinical testing in the second half of 2006. However, our recent restructuring has caused us to delay or eliminate other internal research programs. Research programs to identify new product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

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

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

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

We are highly dependent upon our senior management and scientific staff. The loss of services of one or more of our members of senior management could delay or prevent the successful completion of our pivotal trials or the commercialization of our cryoablation system in the United States. Although we have employment agreements with each of our executive officers, their employment with us is at will, and each executive officer can terminate his agreement with us at any time. We carry key person life insurance on our former Chief Executive Officer, Dr. Ayers, but do not carry this insurance on any of our current executive officers. We will not renew this life insurance policy upon its expiration.

Our vice president of research and development and our vice president of regulatory, quality and clinical affairs recently left CryoCor and we may need to hire replacements. 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

44

Table of Contents

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 annual management assessments of the effectiveness of our internal controls over financial reporting and a report by our independent auditors that both addresses management s assessments and provides for the independent auditor s assessment of the effectiveness of our internal controls. During the course of our future testing, we may identify deficiencies which we may not be able to remediate in time to meet our deadline for compliance with Section 404.

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

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

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

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

***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;

Table of Contents

regulatory developments in the United States and foreign countries;

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

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

ability to manufacture our products to commercial standards;

public concern over our products;

the departure of key personnel;

future sales of our common stock;

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

changes in the structure of healthcare payment systems;

investors perceptions of us; and

general economic, industry and market conditions.

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

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

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

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

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

prohibiting stockholder actions by written consent;

limiting the persons who may call special meetings of stockholders;

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

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

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

***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, 2006, beneficially owned approximately 64% of our common stock based on the SEC s rules for

Table of Contents

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 March 31, 2007. We have also leased a small facility in Cologne, Germany, which was the headquarters of our wholly-owned subsidiary, CryoCor GmbH. We are in the process of vacating this facility which we expect to complete by the end of the second quarter of 2006. We believe that our current United States facility will be sufficient to meet our needs for the foreseeable future.

**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. 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. The USPTO has yet to act on these requests. 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, 2005.

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 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.

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

On March 1, 2006, the last reported sale price of CryoCor s common stock on Nasdaq was $2.50 per share. As of March 1, 2006, there were 10,689,868 shares of common stock outstanding held by approximately 179 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.

Of the net offering proceeds, through December 31, 2005, approximately $3.3 million of the net proceeds have been used for research and development activities, which include clinical trial activities and approximately $990,000 have been used for sales and marketing activities. In addition, approximately $892,000 have been used for our facility, manufacturing and quality system operations, and approximately $1.1 million have been used for working capital and general corporate purposes. We have invested the balance of the net proceeds of the offering in short-term, interest-bearing, investment-grade securities. We cannot predict whether the proceeds will yield a favorable return.

Table of Contents

**Equity Compensation Plan Information**

The following table provides information as of December 31, 2005 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 | 1,085,914 | $ 1.32 | 611,811(1) |
| **Total** | 1,085,914 | $ 1.32 | 611,811 |

(1) Includes 161,290 shares of our common stock available for issuance under our Employee Stock Purchase Plan as of December 31, 2005. Excludes future increases in the number of shares reserved for issuance pursuant to the terms of 2005 Equity Incentive Plan and our 2005 Employee Stock Purchase Plan.

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. Our historical results are not necessarily indicative of the results that may be expected in the future.*

| | Years ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2005 | 2004 | 2003 | 2002 | 2001 |
| | (in thousands except share and per share amounts) | | | | |
| **Consolidated statement of operations data** | | | | | |
| Product sales | $ 843 | $ 493 | $ 342 | $ 281 | $ |
| Operating expenses: | | | | | |
| Cost of sales | 2,824 | 2,800 | 2,649 | 2,844 | |
| Research and development[1] | 8,081 | 7,644 | 6,387 | 4,336 | 5,455 |
| Selling, general and administrative[2] | 6,650 | 5,732 | 2,260 | 2,174 | 1,373 |
| Total costs and expenses | 17,555 | 16,176 | 11,296 | 9,354 | 6,828 |
| Loss from operations | (16,712) | (15,683) | (10,954) | (9,073) | (6,828) |
| Interest and other income (expense), net | (384) | (83) | (218) | 35 | 48 |
| Net loss | (17,096) | (15,766) | (11,172) | (9,038) | (6,780) |
| 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 | $ (19,860) | $ (20,315) | $ (13,360) | $ (9,940) | $ (6,780) |
| Basic and diluted net loss per share common share[3]: | $ (3.96) | $ (769.77) | $ (635.43) | $ (530.11) | $ (390.04) |
| Shares used to compute basic and diluted net loss per common share: | 5,010,247 | 26,391 | 21,025 | 18,751 | 17,383 |

| | As of December 31, | | | | |
|---|---|---|---|---|---|
| | 2005 | 2004 | 2003 | 2002 | 2001 |
| | | | (in thousands) | | |
| **Consolidated balance sheet data** | | | | | |
| Cash and cash equivalents | $ 30,946 | $ 5,436 | $ 7,923 | $ 659 | $ 1,159 |
| Total long term debt | 6,570 | 1,084 | 2,175 | 374 | 445 |
| Redeemable convertible preferred stock | | 33,149 | 16,594 | | |
| Accumulated deficit | (69,960) | (50,202) | (30,128) | (17,315) | (8,277) |
| Total stockholders equity (deficit) | 24,243 | (30,004) | (11,048) | 1,613 | (1,289) |

(1) Research and development includes $1,315,000 and $385,000 of non-cash stock-based compensation for the years ended December 31, 2005 and 2004, respectively.

(2) Selling, general and administrative includes $779,000 and $664,000 of non-cash stock-based compensation for the years ended December 31, 2005 and 2004, respectively.

(3) 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.

Table of Contents

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

*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 and ability to amend our PMA for AFL, statements related our restructuring, 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 add additional clinical sites for and complete enrollment in our AF pivotal trial and submit a PMA for AF, risks involved with our estimates of the size, make-up and costs involved with the Company s restructuring, risks involved with our ability to reduce our cash burn, risks associated with our ability to amend our PMA for AFL and 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, risks associated with our ability to obtain additional financing as necessary, and the other risks and uncertainties identified in the section of this Form 10-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.*

*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, 2005.*

***Overview***

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

We obtained our CE Mark in early 2002 and are approved in Europe for the treatment of AF, AFL and other supraventricular tachycardias. We began our United States pivotal trial for AFL in late 2003, and our United States pivotal trial for AF in late 2004. In July 2005, we submitted the final module of our PMA for AFL to the FDA, which included the safety and effectiveness results of our clinical trial. In January 2006, we were notified by the FDA that our PMA for the treatment of AFL was not approvable as submitted at present. The FDA stated that the data presented did not meet the FDA s chronic efficacy criteria. We are evaluating whether we should

Table of Contents

amend our PMA for the treatment of AFL in 2006 based on a different analysis of chronic efficacy. There can be no assurance that we will decide to amend our PMA for the treatment of AFL, or if we do, that the FDA will accept our analysis or approve the PMA.

As a result of this non-approvable letter, in early March 2006, we restructured our operations and reduced our staffing levels to reduce our monthly cash requirements. This restructuring has reduced our manufacturing capabilities, impacted the timing of some of our internal research and development efforts, and reduced our ability to expand our commercial presence in Europe, but has not impacted our ability to conduct our AF pivotal trial or delayed our efforts to introduce our next generation catheter, Quantum, in clinical testing. We believe, and the FDA has informally indicated to us, that its decision not to approve our cryoablation system for the treatment of AFL based on the data we submitted does not impact our ongoing AF pivotal trial. If our AF clinical trial and the regulatory review proceed as anticipated, we may receive regulatory approval in the United States for our cryoablation system for the treatment of AF in 2008.

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

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

***Clinical Status***

In July 2005, we submitted the final module of our PMA for AFL, with the results of our clinical trial, to the FDA. During 2005, our San Diego facility was inspected by the FDA, and we had continuous discussions with the FDA about the information included in our PMA In January 2006, we were notified by the FDA that our PMA for the treatment of AFL was not approvable as submitted at present. The FDA stated that the data presented did not meet the FDA s chronic efficacy criteria. We are evaluating whether we should amend our PMA for the treatment of AFL in 2006 based on a different analysis of chronic efficacy. There can be no assurance that we will decide to amend our PMA for the treatment of AFL, or if we do, that the FDA will accept our analysis or approve the PMA.

