

IMARX THERAPEUTICS INC

Form 10-K

March 31, 2008

**Table of Contents**

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

**FORM 10-K**

- Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the fiscal year ended December 31, 2007**
- 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**  
**(State or Other Jurisdiction of  
Incorporation or Organization)**

**86-0974730**  
**(I.R.S. Employer  
Identification No.)**

**1730 East River Road, Tucson, AZ**  
**(Address of Principal Executive Offices)**

**85718-5893**  
**(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  NO

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

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  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, 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  Accelerated Filer  Non-accelerated filer  Smaller reporting company   
(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  NO

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.

**TABLE OF CONTENTS**

	<b>Page No.</b>
<b><u>PART I</u></b>	
<u>Item 1. Business</u>	3
<u>Item 1A. Risk Factors</u>	14
<u>Item 2. Properties</u>	30
<u>Item 3. Legal Proceedings</u>	31
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	31
<b><u>PART II</u></b>	
<u>Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	31
<u>Item 6. Selected Financial Data</u>	32
<u>Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	33
<u>Item 7A. Quantitative and Qualitative Disclosures about Market Risk</u>	41
<u>Item 8. Financial Statements and Supplemental Data</u>	41
<u>Item 9A(T). Controls and Procedures</u>	41
<b><u>PART III</u></b>	
<u>Item 10. Directors, Executive Officers and Corporate Governance</u>	42
<u>Item 11. Executive Compensation</u>	42
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	42
<u>Item 13. Certain Relationships and Related Transactions and Director Independence</u>	42
<u>Item 14. Principal Accountant Fees and Services</u>	42
<b><u>PART IV</u></b>	
<u>Item 15. Exhibits and Financial Statement Schedules</u>	43
<b><u>SIGNATURES</u></b>	47

[Exhibit 10.32](#)

[Exhibit 23.1](#)

[Exhibit 31.1](#)

[Exhibit 31.2](#)

[Exhibit 32.1](#)

[Exhibit 32.2](#)

---

**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-801 microbubbles 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 NanO<sub>2</sub> 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](http://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:

<b>Name</b>	<b>Age</b>	<b>Position</b>
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 served 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 Vitebsk, 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](http://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](http://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.





**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.



## **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 our product candidates have not yet been tested at commercial levels, and it may not be possible to manufacture such materials in a cost-effective manner. Further, there is no guarantee that the components of our proposed drug product candidates will be available to our manufacturers when needed on terms acceptable to us. If we are unable to obtain contract manufacturing on commercially reasonable terms, we may not be able to produce additional Kinlytic for sale or to conduct or complete planned or necessary clinical trials or commercialize our product candidates.

***Our product candidates may never achieve market acceptance.***

We cannot be certain that our products will achieve any degree of market acceptance among physicians and other health care providers and payors, even if necessary regulatory approvals are obtained. We believe that recommendations by physicians and other health care providers and payors will be essential for market acceptance of our products, and we cannot be certain we will ever receive any positive recommendations or reimbursement. Recently, the labels of certain microbubbles currently being commercialized as a contrast agent for use in echocardiography were revised by the FDA to include a black-box warning with respect to certain serious cardiopulmonary reactions, including fatalities observed when the bubbles were administered during echocardiography. One of the microbubbles marketed under the brand name Definity® is similar in composition to our MRX-801 microbubble. As a result, our MRX-801 microbubble, if approved, may receive a black-box label as well which could negatively impact use of our product by physicians and may require us to conduct additional clinical tests which would increase our development costs and may delay commercialization of our product. Physicians will not recommend our products unless they conclude, based upon clinical data and other factors, that our products are safe and effective. We are unable to predict whether any of our product candidates will ever achieve market acceptance,

either in the U.S. or internationally. A number of factors may limit the market acceptance of our products, including:

- the timing and scope of regulatory approvals of our products and market entry compared to competitive products;
- the safety and efficacy of our products, including any inconveniences in administration, as compared to alternative treatments;

**Table of Contents**

the rate of adoption of our products by hospitals, doctors and nurses and acceptance by the health care community;  
the product labeling and marketing claims permitted or required by regulatory agencies for each of our products;  
the competitive features of our products, including price, as compared to competitive products;  
the availability of sufficient third party coverage or reimbursement for our products;  
the extent and success of our sales and marketing efforts; and  
possible unfavorable publicity concerning our products or any similar products.

