IMARX THERAPEUTICS INC
Form 10-K/A
April 03, 2008

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K/A
Amendment No. 1

þ **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the fiscal year ended December 31, 2007

o **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 001-33043

ImaRx Therapeutics, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**86-0974730**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
1730 East River Road, Tucson, AZ	**85718-5893**
(Address of Principal Executive Offices)	**(Zip Code)**

(520) 770-1259
(Registrant s Telephone Number, Including Area Code)
Securities registered pursuant to Section 12(b) of the Act:

Common Stock, $0.0001 par value	**NASDAQ Capital Market**
(Title of Each Class)	**(Name of Each exchange on Which Registered)**

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 o NO þ

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 o NO þ

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for at least the past 90 days. YES þ NO o

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. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting

company in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer o Accelerated Filer o Non-accelerated filer o Smaller reporting company þ
(Do not check if a smaller reporting company)

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

As of March 25, 2008, there were 10,046,683 shares of the Registrant s Common Stock outstanding. The Registrant s shares commenced trading on the NASDAQ capital market on July 26, 2007. Therefore, there was no active trading market for the Registrant s common equity as of June 30, 2007, the last business day of the Registrant s most recently completed second fiscal quarter. As of March 25, 2008, the aggregate market value of the Common Stock of the Registrant held by non-affiliates was approximately $3,451,954, based on the closing price per share of the Registrant s Common Stock on such date. This amount excludes an aggregate of 1,416,797 shares of Common Stock held by officers and directors and each person known by the Registrant to own 10% or more of the outstanding Common Stock. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the Registrant, or that the Registrant is controlled by or under common control with such person.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant s Proxy Statement for its 2008 Annual Meeting of Stockholders are incorporated by reference into Items 10 through 14 of Part III of this Report.

Explanatory Note

ImaRx Therapeutics, Inc. (the Company) is filing this Amendment No. 1 (this Amendment) on form 10-K/A to amend the Company s Form 10-K for the fiscal year ended December 31, 2007 (the Original Report) in order to (i) reflect that the provision for deferred federal and state income taxes should have been zero for each of the years ended December 31, 2005, 2006 and 2007 in Note 3 to the Company s Consolidated Financial Statements; (ii) reflect the fact that the basic and diluted net loss attributable to common shareholders should have been $0.22 for the quarter ended December 31, 2007 in Note 14 to the Company s Consolidated Financial Statements; and (iii) to reflect the offset to the increase in research and development expenses related to the Phase I/II clinical trial as $0.7 million in the Results of Operations of Management s Discussion and Analysis of Financial Condition and Results of Operations.

TABLE OF CONTENTS

Table of Contents

PART I

ITEM 1. BUSINESS

Overview

ImaRx Therapeutics, Inc. is a biopharmaceutical company commercializing and developing therapies for vascular disorders. Our commercialization efforts are focused on our urokinase product approved by the U.S. Food and Drug Administration, or FDA, for the treatment of acute massive pulmonary embolism, or blood clots in the lungs. Our development efforts are focused on our SonoLysis program which is focused on the development of therapies for stroke and other vascular disorders, using our proprietary microbubble technology together with ultrasound.

Our commercially available product, urokinase, is a thrombolytic drug, formerly marketed under the brand name Abbokinase® and currently being re-branded as Kinlytic . Urokinase is a natural human protein primarily produced in the kidneys that stimulates the body s natural clot-dissolving processes. Urokinase is FDA approved and marketed for the treatment of acute massive pulmonary embolism. Urokinase has been administered to over 4 million patients since its approval, and we estimate that approximately 700 acute care hospitals in the U.S. include urokinase on their pharmacy formulary today.

Our SonoLysis program is focused on the development of product candidates that involve the administration of our proprietary MRX-801 microbubbles and ultrasound to break up blood clots and restore blood flow to oxygen deprived tissues. We concluded a Phase I/II clinical trial involving the administration of MRX-801 microbubbles, ultrasound and the thrombolytic drug alteplase, or tPA, in patients suffering from acute ischemic stroke in January 2008. Because the safety data following the second cohort indicated that there were a greater number of intracranial hemorrhage events observed in subjects receiving treatment relative to controls in the second cohort, we concluded the study based on these findings. We are evaluating strategic alternatives for continued pursuit and financing of our SonoLysis program.

Market Opportunity

Pulmonary Embolism. According to the American Heart Association, each year approximately 600,000 people in the U.S. experience a blood clot that lodges in the lungs, known as a pulmonary embolism, with approximately 60,000 deaths occurring annually. A portion of these are classified as acute massive pulmonary emboli, meaning that they involve obstruction of blood flow to a lobe or multiple segments of the lungs.

Ischemic Stroke. Approximately 700,000 adults in the U.S., or one every 45 seconds, are afflicted with, and 150,000 die as a result of, some form of stroke each year. Stroke is currently the third leading cause of death, and the leading cause of disability, in the United States. Approximately 3 million Americans are currently disabled from stroke. The American Stroke Association estimates that approximately $62.7 billion was spent in the U.S. in 2007 for stroke-related medical costs and disability. The vast majority of strokes, approximately 87% according to the American Stroke Association, are ischemic in nature, meaning that they are caused by blood clots, while the remainder are the more deadly hemorrhagic strokes caused by bleeding in the brain. However, available treatment options for ischemic stroke are subject to significant therapeutic limitations. For example, the most widely used treatment for ischemic stroke is a clot-dissolving, or thrombolytic, drug that can be administered only during a narrow time window and poses a risk of bleeding, resulting in 7% or less of ischemic stroke patients receiving such treatment. To facilitate increased administration of stroke therapies, the American Stroke Association and related groups have urged the Centers for Medicare and Medicaid Services, or CMS, to create a new code to reimburse hospitals at a higher rate for ischemic stroke patients treated with a thrombolytic drug. In 2005, in response to requests by the American Stroke Association and related groups for higher reimbursement amounts for ischemic stroke patients treated with a thrombolytic drug, the CMS approximately doubled the amount of reimbursement provided for such treatment, to $11,578 per patient.

Table of Contents

Our Commercial and Development Stage Products

Kinlytic. Our commercially available product, urokinase, formerly marketed as Abbokinase, and now being re-branded by us as Kinlytic, is a thrombolytic drug. Urokinase is a natural human protein primarily produced in the kidneys that stimulates the body s natural clot-dissolving processes. Urokinase is FDA approved and marketed for the treatment of acute massive pulmonary embolism. Urokinase has been administered to over 4 million patients since its approval, and we estimate that approximately 700 acute care hospitals in the U.S. include urokinase on their pharmacy formulary today.