We are continuing to enroll patients for our pivotal trial for AF that began in December 2004, and have enrolled 112 patients as of March 22, 2006. We currently have 21 clinical sites that are open for patient enrollment and we do not expect to open additional clinical sites. At our expected patient enrollment rate of between 7-10 patients per month, we believe we will complete enrollment in our AF pivotal trial by the second half of 2006, with an expected PMA submission to the FDA in the second half of 2007. We believe, and the FDA has informally indicated to us, that their decision at present to not approve our cryoablation system for the treatment of AFL does not impact our ongoing AF pivotal trial.

***Financial Operations***

*Product Sales*. Our product sales to date have come from a limited number of commercial sites in Europe. To date, we have not generated substantial revenues in Europe as our financial resources have primarily been

Table of Contents

dedicated to product development and clinical trials in the United States, which 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 efficacy and safety. We do not expect to generate revenues in the United States unless, and until, our cryoablation system has been approved by the FDA and we initiate the sales of our products. We expect that any revenues we generate from sales of our products will fluctuate from quarter-to-quarter.

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

*Selling, General and Administrative Expenses*. Our selling, general and administrative expenses consist primarily of cash and non-cash stock based compensation for executive, finance and administrative personnel. Other significant costs include professional fees for accounting and legal services, including legal services associated with our efforts to obtain and maintain protection for the intellectual property related to our cryoablation system. We expect our selling, general and administrative expenses to increase due to the costs associated with operating as a publicly-traded company.

***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, 2005, 2004 and 2003**

*Product Sales.* Our product sales were $843,000 in 2005, $493,000 in 2004 and $342,000 in 2003. These revenues were generated from the sale of our products in Europe. As of December 31, 2005, we had $205,000 of deferred revenue for catheters that have been shipped to European customers, but for which product sales revenue may not yet be recognized under our revenue recognition policies. 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 $2.8 million in 2005, $2.8 million in 2004 and $2.6 million in 2003. Cost of sales primarily consists of materials, labor and overhead costs associated with the manufacturing and warranty of our products. The majority of our cost of sales is expenses associated with operating our manufacturing facility at less than full capacity, and is consistent year to year. If our products are approved by the FDA and are successfully commercialized, we anticipate that cost of sales as a percentage of revenues will decline as we achieve higher future volumes of product sales.

*Research and Development Expenses.* Our research and development expenses were $8.1 million in 2005, $7.6 million in 2004 and $6.4 million in 2003. The $500,000, or 7% increase, from 2004 to 2005 was primarily due to an increase in non-cash stock-based compensation expenses of $930,000, partially offset by lower payroll costs and lower clinical trial costs related to our AF pivotal trial as compared to higher costs incurred in 2004 associated with our fully enrolled AFL pivotal trial. The $1.2 million, or 19%, increase from 2003 to 2004 was

Table of Contents

primarily due to the increase in costs of our United States clinical trials of $930,000 and higher payroll and non-cash stock-based compensation expenses of $749,000 as we added nine research and development personnel to support our development program. Increases in costs were partially offset by spending reductions for preclinical research programs.

*Selling, General and Administrative Expenses.* Our selling, general and administrative expenses were $6.7 million in 2005, $5.7 million in 2004 and $2.3 million in 2003. The $1.0 million or 18% increase from 2004 to 2005 was primarily due to an increase in non-cash stock-based compensation of $115,000, 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. The $3.4 million, or 148%, increase from 2003 to 2004 was primarily attributable to higher payroll and non-cash stock-based compensation expenses of $1.4 million, which includes $436,000 in severance expense associated with the departure of our former CFO, higher legal and accounting expenses of $857,000 and a general increase in selling expenses related to sales efforts by our European subsidiary.

*Interest Income.* Our interest income was $634,000 in 2005, $109,000 in 2004 and $82,000 in 2003. The fluctuations in these interest income levels relate to our varying cash balances from our initial public offering in 2005 and our private equity placements in 2003 and 2004.

*Interest Expense.* Our interest expense was $1,018,000 in 2005, $192,000 in 2004 and $300,000 in 2003. Our 2005 interest expense includes $227,000 in non-cash interest expense from the amortization of the debt discount for warrants issued in March 2005. In 2004, we incurred $110,000 of interest expense in related to a bank loan issued in mid-2003 that was repaid in March 2005. Interest expense in 2003 was related to the issuance of convertible promissory notes and related warrants. The promissory notes were converted into shares of our Series C and D preferred stock during 2003.

**Liquidity and Capital Resources**

We have incurred losses since our inception in August 2000. As of December 31, 2005, we had an accumulated deficit of $70.0 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, 2005, as well as bank debt and the proceeds of our initial public offering, which was closed in July 2005 and raised aggregate net proceeds of $35.4 million after deducting underwriting expenses and commissions and transaction costs. Concurrent with the closing of the initial public offering, all of our outstanding preferred shares converted into shares of common stock.

As of December 31, 2005, we had long-term debt and capital lease obligations outstanding of $7.0 million (excluding debt discount for warrants of $430,000), working capital of $29.9 million and cash, cash equivalents and short-term investments totaling $30.9 million. We currently invest our cash in money market funds and United States government or corporate bond securities. Based upon our current level of expenditures, we believe the proceeds from our initial public offering, together with cash flows from operating activities will be adequate to meet our anticipated cash requirements for working capital through 2007. In March 2005, we entered into a debt facility and borrowed $7.0 million thereunder. As part of that transaction, we repaid in full an outstanding bank loan of $1.8 million. The new debt facility bears interest at a rate of 11.25% per year and requires interest-only payments through June 2007, at which time the principal is due and payable.

*Net Cash Used in Operating Activities*. Net cash used in operating activities increased $1.2 million to $14.5 million for the year ended December 31, 2005, compared to $13.3 million for the year ended December 31, 2004. The net cash used in both of these periods primarily reflects the net loss for each period, offset in part by depreciation and amortization, non-cash stock-based compensation, amortization of debt discount and changes in operating assets and liabilities.

Table of Contents

*Net Cash Used in Investing Activities*. Net cash used in investing activities increased $20.5 million to $20.8 million for the year ended December 31, 2005, compared to $269,000 for the year ended December 31, 2004. Cash used in investing activities relates to purchases and disposals of property and equipment as well as purchases and maturities of short-term investments. The increase in net cash used in investing activities for the year ended December 31, 2005 is related to purchases of short-term investments subsequent to the receipt of proceeds from the Company s initial public offering in July 2005.

*Net Cash Provided by Financing Activities*. Net cash provided by financing activities increased $29.3 million to $40.4 million for the year ended December 31, 2005, compared to $11.1 million for the year ended December 31, 2004. Net cash provided by financing activities during the year ended December 31, 2005 was primarily attributable to the Company s initial public offering which had net proceeds of $35.4 million as well as borrowing under the Company s new debt facility of $7.0 million, offset by the pay-off of an existing term loan and payments on existing capital leases. Net cash provided by financing activities during the year ended December 31, 2004 was primarily attributable to our issuance of convertible preferred stock, offset by payments against capital leases and bank debt.

**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.

We incurred additional costs in 2005 of approximately $93,000 to recall our Model 1200 out of Europe and to withdraw the use of the Model 1200 from our clinical trial use in the United States. These costs covered the return of the affected Model 1200 catheters, the costs to manufacture and issue replacement CryoBlator catheters, related shipping costs and issuance of credits to customers in the event they declined a replacement catheter. Consistent with our revenue recognition policies, no revenue had been recognized related to any of the Model 1200 catheters that were returned. All Model 1200 catheters have been accounted for and the recall has been completed.

We do not expect to generate significant product revenues until we obtain marketing approval for and begin selling our cryoablation system in the United States. We believe that the net proceeds from our initial public offering, together with our cash and cash equivalent balances, will be sufficient to meet our anticipated cash requirements through 2007. If our available cash and cash equivalents and net proceeds from our initial public offering are insufficient to satisfy our liquidity requirements, or if we develop additional products, we may seek to sell additional equity or debt securities or obtain an additional credit facility. The sale of additional equity and debt securities would result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities, these securities would have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned clinical and commercial activities, and research and development efforts, which could harm our business.

On February 21, 2006, we issued a press release announcing that we will be implementing a restructuring plan intended to reduce our burn rate and to permit us to finance ourselves with our existing cash, cash equivalents and short-term investments through 2007. The decision to implement 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 is not approvable based on the data we submitted. Our Board of Directors approved the restructuring plan on February 14, 2006.

Table of Contents

The restructuring plan includes:

- 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 is anticipated to result in severance-related costs between $350,000 and $400,000, including benefits. We also expect to incur costs between $50,000 and $100,000 associated with terminating various sales and marketing associated contracts, but do not expect other restructuring costs. The Company s facilities are not impacted by the restructuring plan. In total, we expect to incur costs between $400,000 and $500,000 associated with the restructuring plan and we expect the restructuring to be substantially completed by July 2006.