If our products are not commercialized, our business will be materially harmed.

***Technological change and innovation in our market sector may cause our products to become obsolete shortly after or even before such products reach the market.***

New products and technological development in the pharmaceutical and medical device industries may adversely affect our ability to complete required regulatory requirements and introduce our product candidates into the market or may render our products obsolete. The markets into which we plan to introduce our products are characterized by constant and sometimes rapid technological change, new and improved product introductions, changes in regulatory requirements, and evolving industry standards. Our ability to execute our business plan will depend to a substantial extent on our ability to identify new market trends and develop, introduce and support our candidate products on a timely basis. If we fail to develop and commercialize our product candidates on a timely basis, we may be unable to compete effectively. For example, we are aware of other thrombolytic drugs in development such as ancred and desmoteplase, which are currently being developed as treatments for acute ischemic stroke. Since none of our product candidates for treatment of ischemic stroke will be able to achieve regulatory approval for commercial sale in the U.S. any earlier than 2012, if ever, we could by that time find that competitive developments have diminished our product opportunities, which would have an adverse impact on our business prospects and financial condition.

***We intend to rely heavily on third parties to implement critical aspects of our business strategy, and our failure to enter into and maintain these relationships on acceptable business terms, or at all, would materially adversely affect our business.***

We intend to rely on third parties for certain critical aspects of our business, including:

manufacturing of additional urokinase for sale;  
manufacturing of our MRX-801 and other proprietary microbubbles;  
conducting clinical trials;

**Table of Contents**

conducting preclinical studies;  
performing stability and product release testing with respect to urokinase;  
preparing, submitting and maintaining regulatory records sufficient to meet the requirements of the FDA; and  
customer logistics and distribution of our products.

We do not currently have many of these relationships in place. Although we use a third party manufacturer to produce MRX-801 microbubbles for our research purposes on a purchase order basis, that third party does not have the capacity to produce the volume of MRX-801 microbubbles necessary for large-scale clinical trials or commercial sales. Also, although we have entered into a letter of intent with a third party for the manufacture of urokinase, that third party does not have adequate manufacturing facilities, and the establishment of such manufacturing facilities would be subject to regulatory approvals. We currently have agreements with contract research organizations to manage our clinical trials; audit our clinical trials; help us write protocols and study reports for our clinical trials; store, label, package and distribute our commercial product; and conduct stability and product release testing for our commercialized product. We also have agreements with wholesalers to market and distribute our urokinase product, as well as agreements in place with many Group Purchasing Organizations that negotiate prices on behalf of hospitals and clinics. To the extent that we are unable to maintain these relationships or to enter into any one or more of the additional relationships necessary to our business on commercially reasonable terms, or at all, or to eliminate the need for any such relationship by establishing our own capabilities in a particular functional area in a timely manner, we could experience significant delays or cost increases that could have a material adverse effect on our ability to develop, manufacture and commercialize our product and product candidates.

***We rely on third party products, technology and intellectual property, which could negatively affect our ability to sell our MRX-801 microbubbles or other products commercially or could adversely affect our ability to derive revenue from such products.***

Our SonoLysis program may require the use of multiple proprietary technologies, including commercially available ultrasound devices and patented technologies. Manufacturing our products or customizing related ultrasound devices may also require licensing technologies and intellectual property from third parties. Obtaining and maintaining licenses for these technologies may require us to make royalty payments or other payments to several third parties, potentially reducing our revenue or making the cost of our products commercially prohibitive. We cannot be certain that we will be able to establish any or all of the partnering relationships and technology licenses that may be necessary for the pursuit of our business strategy, or, even if such relationships can be established, that they will be on terms favorable to us or that they can be managed in a way that will assist us in executing our business plan.

***We may be unable to attract and retain management and other personnel we need to succeed.***

Our success depends substantially on the services of our senior management and other key employees. The loss of the services of one or more of these employees could have a material adverse effect on our business. Each of our officers may terminate his or her employment without notice and without cause or good reason. We do not carry key person life insurance on any of our officers. We have historically used stock options as key components of our total employee compensation program. Many of our outstanding stock options have exercise prices in excess of our stock price, which reduces their value to employees and could affect our ability to retain present and attract prospective employees. Our future success will depend in large part on our ability to attract, retain and motivate highly skilled employees. We cannot be certain that we will be able to do so.