In April 2006, we acquired from Abbott Laboratories the assets related to urokinase, including the remaining inventory of finished product, all regulatory and clinical documentation, validated cell lines, and intellectual property rights, including trade secrets and know-how relating to the manufacture of urokinase using the tissue culture method. We began selling urokinase in October 2006. To date, urokinase has been marketed by Abbott Laboratories and us under the trade name Abbokinase. Our agreement with Abbott Laboratories prohibits us from marketing urokinase under the Abbokinase trade name beyond the expiration date of the inventory at the time we acquired it. In May 2007 we obtained FDA approval to market urokinase under the trade name Kinlytic and have begun efforts to rebrand the product under the trade name Kinlytic.

The urokinase inventory that we acquired from Abbott Laboratories in April 2006 consisted of both labeled and unlabeled vials of finished product. Once product is labeled, we cannot extend the expiration date of the labeled vials. Once labeled vials expire, they are no longer saleable. As of December 31, 2007, 24% of the vials held in inventory by us or our wholesale distributors were labeled and will expire at various times up to September 2009. The remaining 76% of the vials, as of December 31, 2007 were unlabeled and based on current stability data are not saleable after September 2009. We are conducting an ongoing stability program to extend the expiration dates of our inventory of urokinase. The testing to date has shown that the product changes very little from year to year. For instance, in September 2007 the stability data supported an extension of the inventory expiration date to between July and September of 2009. Based on this extended stability data, the FDA approved the release of three lots of inventory for commercial sale in the first quarter of 2008 that we anticipate will supply the market through September 2009. In order to continue selling existing inventory beyond September, 2009, we would need to conduct stability testing to support additional expiration date extensions into the future.

In connection with our Abbokinase acquisition, we issued a $15.0 million non-recourse promissory note to Abbott Laboratories that matures on March 31, 2008. We agreed to place 50% of the proceeds from our sales of urokinase after the first $5.0 million of sales into an escrow account as collateral for the note. If we are unable to satisfy the remaining debt obligation on this note including accrued interest when due, Abbott Laboratories will have the right to reclaim our remaining inventory of urokinase, as well as all proceeds placed in the escrow account. As of December 31, 2007, the outstanding balance of the note plus accrued interest was $11.7 million. The balance in the escrow account as of March 25, 2008 was $1.1 million. If the amount in escrow were to be applied to the outstanding balance of the promissory note, the remaining balance due under the note after such payment would be approximately $10.8 million as of March 31, 2008. We have reached a tentative agreement with Abbott Laboratories regarding payment of the note which we believe will enable us to continue commercializing urokinase. We believe final agreement with Abbott Laboratories will be completed in the second quarter of 2008. In the event, we are not successful in renegotiating the payment terms of the note, Abbott Laboratories may elect to foreclose on the urokinase assets which aggregate $15.3 million at December 31, 2007.

In January 2008, we entered into a letter of intent with Microbix Biosystems which provides for manufacture of a long-term urokinase supply. Manufacture of additional urokinase will allow us to continue to serve our customers beyond exhaustion of our current inventory, and will also make it possible for us to expand our urokinase sales to additional vascular and acute care institutions. With an additional supply of urokinase, we may research and evaluate additional therapeutic applications for the product as well.

SonoLysis Program. Our SonoLysis program is focused on the development of a product candidate that involves the administration of our proprietary MRX-801 microbubbles and ultrasound to break up blood clots and restore blood flow to oxygen deprived tissues. Our MRX-801 microbubbles are a proprietary formulation of a lipid shell encapsulating an inert biocompatible gas. We believe the sub-micron size of our MRX-801 microbubbles allows them

to penetrate a blood clot, so that when ultrasound is applied their expansion and contraction, or cavitation, can break the clot into very small particles. We believe that our SonoLysis product candidate has the potential to treat a broad variety of vascular disorders associated with blood clots.

Table of Contents

Our initial therapeutic focus for our SonoLysis program is ischemic stroke. The only FDA approved drug for the treatment of ischemic stroke is tPA. The FDA has restricted tPA s use only to patients who are able to begin treatment within three hours of onset of symptoms of ischemic stroke and who do not have certain risk factors for bleeding, such as recent surgery or taking medications that prevent clotting. To administer our SonoLysis therapy, MRX-801 microbubbles are injected intravenously into the bloodstream, disperse naturally throughout the body and are carried to the site of the blood clot. Ultrasound is then administered to the site of the blood clot, and the energy from the ultrasound causes the MRX-801 microbubbles to expand and contract vigorously, or cavitate. We believe this cavitation both mechanically breaks up the blood clot and helps to enhance the body s natural clot dissolving processes. The gas released by the MRX-801 microbubbles is then cleared from the body by exhaling, and the lipid shell is processed like other fats in the body. Because SonoLysis therapy has the potential to be used without a thrombolytic drug and its associated risk of bleeding, we believe SonoLysis therapy may offer advantages over existing treatments for ischemic stroke, including extending the treatment window beyond three hours from onset of symptoms and broadening treatment availability to patients for whom thrombolytic drugs are contraindicated due to risk of bleeding.

In January 2008, we suspended enrollment in our Phase I/II randomized, placebo controlled clinical trial designed to evaluate the safety, tolerability and activity of escalating doses of MRX-801microbubbles and ultrasound as an adjunctive therapy to tPA treatment in subjects with acute ischemic stroke. Because the safety data following the second cohort indicated that there were a greater number of intracranial hemorrhage events observed in subjects receiving treatment relative to controls in the second cohort, we concluded the study based on these findings. This effect was not observed in subjects treated in the first cohort. We have not yet conducted any clinical trials using our proprietary MRX-801 microbubbles with ultrasound to treat blood clot indications without a thrombolytic drug. We estimate that if approved by the FDA over 200,000 ischemic stroke patients in the U.S. could be eligible for SonoLysis therapy.

We are currently evaluating various strategic alternatives for funding and continuation of our SonoLysis therapy research and development program.

*Additional Research Stage Opportunities***.** The status of our research stage programs is summarized as follows:

Targeted SonoLysis Therapy. Our research team has developed MRX-802 as a potential next generation SonoLysis microbubbles with targeting technology that causes the microbubbles to bind to blood clots. We have demonstrated in laboratory experiments that our MRX-802 targeted microbubbles improve binding to blood clots. We believe that our MRX-802 targeted microbubbles may have a greater ability to break-up blood clots than non-targeted microbubbles when combined with ultrasound. We have conducted preclinical animal studies with academic collaborators evaluating MRX-802 targeted microbubbles and ultrasound to treat various clot disorders, including myocardial infarction. To further the research on this technology, we have received and are near the end of our work on an approximately $1.2 million grant from the National Institutes of Health, or NIH, to study MRX-802 targeted microbubbles to treat vascular clots. Upon conclusion of the work supported by the NIH grant we will evaluate future research activities with this technology.