We anticipate spending at least $2.1 million in external costs over the next 15 months for clinical trials and regulatory activities related to using our cryoablation system to treat AFL and AF, including estimated regulatory counsel costs related to amending our PMA for AFL in 2006. We believe the costs for our clinical trials for AFL and AF and the development of our existing product candidates will require approximately $6.9 million over the next 15 months, 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.

At present, we have a wholly owned subsidiary in Cologne, Germany that previously sold our products in Germany, Belgium, and the Netherlands, and we are in the process of closing the subsidiary. We expect to incur a total of $300,000 in costs in connection with the closing of our subsidiary during 2006. We have signed distribution agreements for the sale of our cryoablation system in the United Kingdom and Italy, however the distribution agreement with the Italian distributor is now inactive. We may expand our current network of distributors, however our recent restructuring is expected to delay our commercial expansion in Europe, and we may never sign additional distribution agreements. If we obtain marketing approval from the FDA, we plan to commercialize in the United States with our own sales force.

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 was the first to invent certain primary and pre-cooling refrigeration system designs, and certain heat exchanger designs. If we are not successful in these proceedings, we could fail to get rights to certain patent claims. Although we do not believe this finding would be material to our ability to operate, we believe an award of these rights to us may have a material effect on CryoCath s ability to compete with us in the United States. We may incur substantial costs in pursuit of these proceedings.

Our forecasts of the period of time through which our financial resources will be adequate to support our operations and the costs to complete development of products are forward-looking statements and involve risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed in the Risk Factors section of this Form 10-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:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- our ability to obtain FDA approval or other regulatory approval for our products;
- the costs and timing of seeking regulatory approvals, including FDA advisory panel review;
- clinical trial results;

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

Table of Contents

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 costs of filing, prosecuting, and maintaining our owned and licensed patent applications and patents, and defending and enforcing these patents and other intellectual property rights;

the effect of competing products and technologies; and

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

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

*Contractual Obligations.* The following table summarized our outstanding contractual obligations as of December 31, 2005:

| | | Payments due in | | | |
|---|---|---|---|---|---|
| | Total | Less than 1 Year | 1-3 Years | 3-5 Years | More than 5 Years |
| Operating leases | $ 506,000 | $ 352,000 | $ 154,000 | $ | |
| Bank loan | 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 April 2005, we renewed this lease through March 2007, and the table above includes the payments of approximately $25,000 per month that will be due pursuant to the terms of the lease.

At December 31, 2005, we had purchase commitments outstanding totaling $212,000 for console materials, in addition to $494,000 in console inventory which is recorded within inventory on our balance sheet. The inventory on hand and the inventory purchase commitments represent approximately 34 consoles which will be needed for our United States commercial launch, if we obtain regulatory approval of our cryoablation system from the FDA. We anticipate that we would need to purchase and build additional consoles in addition to our existing inventory levels to be able to sell and market in the United States.

We also have service agreements with clinical sites, individuals and contract research organizations for the conduct of our AF pivotal trial. We make payments to these sites and organizations based upon the actual number of patients enrolled and the period of follow-up in the trials, and we have accrued approximately $695,000 in fees and expenses through December 31, 2005 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 $1.7 million in the next 20 months. However, due to the variability associated with these agreements and the timing of patient enrollment, we are unable to estimate with certainty the future patient enrollment costs we will incur. We expect to incur additional expenses in connection with the preparation of our regulatory filings, including costs associated with employees and consultants and related legal expenses.

**Critical Accounting Policies and Significant Judgments and Estimates**

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

Table of Contents

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

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

*Revenue Recognition*

We comply with SEC Staff Accounting Bulletin No. 101, or SAB 101, *Revenue Recognition in Financial Statements*, as amended by Staff Accounting Bulletin 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 101 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.

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

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

*Stock-Based Compensation*

We have stock option plans to reward our employees and directors. We account for these plans under the recognition and measurement principles of Accounting Principles Board Opinion No. 25, or APB 25, and related interpretations and apply the disclosure provisions of SFAS No. 123, *Share-Based Payment*, or SFAS 123, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure an amendment of FASB Statement No. 123.*

Given the absence of an active market for our common stock and the lack of prospective acquirors of CryoCor through 2004, our Board of Directors (the Board) determined the estimated fair value of our common stock based on several factors, including liquidation preferences on our preferred stock of $65.3 million and $44.9 million at December 31, 2004 and 2003, respectively, progress and milestones achieved in our business,

Table of Contents

our financial condition, including our working capital which ranged from $2.9 million to $11.6 million during 2004, sales of convertible preferred stock, valuations at which other private companies at a similar stage of development had been acquired, and changes in valuation of existing comparable publicly-traded companies. The Board concluded that the preferred stockholders held securities representing the majority of the fair value of CryoCor on the date of grant under each of these scenarios.

In connection with the initiation in 2005 of our initial public offering efforts, we reassessed the estimated fair value of our common stock during 2004. We have recorded stock-based compensation, which is a non-cash charge, based upon the difference between the estimated fair value of common stock on the date of grant and the option exercise price. We amortize stock-based compensation on a straight-line basis over the vesting period of the option, which is generally four years.

During the period from January 1, 2004 through July 13, 2005, we granted options to employees to purchase a total of 1,249,462 shares of common stock at an exercise price of $0.62 per share. We did not obtain contemporaneous valuations from an unrelated valuation specialist during this period. Based upon the reassessment process, we determined that the reassessed fair value of such options ranged from $6.15 to $13.43 per share during this period. In determining the reassessed fair value per share of the common stock as of each grant date, the factors identified above were taken into account. We also considered other material factors and business developments, including the following specific milestones:

Initiation of our United States AFL pivotal trial in December 2003;

Commercial availability of our Model 1200 catheter in Europe in February 2004;

Closing of our second tranche of Series D financing in May 2004;

Approval to initiate a United States pivotal trial for AF in August 2004;

Completion of enrollment of our United States AFL pivotal trial in November 2004;

Enrollment of first patient in our United States AF pivotal trial in December 2004;

Publication of our results from our United States AF feasibility study in December 2004;

Recruitment of key executive officers, including our CFO, and our President and COO, since July 2004; and

Our board of directors authorization to initiate the process of preparing for an initial public offering in the first quarter of 2005.

In assessing the value of common stock in 2004, we estimated a fair value equivalent to the most recent preferred stock sale, $6.15 per share, and increased this estimated fair value relative to the milestones noted above, until the common stock value approximated the estimated value of the common shares in a public offering. We believe this valuation method, which was performed by us and without the assistance of a valuation expert, reflects the increase in value held by the common shareholders that will result from a successful public offering that eliminates the liquidation preferences attributable to our preferred stock. Further, we believe this valuation approach is consistent with valuation methodologies applied to other, similar technology companies pursuing an initial public offering.

Prior to our initial public offering, we recorded deferred stock compensation of approximately $3.0 million and $5.2 million during 2005 and 2004, respectively, for total deferred compensation of $8.2 million. At December 31, 2005, we had a total of $5.0 million in deferred stock compensation remaining to be amortized. Total unamortized deferred stock compensation recorded for all option grants through the date of our

initial public offering is expected to be amortized as follows:

| Years ending December 31, | | | |
|---|---|---|---|
| **2006** | **2007** | **2008** | **2009** |
| $1,775,000 | $1,775,000 | $1,350,000 | $64,000 |

Table of Contents

As of December 31, 2005, we had options to purchase 1,085,914 shares outstanding with a weighted average exercise price of $1.32. We believe these options have an aggregated intrinsic value of approximately $4.7 million based on the closing price of $5.66 on December 31, 2005.

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. These options are valued using the Black-Scholes option valuation model and are subject to periodic adjustment as the underlying options vest. Changes in fair value are amortized over the vesting period on a straight-line basis.

*Inventory*

As of December 31, 2005, we had raw materials, work-in-process and finished goods console inventory totaling $494,000. We have open purchase commitments totaling $212,000 for console components ordered that will be received and paid for during 2006. This total inventory represents approximately 34 finished consoles. We evaluated whether this level of console inventory was excessive based upon the recent communication from the FDA indicating that our cryoablation system was not approvable at present for the treatment of atrial flutter. We concluded that the existing inventory levels, including the open purchase commitments, were not excessive for the following reasons:

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

Based on the above, we concluded that no reserves were needed at December 31, 2005 for either the existing console inventory or the materials on order, to be delivered in 2006. We will continue to evaluate these inventory levels based on our clinical progress.