**Table of Contents*****We may be unable to manage our company's growth effectively.***

If we engage in a pivotal clinical trial or commercialization efforts in the future, our business will undergo significant growth. For example, we will have to expand existing operations in order to conduct a pivotal trial and additional clinical trials, increase our contract manufacturing capabilities, hire and train new personnel to handle the marketing and sales of our products, assist in obtaining reimbursement for the use of our products, and create and develop new applications for our technology. Such growth may place significant strain on our management, financial and operational resources. Successful growth is also dependent upon our ability to implement appropriate financial and management controls, systems, and procedures. Our ability to effectively manage growth depends on our success in attracting and retaining highly qualified personnel, for which the competition may be intense. If we fail to manage these challenges effectively, our business could be harmed.

***We depend on patents and other proprietary rights, some of which are uncertain and unproven. Further, our patent portfolio and other intellectual property rights are expensive to maintain, protect against infringement claims by third parties, and enforce against third party infringements, and are subject to potential adverse claims.***

Because we are developing product candidates that rely on advanced and innovative technologies, our ability to execute our business plan will depend in large part on our ability to obtain and effectively use patents and licensed patent rights, preserve trade secrets and operate without infringing upon the proprietary rights of others. Our Kinlytic product has no patent protection and we have a one-half interest in a patent related to the manufacturing process for urokinase. Some of our intellectual property rights are based on licenses that we have entered into with owners of patents.

Although we have rights to 139 issued U.S. patents, plus some foreign equivalents and numerous pending patent applications, the patent position of pharmaceutical, medical device and biotechnology companies in general is highly uncertain and involves complex legal and factual questions. Effective intellectual property protection may also be unavailable or limited in some foreign countries. We have not pursued foreign patent protection in all jurisdictions or for all of our patentable intellectual property. As a result, our patent protection for our intellectual property will likely be less comprehensive if and when we commence international sales.

There are also companies that are currently commercializing FDA approved microbubbles-based products for diagnostic uses. These companies may promote these products for off-label uses which may directly compete with our products when and if approved. Additionally, physicians may prescribe the use of such products for off-label indications which could have the impact of reducing our revenues for our product candidates when and if approved. In the U.S. and internationally, enforcing intellectual property rights against infringing parties is often costly. Pending patent applications may not issue as patents and may not issue in all countries in which we develop, manufacture or sell our products or in countries where others develop, manufacture and sell products using our technologies. Patents issued to us may be challenged and subsequently narrowed, invalidated or circumvented. In February 2005, a third party filed an opposition claim to one of our patents in Europe that relates to targeted bubbles for therapeutic and diagnostic use. The third party agreed to voluntarily dismiss and terminate this claim, but other such conflicts could occur and could limit the scope of the patents that we may be able to obtain or may result in the denial of our patent applications. If a third party were to obtain intellectual property protection for any of the technologies upon which our business strategy is based, we could be required to challenge such protections, terminate or modify our programs that rely on such technologies or obtain licenses for use of these technologies. For example, 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 its patented method. Although we do not intend to administer our therapies according to the third party's patented method, other similar third party patents, if valid, could require us to seek a license that may not be available on terms acceptable to us or at all, could impose limitations on how we administer our therapies, and may require us to adopt restrictions or requirements as to the manner of administration of our products that we might not otherwise adopt to avoid infringing patents of others. Moreover, we may not have the financial resources to protect our patent and other intellectual property rights and, in that event, our patents may not afford meaningful protection for our technologies or product candidates, which would materially adversely affect our ability to develop and market our product candidates and to generate licensing revenue from our patent portfolio.



**Table of Contents**

Additional risks related to our patent rights and other proprietary rights include:

- challenge, invalidation, circumvention or expiration of issued patents already owned by or licensed to us;
- claims by our consultants, key employees or other third parties that our products or technologies are the result of technological advances independently developed by them and, therefore, not owned by us;
- our failure to pay product development costs, license fees, royalties, milestone payments or other compensation required under our technology license and technology transfer agreements, and the subsequent termination of those agreements;
- failure by our licensors or licensees to comply with the terms of our license agreements;
- misrepresentation by technology owners of the extent to which they have rights to the technologies that we purport to acquire or license from them; and
- loss of rights that we have licensed due to our failure or decision not to fund further research or failure to achieve required development or commercialization milestones or otherwise comply with our obligations under the license and technology transfer agreements.