Targeted Drug Delivery. In addition to our targeted SonoLysis technology, our research team has demonstrated the ability to add a drug payload to our microbubbles or use a liquid instead of a gas core to create sub-micron sized targeted droplets for drug delivery. Our research team was previously conducting targeted drug delivery research using our MRX-803 microbubble under a subcontract with the NIH. In August of 2007, we received an approximately $950,000 Phase I STTR grant from the National Institute of Neurological Disorders and Stroke, a division of the National Institutes of Health (NIH) to study the changes in the permeability of the blood-brain barrier with our proprietary MRX-809 targeted microbubbles and ultrasound. Upon conclusion of the work supported by this grant we will evaluate future research activities with this technology.

We have suspended research efforts on other research programs, including our proprietary MRX-804 emulsion/microbubbles which we call Nan0_2 as a potential oxygen-delivery technology due to funding constraints.

We estimate that we spent approximately $7.4 million in 2007 and $9.1 million in 2006 on our SonoLysis program

and other research and development programs.

Table of Contents

Our Business Strategy

Our goal is to be a leading provider of therapies for vascular disorders. The key elements of our business strategy are to:

Continue to sell our urokinase inventory and benefit from our commercial relationships;

Leverage our commercial platform to create a portfolio of complimentary commercial products over time; and

Evaluate and enter into strategic development alternatives for our SonoLysis program.

Industry Background

The formation of a blood clot is a natural process by which blood thickens and coagulates into a mass of blood cells, platelets and strands of fibrin. Thrombosis occurs when a blood clot, or thrombus, begins to block a blood vessel. Formation of a clot is the body s primary mechanism for obstructing blood flow and curtailing bleeding from wounds or other injuries to blood vessels. Blood clots can be caused by a variety of factors other than injury or trauma, such as the rupture of vulnerable plaque in a vessel. Blood clots can also arise in connection with surgical and other medical procedures, such as catheter-based administration of dialysis or other treatments, which can lead to clotting around the site of an incision or within a penetrated blood vessel. An embolism occurs if all or part of a blood clot breaks away and lodges in another part of the body. When a blood clot blocks normal blood flow within the body, it can have a variety of undesirable effects, such as causing pain and swelling, ischemia or tissue damage, stroke, or even death. Over 8 million people in the U.S. are afflicted each year with complications related to blood clots. Our business is currently focused primarily on two segments of the thrombosis market in which safe and rapid removal of blood clots is essential for patient care, namely ischemic stroke and acute massive pulmonary embolism.

Acute Massive Pulmonary Embolism

According to the National Institutes of Health, approximately 600,000 people in the U.S. every year experience a blood clot that lodges in the lungs, known as a pulmonary embolism. A portion of these are classified as acute massive pulmonary emboli, meaning that they involve obstruction of blood flow to a lobe or multiple segments of the lungs. Acute massive pulmonary emboli, which result in nearly 60,000 deaths in the U.S. annually, must be treated quickly, as most of these deaths occur within 30 to 60 minutes after the onset of symptoms.

Ischemic Stroke

Approximately 700,000 adults in the U.S., or one every 45 seconds, are afflicted with, and 150,000 die as a result of, some form of stroke each year. Stroke is currently the third leading cause of death, and the leading cause of disability, in the United States. Approximately 3 million Americans are currently disabled from stroke. The American Stroke Association estimates that approximately $62.7 billion will be spent in the U.S. in 2007 for stroke related medical costs and disability.

The vast majority of strokes, approximately 87% according to the American Stroke Association, are ischemic strokes, meaning that they are caused by blood clots, while the remainder are hemorrhagic strokes, or caused by bleeding in the brain, and are more deadly. However, available treatment options for ischemic stroke are subject to significant therapeutic limitations. For example, the most widely used treatment for ischemic stroke is a clot-dissolving, or thrombolytic, drug that can be administered only during a narrow time window and poses a risk of bleeding, resulting in 7% or less of ischemic stroke patients receiving such treatment.

When blood clots block arteries that supply blood to the brain, they reduce the oxygen supply to brain tissues, a condition known as cerebral ischemia which can gradually degrade the oxygen-deprived tissues and result in long-term impairment of brain functions. More than 600,000 Americans have an ischemic stroke each year. Approximately 80% of U.S. ischemic stroke patients reach an emergency room within 24 hours after the onset of stroke symptoms, according to Datamonitor; but by contrast, only about 28% of U.S. ischemic stroke patients reach an emergency room within the FDA-mandated three-hour time window for treatment with the currently approved thrombolytic drug, tPA. Due to this three-hour treatment window and other limitations, according to Datamonitor only 1.6% to 2.7% of patients with ischemic stroke in community hospitals, and only 4.1% to 6.3% in academic hospitals or specialized stroke centers, are treated with thrombolytic therapy.

Table of Contents

Existing Blood Clot Therapies and Their Limitations

Various different treatments currently exist for the prevention and treatment of blood clots. Aspirin and other anti-platelets as well as heparin and other anticoagulants are commonly used to prevent or reduce the incidence of blood clots, but have no effect in eliminating such blood clots once they have formed. We focus on the treatment of blood clots once they have formed. Currently available therapeutic approaches for dissolving or otherwise eradicating blood clots before they cause serious medical consequences or death fall into two categories: clot-dissolving drugs, or thrombolytics, and mechanical devices and procedures.

Thrombolytic Drugs

Thrombolytic drugs dissolve blood clots by breaking up fibrin, the protein that provides the structural scaffold of blood clots. The most widely used thrombolytic drug today is a form of tissue plasminogen activator, commonly referred to as tPA. tPA is marketed in several different formulations that are approved for a variety of specific vascular disorders, such as: alteplase for acute ischemic stroke, acute massive pulmonary embolism, central venous catheter clearance and acute myocardial infarction; and reteplase and tenecteplase for acute myocardial infarction. Other thrombolytic agents include our product urokinase, formerly marketed as Abbokinase, and now being re-branded by us as Kinlytic which is approved for treatment of acute massive pulmonary embolism; and streptokinase, which is approved for treatment of acute massive pulmonary embolism, acute myocardial infarction and deep vein thrombosis. Worldwide annual sales of thrombolytic drugs are approximately $500 million.

Thrombolytic drugs involve a variety of risks and potential side effects that can limit their usefulness:

Risk of Bleeding Thrombolytic drugs dissolve blood clots, including those formed naturally as a protective response to vessel injury, which can result in bleeding. The risk of bleeding increases relative to the dosage and duration of treatment and differs among the various thrombolytic drugs. Patients who are already taking other medications to prevent formation of clots, such as anticoagulants or antiplatelets, also may not be good candidates for the use of thrombolytic drugs, due to the increased difficulty of controlling bleeding. As a result, thrombolytic drugs are approved by the FDA subject to strict limitations on when, how long and in what dosages they can be administered.

Time Window for Administration Due to the risk of bleeding, which increases over time, tPA is only approved for administration to ischemic stroke patients within three hours after the onset of stroke symptoms. This three-hour window is considered to be one of the primary limiting factors in treating ischemic stroke. Approximately 28% of ischemic stroke patients in the U.S. recognize their symptoms and reach an emergency room within the three-hour window. However, due to other limitations, fewer than 7% of U.S. ischemic stroke patients ultimately receive treatment with a thrombolytic drug.