**Recent Accounting Pronouncements**

In March 2005, the SEC released Staff Accounting Bulletin No. 107, *Share-Based Payment,* or SAB 107. SAB 107 provides the SEC staff position regarding the application of SFAS No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123(R). SAB 107 contains interpretive guidance related to the interaction between SFAS 123(R) and certain SEC rules and regulations, as well as provides the Staff s views regarding the valuation of share-based payment arrangements for public companies. SAB 107 also highlights the importance of disclosures made related to the accounting for share-based payment transactions. The Company is currently reviewing the effect of SAB 107 on its condensed consolidated financial statements as it prepares to adopt SFAS 123(R).

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

As permitted by SFAS 123, the Company currently accounts for share-based payments to employees using APB Opinion 25 s intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options. Accordingly, the adoption of SFAS 123(R) s fair value method will have a significant impact on the Company s results of operations, although it will have no impact on the Company s overall financial position. The impact of adoption of SFAS 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future and the assumptions for the variables which impact the computation.

Table of Contents

However, had the Company adopted SFAS 123(R) in prior periods, the impact of that standard would have approximated the impact under SFAS 123 as described in the disclosure of pro forma net loss and loss per share in Note 1 to our consolidated financial statements. SFAS 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce the Company s net operating cash flows and increase net financing cash flows in periods after adoption.

**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 and corporate debt securities. Our cash and cash equivalents as of December 31, 2005 included liquid money market accounts, commercial paper, and corporate debt 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.

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 quarter that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

**Limitation on Effectiveness of Controls**

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

**ITEM 9B. OTHER INFORMATION**

None.

Table of Contents

## PART III

### ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Information concerning directors and executive officers and our audit committee financial expert is incorporated herein by reference to the information under the captions Election of Directors and Executive Officers of the Company set forth in our definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after December 31, 2005 for our Annual Meeting of Stockholders to be held on May 3, 2006.

Information concerning compliance with Section 16(a) of the Exchange Act is incorporated herein by reference to the information included under the caption Section 16(a) Beneficial Ownership Reporting Compliance set forth in our definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after December 31, 2005 for our Annual Meeting of Stockholders to be held on May 3, 2006.

Information concerning our Code of Business Conduct and Ethics is incorporated herein by reference to the information included under the caption Code of Ethics set forth in our definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after December 31, 2005 for our Annual Meeting of Stockholders to be held on May 3, 2006.

### ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 is incorporated herein by reference to the information under the caption Executive Compensation set forth in our definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after December 31, 2005 for our Annual Meeting of Stockholders to be held on May 3, 2006.

### 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 the information under the caption Security Ownership of Certain Beneficial Owners and Management and Securities Authorized for Issuance under Equity Compensation Plans in our definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after December 31, 2005 for our Annual Meeting of Stockholders to be held on May 3, 2006.

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this Item 13 is incorporated herein by reference to the information under the caption Certain Relationships and Related Transactions in our definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after December 31, 2005 for our Annual Meeting of Stockholders to be held on May 3, 2006.

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item 14 is incorporated herein by reference to the information under the caption Ratification of Selection of Independent Auditors in our definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after December 31, 2005 for our Annual Meeting of Stockholders to be held on May 3, 2006.

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, 2005



**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. |

**Table of Contents**

| Number | Description of Document |
|---|---|
| 10.8(1)(2) | Executive Employment Agreement made effective as of July 1, 2004, by and between the Registrant and Gregory J. Tibbitts. |
| 10.9(1)(2) | Executive Employment Agreement made effective as of November 12, 2004, by and between the Registrant and David Lentz. |
| 10.10(1)(2) | Employment Offer Letter Agreement dated September 27, 2000, between the Registrant and Russell Olson. |
| 10.11(1)(3) | Lease made as of November 1, 2000 between the Registrant and The Irvine Company, as amended. |
| 10.12(1)(3) | Contribution Agreement entered into as of August 31, 2000, by and between the Registrant and CryoGen, Inc. |
| 10.13(1) | License Agreement entered into as of August 31, 2000, by and between the Registrant and CryoGen, Inc. |
| 10.14(1) | Venture Loan and Security Agreement dated as of March 18, 2005, by and between the Registrant and Horizon Technology Funding Company LLC. |
| 10.15(1) | Commitment Agreement entered into as of March 24, 2005 among the Registrant and certain of its stockholders. |
| 10.16(1) | Research and Development Agreement entered into as of August 31, 2000, by and between the Registrant and CryoGen, Inc. |
| 10.17(4) | Letter Amendment Agreement dated March 21, 2006 between the Registrant and Gregory M. Ayers. |
| 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.*

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 Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| /s/ Edward F. Brennan, Ph.D.<br>**Edward F. Brennan, Ph.D.** | President and Chief Executive Officer and Director<br>*(Principal Executive Officer)* | March 23, 2006 |
| /s/ Gregory J. Tibbitts<br>**Gregory J. Tibbitts** | Vice President, Finance and Chief Financial Officer<br>(*Principal Financial and Accounting Officer*) | March 23, 2006 |
| /s/ Gregory M. Ayers, M.D., Ph.D.<br>**Gregory M. Ayers, M.D., Ph.D.** | Director | March 23, 2006 |
| /s/ Robert Adelman, M.D.<br>**Robert Adelman, M.D.** | Director | March 23, 2006 |
| /s/ David J. Cooney<br>**David J. Cooney** | Director | March 23, 2006 |
| /s/ Jerry C. Griffin, M.D., FACC<br>**Jerry C. Griffin, M.D., FACC** | Director | March 23, 2006 |

| | | | |
|---|---|---|---|
| /s/ ARDA MINOCHERHOMJEE, PH.D.<br>**Arda Minocherhomjee, Ph.D.** | Director | March 23, 2006 |
| /s/ KURT C. WHEELER<br>**Kurt C. Wheeler** | Director | March 23, 2006 |

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, 2005 and 2004, and the related consolidated statements of operations, stockholders equity (deficit) and cash flows for each of the three years in the period ended December 31, 2005. 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.

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, 2005 and 2004, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, in conformity with United States generally accepted accounting principles.

/s/ Ernst & Young LLP

San Diego, California

February 17, 2006

Table of Contents

**CryoCor, Inc.**

**Consolidated Balance Sheets**

***(in thousands except share and per share amounts)***

| | December 31, 2005 | 2004 |
|---|---|---|
| **Assets** | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 10,583 | $ 5,436 |
| Short-term investments | 20,363 | |
| Accounts receivable, net | 100 | 62 |
| Inventories, net | 718 | 638 |
| Prepaid expenses and other current assets | 756 | 218 |
| Amount due from related party, current | | 58 |
| Total current assets | 32,520 | 6,412 |
| Property and equipment, net | 680 | 849 |
| Other assets | 244 | 227 |
| Total assets | $ 33,444 | $ 7,488 |
| **Liabilities and stockholders equity (deficit)** | | |
| Current liabilities: | | |
| Accounts payable | $ 488 | $ 454 |
| Accrued compensation | 758 | 495 |
| Accrued clinical development liabilities | 751 | 667 |
| Accrued liabilities | 427 | 294 |
| Deferred revenue | 205 | 267 |
| Capital lease obligation, current portion | 2 | 82 |
| Current portion of long-term debt | | 1,000 |
| Total current liabilities | 2,631 | 3,259 |
| Long-term debt, less current portion | 6,570 | 1,084 |
| Redeemable convertible preferred stock, zero and 142,000,000 shares authorized at December 31, 2005 and 2004, respectively, 138,975,873 issued and outstanding at December 31, 2004 | | 33,149 |
| Stockholders equity (deficit): | | |
| Convertible preferred stock, $0.001 par value, 5,000,000 and 7,958,311 shares authorized at December 31, 2005 and 2004, respectively, 6,367,834 shares issued and outstanding at December 31, 2004 | | 6 |
| Common stock, $0.001 par value, 75,000,000 and 12,903,225 shares authorized at December 31, 2005 and 2004, respectively; 10,643,999 and 51,332 shares issued and outstanding at December 31, 2005 and 2004, respectively | 11 | |
| Additional paid-in capital | 99,089 | 24,609 |
| Deferred stock compensation | (4,964) | (4,568) |
| Accumulated comprehensive income | 67 | 151 |
| Accumulated deficit | (69,960) | (50,202) |
| Total stockholders equity (deficit) | 24,243 | (30,004) |
| Total liabilities and stockholders equity (deficit) | $ 33,444 | $ 7,488 |

See accompanying notes.

