CRYOCOR INC
Form 10-K
March 30, 2007
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS

PURSUANT TO SECTION 13 OR 15(d) OF THE

SECURITIES EXCHANGE ACT OF 1934

(Mark One)

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

OR

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

Commission file number 000-51410

CRYOCOR, INC.

(Exact Name of Registrant as Specified in its Charter)

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

9717 Pacific Heights Boulevard

San Diego, California 92121

(Address of Principal Executive Offices, including Zip Code)

(858) 909-2200

(Registrant s Telephone Number, Including Area Code)

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

Common Stock, $0.001 par value

(Title of Class)

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

None.

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

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

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

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

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

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

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE

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

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CRYOCOR, INC.

ANNUAL REPORT ON FORM 10-K

For the Year Ended December 31, 2006

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PART I

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

ITEM 1. BUSINESS

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

Overview

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

We have filed an application for premarket approval, or PMA, with the United States Food and Drug Administration, or FDA, for the treatment of AFL with our CryoCor Cardiac Cryoablation System, or cryoablation system. Our PMA was filed initially in July 2005. In January 2006, we were notified by the FDA that the PMA was not approvable at that time as the data presented did not meet the FDA s chronic effectiveness criteria. Subsequent to receiving the non-approvable letter, during 2006, we reevaluated the chronic effectiveness

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for each subject treated in the study, and, after meeting with the FDA, we amended our PMA for the treatment of AFL based on this different analysis of chronic effectiveness. In this analysis, we computed our chronic effectiveness to be greater than 80%. We met with the FDA in February 2007 to discuss the status of their review of our PMA amendment, and were notified that the FDA accepted the process by which our data was analyzed and that the FDA intended to convene an Advisory Panel meeting to advise the FDA on the evaluation of chronic effectiveness in our PMA. In subsequent discussions with the FDA, we provided additional information that we believe supports our basis for approval, and that has resulted in a higher computation of chronic effectiveness than previously submitted. The FDA decided to postpone the Advisory Panel meeting for CryoCor while they evaluate the additional information, and the FDA has indicated that it may no longer be necessary to convene an Advisory Panel meeting. We anticipate that the FDA will render a decision on the approval of our PMA by August 2007. Although we believe our clinical data demonstrate adequate safety and effectiveness to support FDA approval, there can be no assurance that our product will be approved by the FDA for the treatment of AFL.

We are currently enrolling a pivotal trial for the treatment of AF, and expect to complete enrollment in our trial in the second quarter of 2007. As of March 28, 2007, we need to enroll nine to 16 additional patients to allow us to have the required population of evaluable patients. We will need to collect safety and effectiveness data on 140 evaluable patients, 70 that have been treated with cryoablation, and 70 that have been treated with medical management, and we anticipate needing to enroll between 166-173 patients to generate the required number of evaluable patients. In January 2007, the FDA approved our request to increase the size of our pivotal trial, as the trial was initially planned to enroll 160 patients. Some patients in our trial withdrew for various reasons, including being randomized to medical management, or being denied coverage for the procedure by their insurance company. We believe our pivotal trial for the treatment of AF is significantly further along than any competing ablation catheter trial, and we estimate our lead time in enrolling our clinical trial is between 12-18 months ahead of the enrollment pace of the next most advanced AF pivotal trial. Based upon the anticipated timelines for completion of enrollment of our pivotal trial, and the time required to follow our patients subsequent to their cryoablation treatments, we anticipate that we will file a PMA for the treatment of AF in mid-2008, and that a decision from the FDA on whether or not to approve our cryoablation system for the treatment of AF will be received in 2009.

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

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

Our product, the cryoablation system, is designed to treat cardiac arrhythmias through the use of extreme cold, or cryoenergy, to ablate, or destroy, targeted cardiac cells. Unlike radiofrequency, or RF, and other heat-based ablation technologies, which can destroy both the targeted cardiac cells and the extracellular material that binds the cells together, cryoablation leaves the material surrounding the cardiac cells fully intact. As a result, cryoablation may reduce the occurrence and severity of complications observed with heat-based ablation

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technologies. Our cryoablation system utilizes our proprietary technology that allows it to generate, deliver and transfer high levels of cryoenergy enabling large lesion sizes, shorter procedure times and enhanced system versatility. We believe these advantages provide better therapeutic efficacy and give us a greater ability to treat the more complex arrhythmias such as AF and AFL than competing cryoablation technologies. We believe our cryoablation system eliminates or reduces many of the drawbacks and risks associated with surgical and other catheter-based ablation procedures.