Possible Immune Response Some patients experience an immune response due to the continued administration of thrombolytic drugs. For example, thrombolytic drugs that are based on non-human biological material, such as streptokinase, which is produced using streptococcus bacteria, may stimulate such an immune reaction.

Mechanical Devices and Procedures

There are several mechanical means for removing or destroying blood clots. Thrombectomy, or surgical clot removal, is used to treat patients with occluded dialysis grafts and some clots in the peripheral vascular system as well as in acute massive pulmonary embolism. These procedures are invasive and entail delays, costs and risks that accompany any major surgery. Although these procedures are less suitable for removing blood clots from the brain, there are devices approved for these cranial surgical procedures.

Table of Contents

In addition, there are some mechanical devices that can be introduced through a catheter-based delivery system to mechanically break up a blood clot, or to ensnare and retract a clot through the vascular system and out of the body. These mechanical devices are generally not found outside of major medical centers, as they require a catheter laboratory and skilled personnel to administer the therapy. While they do not cause the same bleeding risk as thrombolytic drugs, these mechanical interventions pose some risk of damaging other tissues during treatment, as well as a risk of breaking off a piece of the clot that can itself become the cause of a stroke or embolism in some other part of the body.

Manufacturing

In January 2008, we entered into a letter of intent with Microbix Biosystems providing for the transfer of the manufacturing process for urokinase to Microbix. Closing of the transaction is dependent upon the satisfactory completion of due diligence, Microbix securing the necessary capital resources and obtaining approval from Abbott Laboratories. If successful, this arrangement would provide for manufacture of a long-term urokinase supply. Manufacture of additional urokinase will allow us to continue to serve our current customers beyond exhaustion of our current inventory, and will also make it possible for us to expand our urokinase sales to additional vascular and acute care institutions. With an additional supply of urokinase, we may research and evaluate additional therapeutic applications for the product as well.

Our contract manufacturers will be subject to unannounced inspections by the FDA and corresponding foreign and state agencies to ensure strict compliance with the FDA s current Good Manufacturing Practices, or cGMP, and other applicable governmental quality control and record-keeping regulations. In addition, transfer of ownership of products could trigger a manufacturing inspection requirement from the FDA. We do not have control over and cannot ensure third-party manufacturers compliance with these regulations and standards. If one of our manufacturers fails to maintain compliance, the production of our products or product candidates could be interrupted, which could result in substantial delays, additional costs and lost sales.

We have contracted with a third party to produce small quantities of our MRX-801 microbubbles for clinical research purposes. We manufacture MRX-804 internally in small quantities for research and preclinical purposes.

Sales and Marketing

We commenced selling urokinase in the U.S. in October 2006. Our internal sales and marketing staff, currently consisting of three individuals, manages our relationships with third-party distribution partners and institutional urokinase customers, and oversees our related direct and indirect advertising and promotional activities. We intend to focus our sales and marketing activities on servicing the existing demand for urokinase through existing distribution channels, and we believe that our current staffing will be sufficient to meet these needs.

Competition

The market for therapies to treat vascular disorders associated with blood clots is highly competitive. Numerous companies either offer or are developing competing treatments for ischemic stroke and acute massive pulmonary embolism. Many of these competitors have significantly greater financial resources and expertise in development and regulatory matters than we do, as well as more established products, distribution and reimbursement. We expect that our competitors will also continue to develop new or improved treatments for the vascular disorders we are targeting. There are two principal groups of competitors offering treatments to break up or remove blood clots: thrombolytic drug companies, and vendors of mechanical thrombectomy or similar devices.

Table of Contents

Thrombolytic Drug Competitors

The U.S. market for thrombolytic drugs is dominated by Genentech, Inc., which manufactures tPA, the most widely used thrombolytic drug. We are currently not a significant competitor to Genentech in the sale of thrombolytic drugs, since our only approved product, urokinase, has a single FDA-approved label claim for treatment of acute massive pulmonary embolism. Genentech s tPA in various formulations is currently the only thrombolytic drug that has been approved by the FDA for treatment of ischemic stroke, and is also approved for acute massive pulmonary embolism, as well as catheter occlusion clearance and myocardial infarction indications. We are aware that other thrombolytic drugs are also under development, such as desmoteplase, which is a recombinant form of a derivative of vampire bat saliva being developed by PAION AG, and ancrod, which is an enzyme derived from Malaysian pit viper venom being developed by Neurobiological Technologies, Inc., both of which are being developed for treatment of ischemic stroke. Other companies also offer or are developing thrombolytic drugs for treatment of blood clots associated with myocardial infarction and peripheral vascular occlusions, but since we view thrombolytic drugs as complementary to our SonoLysis therapy, we do not consider those product offerings or programs to be competitive with our current business strategy.

Device Competitors

We believe that one of the primary device-based treatment for ischemic stroke clots is the Mechanical Embolus Removal in Cerebral Ischemia retrieval system or the MERCI system, which is an intravascular catheter-based therapy marketed by Concentric Medical, Inc. This device is used to engage the clot and retract it through the catheter and out of the body. On January 7, 2008, Penumbra, Inc. announced 510(k) clearance of the Penumbra system for use in the revascularization of patients with acute ischemic stroke. The Penumbra System is comprised of an aspiration platform containing multiple devices that are size-matched to the specific neurovascular anatomy allowing clots to be gently aspirated out of intracranial vessels. Other devices are also approved and marketed for treating blood clots associated with peripheral vascular and coronary indications and with dialysis access grafts, such as the Fogarty Catheter by Edwards Lifesciences, formerly a division of Baxter International, AngioJet by Possis Medical, Inc., Micro-Infusion Catheter by EKOS Corp., and Resolution Endovascular System by OmniSonics Medical Technologies, Inc. A variety of companies also offer catheter-delivery systems for thrombolytic drugs or other drugs used in the treatment of blood clots, but we do not consider these devices to be directly competitive with our current business strategy.

We are unaware of any other companies that are developing microbubble technologies for therapeutic use in vascular disorders.

Patents and Proprietary Rights

Our success depends in part on our ability to develop a competitive advantage over potential competitors for the use of microbubbles and ultrasound for treatment of blood clots and vascular diseases in various parts of the body. Our ability to obtain intellectual property that protects our MRX-801 microbubbles and ultrasound treatment in the presence or absence of drugs will be important to our success. Our strategy is to protect our proprietary positions by, among other things, filing U.S. and foreign patent applications related to our technology, inventions and improvements that are directed to the development of our business and our competitive advantages. Our strategy also includes developing know-how and trade secrets, and licensing technology related to bubbles and ultrasound from third parties. We own 57 issued U.S. patents, 30 U.S. pending patent applications, 41 foreign patents and 72 international or foreign patent applications. In addition, we have licensed patents from third parties that grant us rights to 82 U.S. patents, at least five U.S. patent applications, and their respective international and foreign patent and patent application counterparts.