Table of Contents

**CryoCor, Inc.**

**Consolidated Statements of Operations**

***(in thousands except per share amounts)***

| | Year ended December 31, | | |
|---|---|---|---|
| | **2005** | **2004** | **2003** |
| Product sales | $ 843 | $ 493 | $ 342 |
| Operating expenses: | | | |
| Cost of sales | 2,824 | 2,800 | 2,649 |
| Research and development[(1)] | 8,081 | 7,644 | 6,387 |
| Selling, general and administrative[(1)] | 6,650 | 5,732 | 2,260 |
| Total costs and expenses | 17,555 | 16,176 | 11,296 |
| Loss from operations | (16,712) | (15,683) | (10,954) |
| Interest income | 634 | 109 | 82 |
| Interest expense | (1,018) | (192) | (300) |
| Net loss | (17,096) | (15,766) | (11,172) |
| 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) |
| Net loss attributable to common stockholders | $ (19,860) | $ (20,315) | $ (13,360) |
| Basic and diluted net loss per common share | $ (3.96) | $ (769.77) | $ (635.43) |
| Shares used to compute basic and diluted net loss per common share | 5,010 | 26 | 21 |

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

| | | | |
|---|---|---|---|
| Research and development | $ 1,315 | $ 385 | $ |
| Selling, general and administrative | 779 | 664 | |
| | $ 2,094 | $ 1,049 | $ |

See accompanying notes.

Table of Contents

**CryoCor, Inc.**

**Consolidated Statements of Stockholders Equity (Deficit)**

***(in thousands except share and per share amounts)***

| | Convertible preferred stock | | Common stock | | Additional paid-in | Deferred stock | Accumulated comprehensive | Accumulated | Total Stockholders |
|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | in capital | compensation | income | deficit | equity (deficit) |
| Balance at December 31, 2002 | 7,958,311 | 8 | 19,654 | | 18,877 | | 43 | (17,315) | 1,613 |
| Dividends and accretion to redemption value of Series D redeemable convertible preferred stock | | | | | | | | (1,641) | (1,641) |
| Exercise of stock options for cash | | | 50 | | | | | | |
| Conversion of Series A convertible preferred stock to common stock | (1,590,477) | (2) | 2,549 | | 2 | | | | |
| Warrant issued in connection with convertible subordinated debt | | | | | 100 | | | | 100 |
| Comprehensive loss: | | | | | | | | | |
| Foreign currency translation adjustment | | | | | | | 52 | | 52 |
| Net loss | | | | | | | | (11,172) | (11,172) |
| Comprehensive loss | | | | | | | | | (11,120) |
| Balance at December 31, 2003 | 6,367,834 | $ 6 | 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 |
| Exercise of stock options for cash | | | 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 | 6,367,834 | 6 | 51,332 | | 24,609 | (4,568) | 151 | (50,202) | (30,004) |

Table of Contents

**CryoCor, Inc.**

**Consolidated Statements of Stockholders Equity (Deficit) (Continued)**

***(in thousands except share and per share amounts)***

| | Convertible preferred stock | | Common stock | | Additional paid-in | Deferred stock | Accumulated comprehensive | Accumulated | Total Stockholders |
|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | in capital | compensation | income | deficit | equity (deficit) |
| Balance at December 31, 2004 | 6,367,834 | 6 | 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 convertible preferred stock into common stock | (6,367,834) | (6) | 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 |
| Exercise of stock options for cash | | | 236,331 | | 146 | | | | 146 |
| Repurchase of common stock related to stock options | | | (2,966) | | (2) | | | | (2) |
| 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 |

See accompanying notes.

Table of Contents

**CryoCor, Inc.**

**Consolidated Statements of Cash Flows**

***(in thousands)***

| | Years ended December 31, | | |
|---|---|---|---|
| | **2005** | **2004** | **2003** |
| **Operating activities** | | | |
| Net loss | $ (17,096) | $ (15,766) | $ (11,172) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 489 | 532 | 465 |
| Non-cash stock-based compensation | 2,094 | 1,049 | |
| Amortization of debt discount | 227 | | 100 |
| Amortization of premium/discount on short-term investments | 10 | | |
| Accrued interest converted to preferred stock | | | 57 |
| Loss on disposition of property and equipment | | 18 | 10 |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (49) | (26) | 91 |
| Inventories | (95) | 75 | (264) |
| Prepaid expenses and other assets | (506) | 34 | 94 |
| Accounts payable | 37 | 138 | (70) |
| Deferred revenue | (55) | 267 | |
| Accrued liabilities | 490 | 362 | 357 |
| Net cash used in operating activities | (14,454) | (13,317) | (10,332) |
| **Investing activities** | | | |
| Purchases of property and equipment | (322) | (271) | (304) |
| Proceeds from sale of property and equipment | | 2 | 9 |
| Purchases of short-term investments | (22,429) | | |
| Proceeds from sale of short-term investments | 2,000 | | 258 |
| Net cash used in investing activities | (20,751) | (269) | (37) |
| **Financing activities** | | | |
| Net proceeds from issuance of preferred stock | | 12,246 | 11,896 |
| Net proceeds from issuance of common stock | 35,383 | 10 | |
| Proceeds from exercise of stock options | 144 | 3 | |
| Proceeds from convertible subordinated debt | | | 3,000 |
| Proceeds from long-term debt | 7,000 | | 3,000 |
| Principal payments on capital lease | (80) | (293) | (315) |
| Principal payments on long term debt | (2,083) | (916) | |
| Net cash provided by financing activities | 40,364 | 11,050 | 17,581 |
| Effect of exchange rate changes on cash | (12) | 49 | 52 |
| Net increase (decrease) in cash and cash equivalents | 5,147 | (2,487) | 7,264 |
| Cash and cash equivalents at beginning of period | 5,436 | 7,923 | 659 |
| Cash and cash equivalents at end of period | $ 10,583 | $ 5,436 | $ 7,923 |
| **Supplemental disclosures of cash flow information:** | | | |
| Cash payments for interest | $ 788 | $ 134 | $ 107 |

| | | | |
|---|---|---|---|
| Conversion of notes payable and accrued interest to preferred stock | $ | $ | $ 3,057 |

See accompanying notes.

Table of Contents

**CryoCor, Inc.**

**Notes to Consolidated Financial Statements**

**1. Organization and Summary of Significant Accounting Policies**

***Organization***

CryoCor, Inc. ( CryoCor or the Company ) was incorporated in Delaware on August 15, 2000. The Company is a medical technology company that has developed and manufactures a minimally invasive, disposable catheter system based on its proprietary cryoablation technology for the treatment of cardiac arrhythmias.

On August 31, 2000, the Company entered into a contribution agreement with CryoGen, Inc. ( CryoGen ) (the Contribution Agreement ) whereby CryoCor acquired assets, including intellectual property, and assumed liabilities of CryoGen in exchange for Series A preferred stock and common stock of the Company. The Company issued 1,881,933 shares of Series A preferred stock and 17,175 shares of common stock to CryoGen, which represented a 100% interest in the Company as of August 31, 2000. As a result of the significant ownership initially retained by CryoGen, CryoCor s assets acquired and liabilities assumed were recorded at the net book value of $36,000 transferred by CryoGen.

In 2001, the Company established a wholly owned German subsidiary, CryoCor GmbH, in order to market and support the Company s products to the European community. In 2002, the Company received European regulatory approval for the commercial sale of the Company s products. The majority of the Company s revenues relate to sales by CryoCor GmbH. In November 2005, the Company announced its intention to restructure CryoCor GmbH and sell its products directly through distributors. The Company accrued approximately $18,000 in restructuring costs as of December 31, 2005. This restructuring is expected to be completed during 2006 incurring additional restructuring costs of approximately $300,000 which includes one-time termination benefits and contract termination costs.

***Basis of Presentation***

With the completion of our initial public offering, which resulted in net proceeds to the Company of $35.4 million, the Company believes that it has sufficient working capital to fund its operations at least through December 31, 2006; accordingly, the accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. This basis of accounting contemplates the recovery of the Company s assets and the satisfaction of liabilities in the normal course of business. Successful completion of the Company s development program and its transition to attaining profitable operations is dependent upon obtaining additional financing adequate to fulfill its research and development activities and achieving a level of revenue adequate to support its cost structure. The Company does not anticipate having significant commercial operations until 2007, if at all; therefore, it will need to obtain additional financing to fund its operations until it becomes cash flow positive. There can be no assurances that there will be sufficient amounts of financing available at the time the Company seeks to raise additional capital.

***Reclassifications***

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

***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.

Table of Contents

**CryoCor, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

***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 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, 2005, 2004 and 2003.

***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, 2005.

***Revenue Recognition***

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 expects to sell consoles in the future, its current revenue is generated by the sales of catheters and sheaths, with catheters comprising approximately 93% of the 2005 and 2004 revenues. Currently, the Company s customers are primarily hospitals and to a lesser extent distributors. Customers are granted 30-day credit terms and have the right to return catheter products up to one month following expiration of the catheter product, which is six months after its production. As the Company has had limited sales of its catheter products, it currently recognizes revenues when the customer has paid for the product and used the product or the right of return has expired. Any payments received prior to the product being used or prior to expiration of the right of return are recorded as deferred revenue. 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.