If any of these events occurs, our business may be harmed.

***We have limited patent protection for Kinlytic, and third parties likely could develop urokinase without a license from us, which could decrease the market opportunity for Kinlytic.***

We own a one-half interest in a patent related to the manufacturing process for Kinlytic. We also have a license to use trade secrets relating to the manufacturing process for urokinase. A third party could acquire or develop a cell line capable of producing urokinase and could devise a manufacturing process that could yield a product consistent with or superior to our Kinlytic product in quality, safety and activity, in each case without a license from us, which could decrease the market opportunity for Kinlytic.

***Other companies may claim that we infringe their patents or trade secrets, which could subject us to substantial damages.***

A number of third parties, including certain of our competitors, have developed technologies, filed patent applications or obtained patents on technologies and compositions that are related to aspects of our business, including thrombolytic drug therapy, microbubbles and ultrasound. Such third parties may sue us for infringing their patents. If we face an infringement action, defending against such an action could require substantial resources that may not be available to us. In the event of a successful claim of infringement against us, we may be required to:

- pay substantial damages;
- stop using infringing technologies and methods;
- stop certain research and development efforts;
- develop non-infringing products or methods; and
- obtain one or more licenses from third parties.

Any claims of infringement could cause us to incur substantial costs and could divert management's attention away from our business in defending against the claim, even if the claim is invalid. A party making a claim could secure a judgment that requires us to pay substantial damages. A claim of infringement could also be used by our competitors to delay market introduction or acceptance of our products. If we are sued for infringement, we could encounter substantial delays in development, manufacture and commercialization of our product candidates. Any litigation, whether to enforce our patent rights or to defend against allegations that we infringe third party rights, will be costly and time consuming and will likely distract management from other important tasks.

**Table of Contents**

***Our rights to develop and commercialize our SonoLysis product candidate is subject to the terms and conditions of licenses or sublicenses granted to us by third parties, including other pharmaceutical companies, that contain restrictions that may limit our ability to capitalize on this product.***

Our SonoLysis therapy product candidate is based in part on patents and other intellectual property that we license or sublicense from third parties. Our rights to develop and commercialize this product candidate using intellectual property licensed from UNEMED Corporation may terminate, in whole or in part, if we fail to pay royalties to third party licensors, or if we fail to comply with certain restrictions regarding our development activities. In the event of an early termination of any such license or sublicense agreement, rights licensed and developed by us under such agreements may be extinguished, and our rights to the licensed technology may revert back to the licensor. Any termination or reversion of our rights to develop or commercialize any such product candidate may have a material adverse effect on our business.

We are party to an agreement with Bristol-Myers Squibb that restricts us from using our bubble technology for non-targeted diagnostic imaging applications. Bristol-Myers Squibb also has a right of first negotiation should we wish to license to a third party any of our future products or technology related to the use of bubbles for targeted imaging of blood clots, or breaking up blood clots with ultrasound and bubbles. Bristol-Myers Squibb has waived its rights under this agreement with respect to our current generation of MRX-801 microbubbles that we are developing for breaking up blood clots, as well as a new generation of MRX-802 microbubbles that we are developing for breaking up blood clots that include targeting mechanisms to cause the bubbles to attach to blood clots. This right of first negotiation for future technology we may develop in these applications could adversely impact our ability to attract a partner or acquirer for SonoLysis therapy.

In addition, we have been awarded various government funding grants and contracts from The National Institutes of Health and other government agencies. These grants include provisions that provide the U.S. government with the right to use the technologies developed under such grants for certain uses, under certain circumstances. If the government were to exercise its rights, our ability to commercialize such technology would likely be impaired.