The U.S. patents that we own cover certain applications related to microbubble compositions and methods of making and using such microbubbles with ultrasound for the treatment of blood clots. Patents that cover our core technology expire between 2009 and 2024.

We have several pending patent claims, including allowed claims that have not yet issued, that cover additional elements of our microbubble technology. We plan to file additional patent applications on inventions that we believe are patentable and important to our business and intend to aggressively pursue and defend patent protection on our proprietary technologies.

Our ability to operate without infringing the intellectual property rights of others and to prevent others from infringing our intellectual property rights will also be important to our success. To this end, we have reviewed all patents owned by third parties of which we are aware that are related to microbubble technology and gas filled vesicles, in the presence or absence of ultrasound, and thrombolysis using gas filled vesicles, and believe that our current products do not infringe any valid claims of the third party patents that we have analyzed. There are a large number of patents directed to therapies for blood clots, and there may be other patents or pending patent applications of which we are currently unaware that may impair our ability to operate. We are currently not aware of any third parties infringing our issued claims.

Table of Contents

In July 2003 we received a notice from a third party who owns a patent relating to the administration of ultrasound to break up blood clots indicating that we may need a license to its patent if we intend to administer our therapies according to the methods claimed in its patent.

When appropriate, we actively seek protection for our products, technologies, know-how and proprietary information by licensing intellectual property from third parties. We have obtained rights relating to our product candidates and future development programs from third parties as appropriate.

Government Regulation

We are subject to extensive regulation by the FDA and comparable regulatory agencies in state, local and foreign jurisdictions in connection with the development, manufacture and commercialization of our product candidates.

Categories of Regulation

In the U.S., our marketed product is subject to regulation as a biologic, which are drugs derived from a living source. In some cases, our product candidates may fall into multiple categories and require regulatory approval in more than one category. For example, urokinase is a biologic, but it is subject to regulation as a drug. Our SonoLysis therapy involves a combination of drug and device, which would require approval as a combination product before we could market either of these therapies. Our proprietary MRX-801 microbubbles, which are injected into the bloodstream, have been designated as a drug by the FDA. Outside the U.S., our product candidates are also subject to regulation as drugs, biologics or medical devices, and must meet similar regulatory hurdles as in the U.S. to gain approval and reach the market.

Drug and Biologics Regulation

The process required by the FDA before drug or biologic product candidates may be marketed in the U.S. generally involves the following:

- preclinical laboratory and animal tests;
- submission and approval of an Investigational New Drug application, or IND application;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of proposed drugs for their intended use and safety, purity and potency of biologic products for their intended use;
- preapproval inspection of manufacturing facilities, company regulatory files and selected clinical investigators;
- for drugs, FDA approval of a new drug application, or NDA, or FDA approval of an NDA supplement in the case of a new indication if the product is already approved for another indication; and
- for biologics, FDA approval of a biologics license application, or BLA, or FDA approval of a BLA supplement in the case of a new indication if the product is already approved for another indication.

Table of Contents

Prior to commencing the first human clinical trial, we must submit an IND application to the FDA. The IND application automatically becomes effective 30 days after receipt by the FDA, unless the FDA within such period raises concerns or questions about the preclinical drug testing or nonclinical safety evaluation in animals, or the design or conduct of the first proposed clinical trial. In such a case, the IND application sponsor and the FDA must resolve any outstanding concerns before the clinical trial may begin. A separate submission must be made for each successive clinical trial conducted during product development. The FDA must not object to the submission before each clinical trial may start and continue. Further, an independent Institutional Review Board, or IRB, for investigations in human subjects within each medical center in which an investigator wishes to participate in the clinical trial must review and approve the preclinical drug testing and nonclinical safety evaluation and efficacy in animals or prior human clinical trials as well as the design and goals of the proposed clinical trial before the clinical trial commences at that center. Regulatory authorities, an IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

For purposes of NDA or BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap. Moreover, the objectives of each phase may be split or combined, leading to Phase I/II and other similar trials that may be used to satisfy the requirements of otherwise separate clinical trials as follows:

Phase I: Phase I clinical trials are usually conducted in normal, healthy volunteers or a limited patient population to evaluate the product candidate for safety, dosage tolerance, absorption, metabolism, distribution and excretion.

Phase II: Phase II clinical trials are conducted in a limited patient population, the population for which the indication applies, to further identify and measure possible adverse effects or other safety risks, to determine the efficacy of the product candidate for the specific targeted disease and to determine dosage tolerance and optimal dosage. Multiple Phase II clinical trials may be conducted to obtain information prior to beginning Phase III clinical trials.

Phase III: When Phase II clinical trials demonstrate that a dose range of the product candidate appears to be effective and has an acceptable safety profile, Phase III clinical trials are undertaken in a larger patient population to confirm clinical efficacy and to further evaluate safety at multiple, and often internationally located, clinical trial sites.

Phase II or III studies of drugs are generally required to be listed in a public clinical trials registry, such as www.clinicaltrials.gov. The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase IV clinical studies may be made a condition to be satisfied after a drug receives approval. The results of Phase IV clinical studies may confirm the effectiveness of a product and may provide important safety information to augment the FDA s voluntary adverse drug reaction reporting system.

The results of product development, preclinical testing and clinical trials are submitted to the FDA as part of an NDA or BLA. The submission of an NDA or BLA must be accompanied by a user fee of several hundred thousand dollars, unless a particular waiver applies. The FDA may deny approval of an NDA or BLA if the applicable regulatory criteria are not satisfied or for any other reason, or it may require additional clinical data or an additional Phase III clinical trial. Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years.

Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the products. The FDA also closely regulates the marketing and promotion of commercialized products. A company is permitted to make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

Medical Device Regulation

The process required by the FDA before medical devices may be marketed in the U.S. pursuant to clearance or approval generally involves FDA review of the following:

- product design, development and manufacture;
- product safety, testing, labeling and storage;
- preclinical testing in animals and in the laboratory; and
- clinical investigations in humans.

Table of Contents

Unless an exemption applies, each medical device distributed commercially in the U.S. requires either prior 510(k) clearance or pre-market approval, referred to as a PMA, from the FDA. The FDA classifies medical devices into one of three classes. Class I devices are subject only to general controls, such as establishment registration and device listing, labeling, medical devices reporting, and prohibitions against adulteration and misbranding. Class II medical devices require prior 510(k) clearance before they may be commercially marketed in the U.S. The FDA will clear marketing of a medical device through the 510(k) process if the FDA is satisfied that the new product has been demonstrated to have the same intended use and is substantially equivalent to another legally marketed device, including a 510(k)-cleared, or predicate, device, and otherwise meets the FDA s requirements. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a predicate device, are placed in Class III, generally requiring submission of a PMA supported by clinical trial data. Currently we have one shaker device that is a Class I device that we use to form our MRX-801 microbubbles.