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 products. The Company s intention is not to reclaim the consoles and to date, the Company has not reclaimed any consoles it has placed. However, the Company retains the right to do so in the event it becomes dissatisfied with a customer s use of the console. The Company has not modified the pricing of its disposable catheters to

Table of Contents

**CryoCor, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

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.

The Company complies with Securities and Exchange Commission ( SEC ) Staff Accounting Bulletin ( SAB ) No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB 104, and SFAS No. 48, *Revenue Recognition When Right of Return Exists* ( SFAS 48 ). These pronouncements 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.

***Research and Development***

Research and development expenses consist primarily of costs incurred to further the Company s research and development activities and include salaries and related employee benefits, costs associated with clinical trials, non-clinical activities, regulatory activities, research-related overhead expenses and fees paid to external service providers and contract 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.

***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, 2005, the Company s cash and cash equivalents were held in financial institutions in the United States and consist of deposits in money market funds and United States government securities, which were unrestricted as to withdrawal or use.

***Investment Securities***

The Company considers investments with a maturity date of more than three months from the date of purchase to be short-term investments and has classified these securities as available-for-sale. Such investments are carried at fair value, with unrealized gains and losses included as accumulated other comprehensive income (loss) in stockholders equity. The cost of available-for-sale securities sold is determined based on the specific identification method.

***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 medical products.

Table of Contents

**CryoCor, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

***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.

***Stock-Based Compensation***

The Company accounts for stock-based employee compensation arrangements in accordance with the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ( APB 25 ) and its interpretations and complies with the disclosure provisions of SFAS No. 123, *Accounting for Stock-Based Compensation* ( SFAS 123 ). Under APB 25, compensation expense is based on the difference, if any, on the date of the grant between the fair value of the Company s stock and the exercise price. Employee stock-based compensation is amortized on a straight-line basis over the vesting period of the underlying options. SFAS 123 defines a fair value based method of accounting for an employee stock option or similar equity investment.

The following table illustrates the effect on net loss if the Company had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation arrangements:

| | Years ended December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| | (in thousands, except per share amounts) | | |
| Net loss attributable to common stockholders, as reported | $ (19,860) | $ (20,315) | $ (13,360) |
| Deduct: Stock-based employee compensation expense included in net loss, as reported | 1,954 | 622 | |
| Add: Stock-based employee compensation expense determined under fair value method for all awards | (2,022) | $ (711) | $ (26) |
| Pro forma net loss attributable to common stockholders | $ (19,928) | $ (20,404) | $ (13,386) |
| Basic and diluted net loss per common share | $ (3.96) | $ (769.77) | $ (635.43) |
| Pro forma basic and diluted net loss per common share | $ (3.98) | $ (773.14) | $ (636.67) |

The above pro forma effects on net loss may not be representative of the effects on future results as options granted typically vest over several years and additional grants are expected to be made in future years.

Prior to the Company s initial public offering, the fair value for each option grant was determined using the minimum value method. Upon completion of the initial public offering in July 2005, the Company began using the Black-Scholes model to estimate fair value. No dividend yield was assumed as the Company has not paid dividends and has no intentions to do so. In accordance with the provisions of SFAS 123, the fair value of each option is estimated using the following weighted average assumptions:

| | Years ended December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| Expected dividend yield | 0% | 0% | 0% |
| Risk-free interest rate | 3.52% | 3.25% | 4.25% |
| Expected life | 6 years | 6 years | 6 years |

| | | | |
|---|---|---|---|
| Expected volatility | 70% | 0% | 0% |

Table of Contents

**CryoCor, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

The fair value of the Company s employee stock purchase plan ( ESPP ) purchase rights were estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions for 2005: expected dividend yield of 0%, expected volatility of 70%, risk-free interest rate of 2.5% and expected life of 1.41 years. The weighted average grant date fair value of ESPP purchase rights was $5.11 per share for 2005.

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 stock-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.

***Deferred Stock Compensation***

No employee stock compensation expense was reflected in the Company s reported net loss in any period prior to 2004 as all options granted had an exercise price equal to the estimated fair value of the underlying common stock on the date of the grant.

On February 10, 2005, the Company commenced the initial public offering process and based on discussions with its investment bankers, reassessed the fair value of its common stock going back to January 1, 2004. The Company s management, all of whom qualify as related parties, determined that the stock options granted during 2004 were granted at exercise prices that were below the reassessed fair value of the common stock on the date of grant. The Company completed the reassessment of its fair value without the use of an unrelated valuation specialist and started with the proposed valuation from its investment bankers, considering a number of accomplishments in 2004 that would impact its valuation, including the achievement of key clinical milestones, hiring of executive officers, and the increased possibility of completing an initial public offering. Accordingly, deferred compensation of $5,215,000 was recorded during 2004 which represented the difference between the weighted average exercise price of $0.62 and the weighted average fair value of $6.22 on 931,886 options granted to employees during 2004. The deferred stock compensation is being amortized on a straight-line basis over the vesting period of the related awards, which is generally four years. During 2005, the Company recorded additional deferred compensation of $2,956,000 related to grants of 262,480 employee stock options with a weighted average exercise price of $0.62 per share and a weighted average fair value of $13.43. Of the shares granted in 2005, 31,193 were canceled shortly after grant, and no deferred compensation was recorded on these options. The Company recorded amortization expense for deferred compensation of $1,954,000 and $622,000 in 2005 and 2004, respectively.

The expected future amortization expense for deferred stock compensation for stock options granted through December 31, 2005, is as follows (in thousands):

| **Years ending December 31,** | |
|---|---|
| 2006 | $ 1,775 |
| 2007 | 1,775 |
| 2008 | 1,350 |
| 2009 | 64 |
| | $ 4,964 |

Table of Contents

**CryoCor, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

***Comprehensive Income (Loss)***

In accordance with SFAS No. 130, *Reporting Comprehensive Income,* the Company reports comprehensive income (loss) and its components, including foreign currency translation adjustments, in stockholders equity. Comprehensive income is displayed in the consolidated statements of stockholders equity and includes items not currently included in net income (loss). Comprehensive income (loss) does not have an impact on the Company s results of operations.

***Recently Issued Accounting Standards***

In March 2005, the SEC released SAB No. 107, *Share-Based Payment* ( SAB 107 ). SAB 107 provides the SEC staff position regarding the application of SFAS No. 123 (revised 2004), *Share-Based Payment* ( SFAS 123(R) ). SAB 107 contains interpretive guidance related to the interaction between SFAS 123(R) and certain SEC rules and regulations, as well as provides its views regarding the valuation of share-based payment arrangements for public companies. SAB 107 also highlights the importance of disclosures made related to the accounting for share-based payment transactions. The Company is currently reviewing the effect of SAB 107 on its consolidated financial statements as it prepares to adopt SFAS 123(R).

In December 2004, the FASB issued SFAS 123(R) which is a revision of SFAS 123. SFAS 123(R) supersedes APB 25 and amends SFAS No. 95, *Statement of Cash Flows.* Generally, the approach under SFAS 123(R) is similar to the approach described in SFAS 123. However, SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, be recognized in the financial statements based on their fair values. Pro forma disclosure will no longer be an alternative. The Company adopted SFAS 123(R) on January 1, 2006.

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

***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.

**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

Table of Contents

**CryoCor, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

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, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| | (in thousands, except per share amounts) | | |
| **Historical** | | | |
| Numerator: | | | |
| Net loss attributable to common stockholders | $ (19,860) | $ (20,315) | $ (13,360) |
| Denominator: | | | |
| Weighted-average common shares outstanding | 5,090 | 26 | 21 |
| Weighted-average unvested common shares subject to repurchase | (80) | | |
| Denominator for basic and diluted net loss per share attributable to common stockholders | 5,010 | 26 | 21 |
| Basic and diluted net loss per share attributable to common stockholders | $ (3.96) | $ (769.77) | $ (635.43) |
| **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 | 2,605 |
| Convertible preferred stock (1) | | 1,566 | 1,548 |
| Options to purchase common stock | 1,086 | 1,159 | 203 |
| Warrants to purchase common and convertible preferred stock | 83 | 166 | 166 |
| | 1,169 | 7,783 | 4,522 |

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

**3. Balance Sheet Information**

***Investment Securities***

Investment securities consist of high-grade auction rate securities and United States government and corporate debt securities. The Company classifies all securities as available-for-sale, as the sale of such securities may be required prior to maturity to implement management strategies. These securities are carried at fair value, with the unrealized gains and losses reported as a component of other comprehensive income (loss) until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis. A decline in the market value of any available-for-sale security below cost that is determined to be other than temporary results in a revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. No such impairment charges were recorded for the period presented. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method. Interest income is recognized when earned. Realized gains and losses on investments in securities have not been material for any period presented. The amortization and accretion, interest income and realized gains and losses are included in interest income within the Consolidated Statements of Operations. As of December 31, 2005, the contractual maturity of all

investment securities was less than one year.