***We could be exposed to significant product liability claims, which could be time consuming and costly to defend, divert management attention and adversely impact our ability to obtain and maintain insurance coverage. The expense and potential unavailability of insurance coverage for our company or our customers could adversely affect our ability to sell our products, which would negatively impact our business.***

We face a risk of product liability exposure related to the testing of our product candidates in clinical trials and will face even greater risks upon any commercialization by us of our product candidates. Thrombolytic drugs are known to involve certain medical hazards, such as risks of bleeding or immune reactions. Our product candidates may also involve presently unknown medical risks of equal or even greater severity. Product liability claims or other claims related to our products, or their off-label use, regardless of their merits or outcomes, could harm our reputation in the industry, and reduce our product sales. Additionally, any lawsuits or product liability claims against us may divert our management from pursuing our business strategy and may be costly to defend. Further, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forego further commercialization of one or more of our products. A product liability related claim or recall could be materially detrimental to our business. Our current product liability insurance, which provides us with \$10 million of coverage in the aggregate, may be insufficient. We may not be able to obtain or maintain such insurance in adequate amounts, or on acceptable terms, to provide coverage against potential liabilities. The product liability coverage we currently have for our clinical trials may be insufficient to cover fully the costs of any claim or any ultimate damages we may be required to pay. Our inability to obtain or maintain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or limit the commercialization of any products we develop, and could leave us exposed to significant financial losses relating to any products that we do develop and commercialize.

**Table of Contents**

Moreover, Kinlytic is made from human neonatal kidney cells. Products made from human source material may contain infectious agents, such as viruses, that can cause disease. We believe the risk that Kinlytic will transmit an infectious agent has been reduced by changes made by Abbott Laboratories to its tissue acquisition and related manufacturing process that included screening donors for prior exposure to certain viruses, testing donors for the presence of certain current virus infections, testing for certain viruses during manufacturing and inactivating and/or removing certain viruses. All of our inventory was produced after these changes were made. Despite these measures, Kinlytic may still present a risk of transmitting infectious agents, which could expose us to product liability lawsuits. ***If we use hazardous or biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.***

Our research and development activities involve the controlled use of potentially hazardous substances, including toxic chemical and biological materials. Our sale of urokinase requires our involvement in the handling and distribution of biological materials. In addition, our operations produce hazardous waste products. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous and biological materials. While we believe that we are currently in compliance with these laws and regulations, continued compliance may be expensive, and current and future environmental regulations may impair our research, development and manufacturing efforts. In addition, if we fail to comply with these laws and regulations at any point in the future, we may be subject to criminal sanctions and substantial civil liabilities and could be required to suspend or modify our operations. Even if we continue to comply with all applicable laws and regulations regarding hazardous materials, we cannot eliminate the risk of accidental contamination or discharge and our resultant liability for any injuries or other damages caused by these accidents. Although we maintain general liability insurance, this insurance may not fully cover potential liabilities for these damages, and the amount of uninsured liabilities may exceed our financial resources and materially harm our business.

***The FDA approval process for drugs involves substantial time, effort and financial resources, and we may not receive any new approvals for our product candidates on a timely basis, or at all.***

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

- preclinical laboratory and animal testing;
- submission of an IND application which must become effective before clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of proposed drugs or biologics for their intended use;
- pre-approval inspection of manufacturing facilities, company regulatory files and selected clinical investigators; and
- 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.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any new approvals for our product candidates will be granted on a timely basis, if at all. We have failed in the past, and may in the future fail, to make timely submissions of required reports or modifications to clinical trial documents, and such delays as well as possible errors or omissions in such submissions could endanger regulatory acceptance of clinical trial results or even our ability to continue with our clinical trials.

The results of product development, preclinical tests and clinical trials are submitted to the FDA as part of an NDA, or as part of an NDA supplement. The FDA may deny approval of an NDA or NDA supplement if the applicable regulatory criteria are not satisfied, or it may require additional clinical data or an additional pivotal Phase III clinical trial. Even if such data are submitted, the FDA may ultimately decide that the NDA or NDA supplement does not satisfy the criteria for approval. The FDA may move to withdraw product approval, once issued, if ongoing regulatory standards are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA may move to prevent or limit further marketing of a product based on the results of these post-marketing programs.



**Table of Contents**

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Government regulation may delay or prevent marketing of product candidates for new indications for a considerable period of time and impose costly procedures upon our activities. The FDA or any other regulatory agency may not grant approvals for new indications for our product candidates on a timely basis, if at all. Success in early stage clinical trials does not ensure success in later stage clinical trials. Data obtained from clinical trials is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Even if a product candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain, additional regulatory approvals for our products would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

The FDA's policies may change and additional government regulations may be enacted, which could prevent or delay regulatory approval of our product candidates or approval of new indications for our product candidates. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or internationally.