To obtain 510(k) clearance, a notification must be submitted to the FDA demonstrating that a proposed device is substantially equivalent to a predicate device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of a PMA application. The FDA s 510(k) clearance process generally takes from three to 12 months from the date the application is submitted, but can take significantly longer. If the FDA determines that the device, or its intended use, is not substantially equivalent to a previously-cleared device or use, the device is automatically placed into Class III, requiring the submission of a PMA. Any modification to a 510(k)-cleared device that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, in connection with safety and effectiveness, a PMA.

Clinical trials are generally required to support a PMA application and are sometimes required for 510(k) clearance. To perform a clinical trial in the U.S. for a significant risk device, prior submission of an application for an IDE to the FDA is required. An IDE amendment must also be submitted before initiating a new clinical study under an existing IDE, such as initiating a pivotal clinical trial following the conclusion of a feasibility clinical trial. The FDA responds to an IDE or an IDE amendment for a new clinical trial within 30 days. The FDA may approve the IDE or amendment, grant an approval with certain conditions, or identify deficiencies and request additional information. It is common for the FDA to require additional information before approving an IDE or amendment for a new clinical trial, and thus final FDA approval on a submission may require more than the initial 30 days. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, and any available data on human clinical experience, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The animal and laboratory testing must meet the FDA s good laboratory practice requirements.

Clinical trials are subject to extensive recordkeeping and reporting requirements. Our clinical trials must be conducted under the oversight of an IRB for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. We, the FDA or the IRB may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a clinical trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA approval to market the product in the U.S. Similarly, in Europe the clinical study must be approved by a local ethics committee and in some cases, including studies with high-risk devices, by the ministry of health in the applicable country.

Once a device is in commercial distribution, we or our agents are subject to ongoing regulatory compliance including Quality System Regulation and cGMP compliance, recordkeeping, adverse experience reporting, and conformity of promotion and advertising materials to the approved instructions for use.

Table of Contents

Regulatory Enforcement

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA or state authorities, which may include any of the following sanctions:

warning letters, fines, injunctions, consent decrees and civil penalties;
product recalls or market withdrawals;
customer notifications, repair, replacement, refunds, recall or seizure of our products;
operating restrictions, partial suspension or total shutdown of production;
refusal to grant new regulatory approvals;
withdrawing NDAs, BLAs, 510(k) clearance or PMA that have already been granted; and
criminal prosecution.

Employees

We had 27 full-time employees as of March 25, 2008 of whom 13 were engaged in executive, administrative, business development and intellectual property functions, and 14 were engaged in research, development and clinical or regulatory activities. We believe relations with our employees are generally good. None of our employees is covered by a collective bargaining agreement.

Executive Officers and Directors

Our executive officers and directors as of March 25, 2008 are as follows:

Name	Age	Position
Bradford A. Zakes	42	President, Chief Executive Officer and Director
Greg Cobb	38	Chief Financial Officer
Garen Manvelian, MD.	44	Chief Medical Officer and Vice President, Clinical Development
Jennifer Marshall	44	Vice President, Corporate Development
Kevin Ontiveros	47	Vice President, Legal Affairs, General Counsel and Secretary
Rajan Ramaswami, Ph.D.	55	Vice President, Product Development
Lynne E. Weissberger, Ph.D.	60	Vice President, Regulatory Affairs, Quality Assurance and Regulatory Compliance
Reena Zutshi, Ph.D.	40	Vice President, Operations

Bradford A. Zakes has served as our President and Chief Executive Officer since October 2006 and as a director since March 2007. From July 2006 to October 2006, Mr. Zakes served as our Chief Operating Officer, and from August 2005 to July 2006, Mr. Zakes served as our Vice President, Business Development. From December 2001 to August 2005, Mr. Zakes served as Director, Business Management at ICOS Corporation, a biotechnology company. From March 1999 to December 2001, Mr. Zakes served as President of Heart Research Centers International, a clinical research organization. Mr. Zakes holds a B.S. in Biology from Oregon State University, an M.S. degree in Toxicology from the American University and an M.B.A. from Duke University s Fuqua School of Business.

Greg Cobb has served as our Chief Financial Officer since April 2005. He was a co-founder and Managing Director of Catalyst Partners, LLC, a boutique merger, acquisition and business development firm, from April 2002 to April 2005. Mr. Cobb served as our interim Chief Financial Officer from October 2001 to April 2002. From July 2000 to November 2001, he was a Managing Director of the Arizona Angels Investor Network, Inc. Mr. Cobb holds a B.S. in Computer Engineering from Iowa State University and a J.D. and an M.B.A. from Arizona State University.

Garen Manvelian, MD has serves as our Chief Medical Officer and Vice President, Clinical Development since September 2007. Prior to joining us he served as Chief Medical Officer, Vice President of Clinical and Regulatory Affairs at New River Pharmaceuticals, Inc. from 2006 to 2007. From 2000 to 2006, he served as Senior Director, Clinical and Medical Affairs at SkyePharma, Inc. Prior to that, he served as a Clinical Research Scientist at Quintiles CNS Therapeutics. Dr. Manvelian holds a M.D. degree from the Vitebsk State Medical University in Vitesbk, Belarus.

Jennifer Marshall has served as our Vice President, Corporate Development since September 2007. From April 2005 to July 2007, Ms. Marshall served as our Sr. Director of Finance and from January 2000 to April 2005 as our Controller. Ms. Marshall holds an MBA and Masters of Accounting degree from the University of Arizona.

Table of Contents

Kevin Ontiveros has served as our Vice President, Legal Affairs and General Counsel since March 2007 and has served as our Secretary since July 2007. Prior to joining us he was employed from April 1996 to March 2007 at NPS Pharmaceuticals, Inc. a biopharmaceutical company, where he served in several positions, including Vice President Corporate Law, Associate General Counsel, Assistant Corporate Secretary and Senior Director Corporate Law. Mr. Ontiveros holds a L.L.M. Taxation from the University of Florida College of Law and a J.D. from the University of Utah College of Law.

Rajan Ramaswami, Ph.D. has served as our Vice President, Product Development since March 2005. From September 2001 to February 2005, Dr. Ramaswami served as our Vice President, Research and Development, and from October 1999 to September 2001, he served as our Senior Director of Product Development. Dr. Ramaswami holds a MS/Ph.D. in Polymer Chemistry from Carnegie-Mellon University.

Lynne E. Weissberger, Ph.D. has served as our Vice President, Regulatory Affairs, Quality Assurance and Regulatory Compliance since February 2006. From January 2004 to December 2005, Dr. Weissberger served as Senior Director at Myogen, Inc., a biotechnology company. From April 1996 to December 2003, Dr. Weissberger served as an Associate Director for G.D. Searle, Pharmacia and Pfizer, which are pharmaceutical companies. Dr. Weissberger holds a Ph.D. in Nutrition and Physiology from Cornell University.