Table of Contents

**CryoCor, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

The composition of investment securities and gross unrealized losses at December 31, 2005 is as follows (in thousands):

| | Amortized Cost | Unrealized Gains | Unrealized Losses | Fair Value |
|---|---|---|---|---|
| Corporate debt securities | $ 15,924 | $ | $ (48) | $ 15,876 |
| U.S. government securities. | 4,495 | | (8) | 4,487 |
| | $ 20,419 | $ | $ (56) | $ 20,363 |

***Inventories***

Inventories consist of the following (in thousands):

| | December 31, 2005 | 2004 |
|---|---|---|
| Raw materials | $ 504 | $ 552 |
| Work in process | 94 | 42 |
| Finished goods | 170 | 124 |
| | 768 | 718 |
| Reserves for excess and obsolete inventory | (50) | (80) |
| Inventory, net | $ 718 | $ 638 |

During 2005, 2004 and 2003, the Company recorded inventory reserves of $99,000, $68,000 and $9,000, respectively against cost of sales. In addition, the Company wrote off inventory against the reserve of $129,000, $5,000 and $88,000 during 2005, 2004 and 2003, respectively.

As of December 31, 2005, the Company had open purchase commitments totalling $212,000 for console components ordered that will be received and paid for during 2006. This total inventory represents approximately 34 finished consoles. The Company evaluated whether this level of console inventory was excessive based upon the recent communication from the United States Food and Drug Administration (the FDA ) indicating that the Company s cryoablation system was not approvable at present for the treatment of atrial flutter. The Company concluded that the existing inventory levels, including the open purchase commitments, were not excessive for the following reasons:

- completed consoles can be deployed in Europe where its product has been approved for sale;
- the Company expects to need between 125 to 160 consoles to effectively commercialize our product in the United States;
- the Company believes it will receive approval to sell our product in the United States in either 2007 or 2008; and

the console is not subject to obsolescence in the time period contemplated for commercialization.

Based on the above, the Company concluded that no reserves were needed at December 31, 2005 for either the existing console inventory or the materials on order, to be delivered in 2006. The Company will continue to evaluate these inventory levels based on its clinical progress.

Table of Contents

**CryoCor, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

***Property and Equipment***

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

| | December 31, 2005 | 2004 |
|---|---|---|
| Manufacturing and laboratory equipment | $ 1,022 | $ 911 |
| Computers and software | 792 | 664 |
| Office furniture and equipment | 535 | 474 |
| Leasehold improvements | 440 | 440 |
| | 2,789 | 2,489 |
| Less accumulated depreciation and amortization | (2,109) | (1,640) |
| | $ 680 | $ 849 |

Property and equipment, net related to CryoCor GmbH totaled $2,000 and $19,000 as of December 31, 2005 and 2004, respectively.

Depreciation and amortization expense from operations related to property and equipment for the year ended December 31, 2005, 2004 and 2003 was $489,000, $532,000 and $465,000, respectively.

**4. Commitments and Contingencies**

***Leases***

The Company leases its facilities and certain equipment under non-cancelable operating leases, which expire at various times between 2006 and 2007. The leases require 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 Company leases 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 2005 and approximately $2,000 remains payable under its capital leases as of December 31, 2005.

Table of Contents

**CryoCor, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

Annual future minimum obligations for operating leases as of December 31, 2005 are as follows (in thousands):

| | |
|---|---|
| 2006 | $ 352 |
| 2007 | 122 |
| 2008 | 32 |
| 2009 | |
| 2010 and thereafter | |
| Total minimum lease payments | $ 506 |

Rent expense was $398,000, $411,000 and $366,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

***Long-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. This facility places restrictive covenants on the Company s operations, which preclude the Company from incurring new debt or placing liens on its assets, disposing of property, making dividend payments or distributions to stockholders, or entering into transactions that would result in a change of control. The new debt facility bears interest at a rate of 11.25% per annum and requires monthly interest-only payments through June 2007, at which time all remaining principal is due and payable. In conjunction with the facility, the Company issued two warrants to purchase a total of 68,288 shares of common stock. The fair value of the warrants was $657,000 based upon an estimated fair value upon the date of grant of $13.43 per common share, an estimated life of six years, a volatility rate of 70% and a risk free interest rate of 4.34%. The fair value of the warrant was recorded as a discount to the new debt facility and is being amortized to interest expense on a straight-line basis over the term of the loan. The remaining unamortized fair value of the warrants is $430,000 at December 31, 2005. The warrants are exercisable through 2015.

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

| | 2005 | 2004 |
|---|---|---|
| Long-term debt | $ 7,000 | $ 2,084 |
| Less: current portion | | (1,000) |
| Less: debt discount | (430) | |
| | $ 6,570 | $ 1,084 |

***License Agreement***

In August 2000, in connection with the Contribution Agreement, the Company executed an exclusive, irrevocable, perpetual, worldwide, non-transferable, royalty-free, fully-paid up license agreement with CryoGen for the exclusive use of CryoGen s 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.

Table of Contents

**CryoCor, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

***Product Recall***

In April 2005, during routine quality control testing of a lot of Model 1200 catheters, the Company identified several instances of inadequate seals in the joint where the articulation section is welded to the catheter shaft, which could allow a leak of nitrous oxide into a patient. The Company initiated an investigation which covered several weeks to identify the source of the catheter integrity breaches, but was unable to find a specific root cause. In May 2005, the Company initiated a voluntary recall in Europe of all remaining catheters from eight of its outstanding lots of its Model 1200 catheter and removed the Model 1200 from clinical trial use.

The Company incurred costs in 2005 of approximately $93,000 to recall its Model 1200 out of Europe and to withdraw the use of the Model 1200 from its IDE. These costs covered the return of the affected Model 1200 catheters, the costs to manufacture and issue replacement CryoBlator catheters and related shipping costs. Consistent with the Company s revenue recognition policies, no revenue had been recognized related to any of the Model 1200 catheters that were returned.

**5. Preferred Stock and Stockholders Equity (Deficit)**

***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, the Company recorded $2,764,000 for dividends and accretion.

***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.

***Stock Warrants***

During 2003, in conjunction with the issuance of subordinated bridge notes related to a preferred stock financing, the Company issued warrants to purchase 146,326 shares of common stock at a purchase price of $8.37 per share: 50% expiring February 3, 2008 and 50% expiring March 28, 2008. The estimated fair value of the warrants issued in conjunction with the subordinated bridge notes of $0.34 per share was recorded as a discount against the debt and was computed using the Black Scholes valuation model using a 60% volatility rate, 5 year estimated life, and estimated fair value of the underlying common stock of $8.37. In addition, the debt discount created a beneficial conversion feature in accordance with EITF No. 00-27, *Application of EITF Issue No. 98-5, Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios, to Certain Convertible Instruments*, which is accounted for as additional debt discount. The beneficial conversion and the debt discount of $100,000 were recorded as additional interest expense in 2003.

Table of Contents

**CryoCor, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

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, 2005, the Company had outstanding warrants to purchase 83,491 shares of common stock.

***Stock Option Plans***

The Company has adopted three stock option plans: the 2000 Stock Option Plan, 2005 Equity Incentive Plan and the 2005 Non-Employee Directors Stock Option Plan (the Plans ). As of December 31, 2005, 1,085,914 shares of the Company s common stock were reserved for issuance upon exercise of options granted by the Company and 450,521 shares were available for future grant or issuance. The Plans provide for the grant of incentive and non-statutory options to employees, directors and consultants.

The exercise price of incentive stock options must equal at least the deemed fair value on the date of grant and the exercise price of non-statutory stock options may be no less than 85% of the deemed fair market value on the date of grant. Options granted under the Plans generally expire no later than ten years from the date of grant. Options generally vest over a period of four years. Unvested common shares obtained through early exercise of options are subject to repurchase by the Company at the original issue price. During 2005, 2,966 shares have been repurchased by the Company and at December 31, 2005, 64,801 shares are subject to repurchase.

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, 2002 | 17,808 | 46,649 | $ 9.95 |
| Authorized | 1,181,114 | | |
| Granted | (163,319) | 163,319 | $ 0.65 |
| Exercised | | (50) | $ 12.56 |
| Canceled | 6,370 | (6,370) | $ 1.91 |
| 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 |

Table of Contents

**CryoCor, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

The weighted-average fair value of options granted during 2005, 2004 and the 2003, was $11.87, $6.22 and $0.65 per share, respectively. At December 31, 2005, 2004 and 2003, the weighted-average remaining contractual life of outstanding options was 8.59 years, 9.36 years and 9.30 years, respectively.