The Normal Heart

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

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

Heart Rate and Rhythm Disorders

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

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Abnormal tachycardias can be characterized in the following ways:

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

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

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

Supraventricular Tachycardias

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

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

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

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

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

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

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

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

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Market Overview

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

Atrial Fibrillation

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

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

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

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

Atrial Flutter

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

Conventional Treatments and Their Limitations

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

Cardioversion

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

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

Drug Therapy

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

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

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

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

Cardiac Ablation

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

Surgical Ablation

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

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

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

Minimally Invasive, Catheter-Based Ablation

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

RF Ablation

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

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

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

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

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

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

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

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

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

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

Cryoablation

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

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

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

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We believe the principal benefits of our cryoablation system are:

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

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

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

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

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

Our Strategy

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

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

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

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

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

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

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

CryoCor Cardiac Cryoablation System

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

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

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

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Console and Pre-Cooler

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

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

Disposables

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

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

Quantum Catheter

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

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The CryoCor Cryoablation Procedure

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

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

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

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

AF Cryoablation Procedure

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

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

AFL Cryoablation Procedure

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

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CryoCor s Clinical Development Program and Status

Overview

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

Clinical Status in the United States

We have filed an application for premarket approval, or PMA, with the United States Food and Drug Administration, or FDA, for the treatment of AFL with our CryoCor Cardiac Cryoablation System, or cryoablation system. Our PMA was filed initially in July 2005. In January 2006, we were notified by the FDA that the PMA was not approvable at that time as the data presented did not meet the FDA s chronic effectiveness criteria. Subsequent to receiving the non-approvable letter, during 2006, we reevaluated the chronic effectiveness for each subject treated in the study, and, after meeting with the FDA, we amended our PMA for the treatment of AFL based on this different analysis of chronic effectiveness. In this analysis, we computed our chronic effectiveness to be greater than 80%. We met with the FDA in February 2007 to discuss the status of their review of our PMA amendment, and were notified that the FDA accepted the process by which our data was analyzed and that the FDA intended to convene an Advisory Panel meeting to advise the FDA on the evaluation of chronic effectiveness in our PMA. In subsequent discussions with the FDA, we provided additional information that we believe supports our basis for approval, and that has resulted in a higher computation of chronic effectiveness than previously submitted. The FDA decided to postpone the Advisory Panel meeting for CryoCor while they evaluate the additional information, and the FDA has indicated that it may no longer be necessary to convene an Advisory Panel meeting. We anticipate that the FDA will render a decision on the approval of our PMA by August 2007. Although we believe our clinical data demonstrate adequate safety and effectiveness to support FDA approval, there can be no assurance that our product will be approved by the FDA for the treatment of AFL.

We are currently enrolling a pivotal trial for the treatment of AF, and expect to complete enrollment in our trial in the second quarter of 2007. As of March 28, 2007, we need to enroll nine to 16 additional patients to allow us to have the required population of evaluable patients. We will need to collect safety and effectiveness data on 140 evaluable patients, 70 that have been treated with cryoablation, and 70 that have been treated with medical management, and we anticipate needing to enroll between 166-173 patients to generate the required number of evaluable patients. In January 2007, the FDA approved our request to increase the size of our pivotal trial, as the trial was initially planned to enroll 160 patients. Some patients in our trial withdrew for various reasons, including being randomized to medical management, or being denied coverage for the procedure by their insurance company. We believe our pivotal trial for the treatment of AF is significantly further along than any competing ablation catheter trial, and we estimate our lead time in enrolling our clinical trial at between 12-18 months ahead of the enrollment pace of the next most advanced AF pivotal trial. Based upon the anticipated timelines for completion of enrollment of our pivotal trial, and the time required to follow our patients subsequent to their cryoablation treatments, we anticipate that we will file a PMA for the treatment of AF in mid-2008, and that a decision from the FDA on whether or not to approve our cryoablation system for the treatment of AF will be received in 2009.

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AFL-02 Pivotal Trial

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

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

AFL Pivotal Trial (AFL-02)

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

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

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

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

AF-02 Pivotal Trial

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

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

Sales and Marketing

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

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

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Competition

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

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

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

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

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

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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