Reena Zutshi, Ph.D. has served as our Vice President, Operations since October 2006. Prior to being appointed to that position she served as Vice President, Program Management from October 2005 to October 2006. From June 2001 to October 2005, Dr. Zutshi held various positions with us, including Director of Research and Development. Dr. Zutshi holds a Ph.D. in Organic Chemistry from Purdue University. She received her postdoctoral training at Yale University, Department of Chemistry.

Available Information

Our Internet website address is www.imarx.com. We provide free access to various reports that we file with, or furnish to, the United States Securities and Exchange Commission, or SEC, through our website, as soon as reasonably practicable after they have been filed or furnished. These reports include, but are not limited to, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports. Our SEC reports can be accessed through the investor relations section of our website, or through www.sec.gov. Also available on our website are printable versions of ImaRx s Code of Conduct and charters of the Audit, Compensation, and Nominating and Governance Committees of our Board of Directors. Information on our website does not constitute part of this annual report on Form 10-K or any other report we file or furnish with the SEC.

ITEM 1A. RISK FACTORS

The following important factors, among others, could cause our actual operating results to differ materially from those indicated or suggested by forward-looking statements made in this Annual Report on Form 10-K or presented elsewhere by management from time to time.

Risks Related to Our Business and Industry

Unless we are able to generate sufficient product or other revenue, we will continue to incur losses from operations and may never achieve or maintain profitability.

We have a history of net losses and negative cash flow from operations since inception. As of December 31, 2007, we had an accumulated deficit of $81.2 million. We have incurred losses in each year since our inception. Our net losses applicable to common stockholders for the fiscal years ended December 31, 2007, 2006, and 2005 were $18.6 million, $1.9 million, and $28.5 million, respectively. Except for urokinase, which is approved and marketed for the treatment of acute massive pulmonary embolism, we do not have regulatory approval for any of our product candidates. We expect our product development expenses to increase in connection with our ongoing and future product development initiatives. In addition, we expect to incur significant corporate infrastructure and sales and marketing expenses, prior to recording sufficient revenue to offset these expenses, if we are able to obtain FDA approval to manufacture and sell additional urokinase. Because of the numerous risks and uncertainties associated with developing new medical drugs and devices, we are unable to predict the extent of any future losses or when we will become profitable, if ever.

14

Table of Contents

We incurred significant indebtedness in connection with our acquisition of urokinase assets from Abbott Laboratories. We anticipate that we will not be able to satisfy this obligation by its March 31, 2008 due date, in which case Abbott Laboratories will have a right to reclaim our remaining inventory of urokinase, along with a portion of the cash we have received from our sales of urokinase.

In connection with our April 2006 acquisition of the remaining inventory of and certain rights related to urokinase previously marketed by Abbott Laboratories and us as Abbokinase, and now marketed by us as Kinlytic, we issued to Abbott Laboratories a $15.0 million non-recourse note that is secured by the inventory and rights acquired and matures on March 31, 2008. As of March 25, 2008 there was $11.9 million including accrued interest outstanding on the nonrecourse note and $1.1 million in the escrow account. We do not have sufficient funds to pay off the note and continue operating the business. If we are unable to repay the note by its maturity date and unsuccessful in renegotiating the note with Abbott Laboratories, Abbott will have the right to reclaim our remaining inventory of urokinase, along with the portion of the cash we have received from our sales of urokinase that is in the escrow account.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

We have received an audit report from our independent registered accounting firm containing an explanatory paragraph stating that our historical recurring losses from operations which has resulted in an accumulated deficit of $81.2 million at December 31, 2007 raises substantial doubt about our ability to continue as a going concern. In addition, we may default on the $11.6 million principal balance of the $15.0 million note due to Abbott Laboratories on March 31, 2008. Should we default on the note, Abbott Laboratories may exercise its right to reclaim our remaining inventory of urokinase, which is our primary source of revenue, along with the portion of the cash we have received from our sales of urokinase that is in the escrow account. We do not have sufficient resources to pay off the full amount owing on the note to Abbott Laboratories when due and thereafter continue operations. We have reached a tentative agreement with Abbott Laboratories regarding payment of the note on terms that we believe will enable us to continue operations for at least the next 12 months. We believe a final binding agreement with Abbott Laboratories will be completed in the second quarter of 2008. In the event we are not successful in renegotiating the payment terms of the note, Abbott Laboratories may elect to foreclose on the urokinase assets.

The manufacturing facilities of our suppliers must comply with applicable regulatory requirements. If these manufacturing facilities do not maintain or receive regulatory approval, our business and our results of operations would be harmed.

As part of our acquisition of urokinase from Abbott Laboratories, we acquired cell lines that could be used to manufacture urokinase. If Abbott Laboratories does not reclaim the rights to urokinase, we intend to transfer the manufacturing process and NDA for Kinlytic to Microbix Biosystems Inc. in Toronto. Production of an additional supply of urokinase requires access to manufacturing facilities that meet applicable regulatory standards to manufacture a sufficient supply of urokinase. We would need to demonstrate that our manufactured material is comparable to the urokinase we purchased from Abbott Laboratories. To demonstrate this, we would need to have our manufacturing process validated by the FDA and may be required to conduct additional preclinical studies, and possibly additional clinical trials, to demonstrate its safety and efficacy. Microbix Biosystems does not currently have a facility at which it can manufacture urokinase, and would need to obtain adequate funding to develop such a facility. The FDA must determine that compliance is satisfactory at facilities that manufacture our products. Microbix Biosystems and other suppliers of our products must also comply with FDA regulation, which often requires significant time, money, and record-keeping and quality assurance efforts, and subjects us and our suppliers to potential regulatory inspections and stoppages. Our suppliers may not satisfy these requirements. If the FDA finds their compliance status to be unsatisfactory, we may not be able to obtain additional inventory of urokinase, which would harm our business and our results of operations.

Table of Contents

We rely on a third party to manufacture our urokinase product. The loss of this manufacturer relationship could prevent us from obtaining additional urokinase inventory to sell.

The manufacturing process for urokinase involves a roller bottle production method that is used infrequently today. We have entered into a non-binding letter of intent with Microbix Biosystems, but we do not yet have a definitive agreement with them. Closing the Microbix Biosystems transaction is subject to satisfactory completion of due diligence, finalization of definitive agreements, Microbix securing adequate financing to transfer the process, and Abbott s consent to the transfer of the assets. There is substantial risk that Microbix Biosystems will be unable to meet these obligations. The complexity of manufacturing urokinase significantly limits our ability to work with other suppliers to develop backup sources of urokinase. If Microbix Biosystems is unable or unwilling to meet our demand for urokinase, or if the finished product that they supply does not meet quality and other specifications, we would be unable to obtain additional urokinase to sell.