A summary of activity and related fair and intrinsic value information for the years ended December 31, 2005 and 2004 under the Plans is as follows:

| Grant Date | Shares Granted | Exercise Price | Fair Value of Common Stock on Date of Grant | Intrinsic Value per Share |
|---|---|---|---|---|
| 2004: | | | | |
| Employee grants | | | | |
| January July 2004 | 914,953 | $ 0.62 | $ 6.15 | $ 5.53 |
| September 2004 | 13,063 | $ 0.62 | $ 9.06 | $ 8.44 |
| November 2004 | 3,870 | $ 0.62 | $ 11.97 | $ 11.35 |
| Non-employee grants | | | | |
| January July 2004 | 49,452 | $ 0.62 | $ 6.15 | $ 5.53 |
| November 2004 | 806 | $ 0.62 | $ 11.97 | $ 11.35 |
| Total 2004 grants | 982,144 | | | |
| 2005: | | | | |
| Employee grants | | | | |
| February 2005 | 31,193 | $ 0.62 | $ 13.43 | $ 12.81 |
| March 2005 | 228,868 | $ 0.62 | $ 13.43 | $ 12.81 |
| May 2005 | 2,419 | $ 0.62 | $ 11.00 | $ 10.38 |
| September 2005 | 15,500 | $ 7.01 - $7.50 | $ 7.01 - $ 7.50 | $ |
| October 2005 | 6,300 | $ 5.84 - $6.18 | $ 5.84 - $ 6.18 | $ |
| November 2005 | 43,173 | $ 6.17 | $ 6.17 | $ |
| December 2005 | 5,500 | $ 5.65 - $5.89 | $ 5.65 - $ 5.89 | $ |
| Non-employee grants | | | | |
| March 2005 | 4,838 | $ 0.62 | $ 13.43 | $ 12.81 |
| Total 2005 grants | 337,791 | | | |

Note 1, under Deferred Stock Compensation , discusses the determination of the intrinsic value per share. The 31,193 shares granted in February 2005 were canceled shortly after grant and no deferred compensation was recorded on these options.

The following is a breakdown of the options outstanding as of December 31, 2005:

| Range of Exercise Prices | Options Outstanding | Weighted Average Remaining Life in Years | Weighted Average Exercise Price | Options Exercisable | Weighted Average Exercise Price of Options Exercisable |
|---|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| $0.62 | 977,457 | 8.62 | $ 0.62 | 977,457 | $ 0.62 |
| $5.65-$8.37 | 96,115 | 8.77 | $ 6.95 | 27,884 | $ 8.29 |
| $13.02 | 12,342 | 4.81 | $ 13.02 | 12,342 | $ 13.02 |
| $0.62-13.02 | 1,085,914 | | | 1,017,683 | |

Table of Contents

**CryoCor, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

At December 31, 2005, 327,007 of the options outstanding were vested.

The Company adopted an ESPP during March 2005 which became effective upon the effective date of its initial public offering. An aggregate of 161,290 shares of our common stock are reserved for issuance under the ESPP. This amount will be increased annually on the first day of our fiscal year, from 2006 until 2015, by the lesser of (i) 1.0% of the Company s common stock outstanding on December 31 of the preceding fiscal year, (ii) 322,580 shares of common stock, or (iii) a lesser amount determined by the Company s Board of Directors. Under the terms of the ESPP, all regular employees can elect to have up to 15% of their annual compensation withheld to purchase shares of our common stock. The purchase price of the common stock is equal to 85% of the lower of the fair market value per share of the Company s common stock on the commencement date of the applicable offering period or the purchase date. No shares were purchased under the ESPP during 2005.

***Stock Options Granted to Non-employees***

As described in Footnote 1, under Stock-Based Compensation , the Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and EITF 96-18. The following table illustrates the weighted-average assumptions for the Black-Scholes model used in determining the fair value of options granted to non-employees:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| Dividend yield | 0% | 0% | 0% |
| Risk-free interest rate | 4.34% | 4.34% | 4.33% |
| Volatility | 70% | 70% | 70% |
| Expected life | 10 years | 10 years | 10 years |

During the years ended December 31, 2005, 2004 and 2003, the Company granted options to purchase 4,838, 50,258 and 12,531 shares, respectively, of common stock to consultants at a weighted-average exercise price of $0.62, $0.62 and $0.96 per share, respectively. These options generally vest over a four-year period and have a ten year life. The related stock-based compensation expense was $130,000, and $83,000 for the years ended December 31, 2005 and 2004 respectively, and was not material during the year ended December 31, 2003.

**6. Income Taxes**

Significant components of the Company s deferred tax assets as of December 31, 2005 and 2004 are shown below. Valuation allowances of $23,648,000 and $17,573,000 were established at December 31, 2005 and 2004, respectively, as realization of such assets is uncertain.

| | December 31, | |
|---|---|---|
| | 2005 | 2004 |
| | (in thousands) | |
| Deferred tax assets: | | |
| Net operating loss carryforwards | $ 13,879 | $ 12,466 |
| Research and development credits | 2,368 | 2,050 |
| Capitalized research and development | 7,007 | 2,461 |
| Other, net | 394 | 596 |
| Total deferred tax assets | 23,648 | 17,573 |
| Valuation allowance | (23,648) | (17,573) |
| Net deferred tax assets | $ | $ |

Table of Contents

**CryoCor, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

At December 31, 2005, the Company had federal and California tax net operating loss carryforwards of approximately $36.5 million and $19.3 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 $1.5 million and $1.3 million, respectively. The federal research and development credit will begin expiring in 2020, unless previously utilized.

At December 31, 2005, the Company s wholly owned foreign subsidiary did not have tax net operating loss carryforwards.

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.

**7. Related Party Transactions**

During 2002, the Company issued a 6% interest-bearing loan of $650,000 to the former Chief Executive Officer (the former CEO ), secured by a second deed of trust on his personal residence. In 2002, $350,000 of the loan was repaid and $125,000 was forgiven in accordance with terms in the former CEO s amended employment agreement. The remaining balance of $175,000 was repaid in equal amounts, plus accrued interest, over a three-year period, pursuant to the terms of a Secured Promissory Note dated November 30, 2002.

CryoCor GmbH leases office space in Germany from Innovative Medical Products GmbH ( IMed Pro ) and retains IMed Pro for consulting services associated with supporting some of the Company s commercial centers. In addition, an employee of CryoCor GmbH utilizes a car leased in IMed Pro s name, the costs for which are reimbursed by the Company. The Company s former CEO, a current member of the Company s Board of Directors, is a general manager of IMed Pro. During the years ending December 31, 2005, 2004 and 2003, the Company made payments to IMed Pro of approximately $147,000, $95,000 and $80,000, respectively for these operating costs.

**8. 401(k) Defined Contribution Plan**

During 2000, the Company adopted a 401(k) defined contribution plan (the 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 nonelective 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 nonelective 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, 2005, the Company had made no contributions to the Plan.

Table of Contents

**CryoCor, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**9. Quarterly Financial Information (unaudited)**

Summarized quarterly results of operations for the years ended December 31, 2005 and 2004 are as follows (in thousands, except per share amounts):

| | Year ended December 31, 2005 | | | |
|---|---|---|---|---|
| | First | Second | Third | Fourth |
| Product sales | $ 329 | $ 201 | $ 152 | $ 161 |
| Cost of sales | 697 | 778 | 650 | 699 |
| Research and development expenses | 1,711 | 2,343 | 1,831 | 2,196 |
| 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) |

| | Year ended December 31, 2004 | | | |
|---|---|---|---|---|
| | First | Second | Third | Fourth |
| Product sales | $ 157 | $ 160 | $ 141 | $ 35 |
| Cost of sales | 663 | 664 | 638 | 835 |
| Research and development expenses | 1,670 | 1,768 | 2,056 | 2,150 |
| Net loss attributable to common stockholders | (3,957) | (4,367) | (5,545) | (6,446) |
| Basic and diluted net loss per common share | (177.92) | (195.95) | (236.54) | (171.86) |

**10. Subsequent Event**

In January 2006, the Company received a communication from the FDA that its application for premarket approval ( PMA ) for the treatment of atrial flutter was not approvable at present because the data presented did not meet the FDA s chronic efficacy criteria. The Company is evaluating whether it should amend its PMA based on a different analysis of chronic efficacy. There can be no assurance that the Company will decide to amend its PMA for the treatment of atrial flutter, or if it does, that the FDA will accept its analysis or approve the PMA.