Even if Microbix Biosystems is able to develop a manufacturing facility and we obtain regulatory approval to manufacture additional urokinase, we will need to develop an infrastructure, or contract with a third party, capable of successfully marketing and selling our products.

To generate additional sales, we will need to develop a sales and marketing infrastructure or contract with a third party to perform that function. We currently have limited marketing and sales capabilities. Establishing these capabilities will be expensive and time-consuming. We may be unable to develop an effective sales and marketing organization. If we are unable to establish and maintain effective sales and marketing capabilities, independently or with others, we may not be able to generate product revenue and may not become profitable.

The Kinlytic brand name for our urokinase product is unfamiliar to our market. We have limited sales and marketing capabilities and depend on drug wholesalers to distribute our Kinlytic product.

Our urokinase product was previously marketed by Abbott Laboratories and us as Abbokinase. Following extension of the expiration dates of our urokinase inventory, we were required pursuant to the terms of the asset purchase agreement with Abbott Laboratories to re-brand the urokinase inventory. We received FDA approval to use the Kinlytic brand name in our labeling of urokinase. We cannot be certain that we have sufficient resources to effectively market or sell urokinase under the brand name Kinlytic. We have a limited sales and marketing staff and depend on the efforts of third parties for the sale and distribution of Kinlytic to hospitals and clinics. The new brand name Kinlytic may cause confusion or lead to rejection of the product by hospitals and clinics whose pharmaceutical formularies include Abbokinase, but not Kinlytic. If we are unable to maintain effective third party distribution on commercially reasonable terms, we may be unable to market and sell Kinlytic in commercial quantities. Drug wholesale companies may be unwilling to continue selling Kinlytic, or we may be forced to accept lower prices or other unfavorable terms or to expend significant additional resources to sell our Kinlytic inventory.

Table of Contents

We will need substantial additional capital to fund our operations. If we are unable to raise capital when needed, we may be forced to delay, reduce or eliminate our research and development programs or commercialization efforts, and we may be unable to timely pay our debts or may be forced to sell or license assets or otherwise terminate further development of one or more of our programs.

We believe that our cash, cash equivalents and investments will be sufficient to fund our continuing operations and other demands and commitments through at least the next 12 months. Our funding requirements will, however, depend on numerous factors, including:

- our ability to renegotiate the payment terms of the outstanding balance on our $15.0 million secured non-recourse note due to Abbott Laboratories on March 31, 2008;
- the timing of completing a strategic alternative for our SonoLysis program;
- the timing and amount of revenue from sales of urokinase;
- the timing and amount of revenue from grants and other sources;
- the timing, scope and results of our preclinical studies and clinical trials;
- the timing of initiation of manufacturing for urokinase;
- the timing of, and the costs involved in, obtaining regulatory approvals;
- our ability to establish and maintain collaborative relationships;
- personnel, facilities and equipment requirements; and
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs, if any, and the result of any such litigation.

One or more of these factors may require us to seek additional funding from a variety of sources, which may include collaborations involving our technology, technology licensing, grants and public or private equity and debt financings. We cannot be certain that any additional funding will be available on terms acceptable to us, or at all. Accordingly, we may not be able to secure the substantial funding that is required to maintain and continue our commercialization and development programs at levels that may be required in the future. We may be forced to accept funds on terms or pricing that are highly dilutive or otherwise disadvantageous to our existing stockholders. We are restricted from granting any additional security interest in our urokinase assets that we acquired in 2006. Raising additional funds through debt financing, if available, may involve covenants that restrict our business activities. To the extent that we raise additional funds through collaborations and licensing arrangements, we may have to relinquish valuable rights and control over our technologies, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to secure adequate financing, we could be required to sell or license assets, delay, scale back or eliminate one or more of our development programs or enter into licenses or other arrangements with third parties to commercialize products or technologies that we would otherwise seek to develop and commercialize ourselves.

Our competitors generally are larger than we are, have greater financial resources available to them than we do and may have a superior ability to develop and commercialize competitive products. In addition, if our competitors have products that are approved in advance of ours, marketed more effectively or demonstrated to be safer or more effective than ours, our commercial opportunity will be reduced or eliminated and our business will be harmed.

Our industry sector is intensely competitive, and we expect competition to continue to increase. Many of our actual or potential competitors have substantially longer operating histories and greater financial, research and development and marketing capabilities than we do. Many of them also have substantially greater experience than we have in undertaking preclinical studies and clinical trials, obtaining regulatory approvals and manufacturing and distributing products. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical companies. In addition, academic institutions, government agencies and other public and private research organizations also conduct research, seek patent protection and establish collaborative arrangements for product development and marketing. We may not be able to develop products that are more effective or achieve greater market acceptance than our competitors products. Any company that brings competitive products to market before us may achieve a significant competitive advantage.

17

Table of Contents

We believe that the primary competitive factors in the market for treatments of vascular disorders include safety and efficacy, access to and acceptance by leading physicians, cost-effectiveness, physician relationships and sales and marketing capabilities. We may be unable to compete successfully on the basis of any one or more of these factors, which could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to develop, manufacture and commercialize our product and product candidate, we may not generate sufficient revenue to continue our business.

We currently have only one product, urokinase, currently marketed as urokinase, that has received regulatory approval, and we have limited experience commercializing urokinase. The process to develop, obtain regulatory approval for and commercialize potential drug candidates is long, complex and costly. Our proprietary SonoLysis microbubble technology has not been used in clinical trials other than our concluded Phase I/II clinical trial of our SonoLysis therapy in combination with tPA. As a result, our business in the near term is substantially dependent upon our ability to sell our remaining inventory of urokinase, develop and obtain regulatory approval for the manufacture of additional Kinlytic inventory, and to complete development, obtain regulatory approval for and commercialize our SonoLysis product candidate in a timely manner. If we are unable to develop manufacturing capability for urokinase or to further develop, commercialize or license our SonoLysis product candidates, we may not be able to earn sufficient revenue to continue our business.

We do not plan to manufacture any of our product candidates and will depend on commercial contract manufacturers to manufacture our products.

We do not have our own manufacturing facilities, have no experience in large-scale product manufacturing, and do not intend to develop such facilities or capabilities. Our ability to conduct clinical trials and commercialize our product candidates will depend, in part, on our ability to manufacture our products through contract manufacturers. For all of our product candidates, we or our contract manufacturers will need to have sufficient production and processing capacity to support human clinical trials, and if those clinical trials are successful and regulatory approvals are obtained, to produce products in commercial quantities. Delays in providing or increasing production or processing capacity could result in additional expense or delays in our clinical trials, regulatory submissions and commercialization of our products. In addition, we will be dependent on such contract manufacturers to adhere to the FDA s current Good Manufacturing Practices, or cGMP, and other regulatory requirements.

Establishing contract manufacturing is costly and time-consuming and we cannot be certain that we will be able to engage contract manufacturers who can meet our quantity and quality requirements in a timely manner and at competitive costs. The manufacturing processes for