***If we or our contract manufacturers fail to comply with applicable regulations, sales of our products could be delayed and our revenue could be harmed.***

Every medical product manufacturer is required to demonstrate and maintain compliance with cGMP. We and any third party manufacturers or suppliers with whom we enter into agreements will be required to meet these requirements. Our contract manufacturers will be subject to unannounced inspections by the FDA and corresponding foreign and state agencies to ensure strict compliance with cGMP and other applicable government quality control and record-keeping regulations. In addition, transfer of ownership of products triggers a mandatory manufacturing inspection requirement from the FDA. We cannot be certain that we or our contract manufacturers will pass any of these inspections. If we or our contract manufacturers fail one of these inspections in the future, our operations could be disrupted and our manufacturing and sales delayed significantly until we can demonstrate adequate compliance. If we or our contract manufacturers fail to take adequate corrective action in a timely fashion in response to a quality system regulations inspection, the FDA could shut down our or our contract manufacturers' manufacturing operations and require us, among other things, to recall our products, either of which would harm our business.

Failure to comply with cGMP or other applicable legal requirements can lead to federal seizure of violative products, injunctive actions brought by the federal government, and potential criminal and civil liability on the part of a company and its officers and employees. Because of these and other factors, we may not be able to replace our manufacturing capacity quickly or efficiently in the event that our contract manufacturers are unable to manufacture our products at one or more of their facilities. As a result, the sale and marketing of our products could be delayed or we could be forced to develop our own manufacturing capacity, which would require substantial additional funds and personnel and compliance with extensive regulations.

***Our products will remain subject to ongoing regulatory review even if they receive marketing approval. If we fail to comply with applicable regulations, we could lose these approvals, and the sale of our products could be suspended.***

Even if we receive regulatory approval to market a particular product candidate, the FDA or foreign regulatory authority could condition approval on conducting additional and costly post-approval clinical trials or could limit the scope of approved labeling. For example, to sell Kinlytic, we are required to continue an ongoing immunogenicity clinical trial that Abbott Laboratories commenced in 2003. Moreover, the product may later cause adverse effects that limit or prevent its widespread use, force us to withdraw it from the market or impede or delay our ability to obtain regulatory approvals in additional countries. In addition, the manufacturer of the product and its facilities will continue to be subject to FDA review and periodic inspections to ensure adherence to applicable regulations. After receiving marketing approval, the FDA imposes extensive regulatory requirements on the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product. We may not promote or advertise any future FDA-cleared or approved products for use outside the scope of our product's label

or make unsupported promotional claims about the benefits of our products. If the FDA determines that our claims are outside the scope of our label or are unsupported, it could require us to revise our promotional claims, correct any prior statements or bring an enforcement action against us. Moreover, the FDA or other regulatory authorities may bring charges against us or convict us of violating these laws, and we could become subject to third party litigation relating to our promotional practices and there could be a material adverse effect on our business.



**Table of Contents**

If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities or discover previously unknown problems with our products, manufacturers or manufacturing processes, we could be subject to administrative or judicially imposed sanctions, including:

restrictions on the products, manufacturers or manufacturing processes;

warning letters;

civil or criminal penalties or fines;

injunctions;

product seizures, detentions or import bans;

voluntary or mandatory product recalls and publicity requirements;

suspension or withdrawal of regulatory approvals;

total or partial suspension of production; and

refusal to approve pending applications of marketing approval of new drugs or supplements to approved applications.

If we were subject to any of the foregoing actions by the FDA, our sales could be delayed, our revenue could decline and our reputation among clinicians, doctors, inventors and research and academic institutions could be harmed.

***Marketing and reimbursement practices and claims processing in the pharmaceutical and medical device industries are subject to significant regulation in the U.S.***

In addition to FDA restrictions on marketing of pharmaceutical products, several other state and federal laws have been applied to regulate certain marketing practices in the pharmaceutical and medical device industries in recent years, in particular anti-kickback statutes and false claims statutes.

The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and formulary managers on the other.

Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from potential liability, the exemptions and safe harbors are drawn narrowly. Practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our future practices may not in all cases meet the criteria for safe harbor protection from anti-kickback liability.

**Table of Contents**

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. For example, several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the company's marketing of the product for unapproved, and thus non-reimbursable, uses. The majority of states also have statutes or regulations similar to the federal anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment.

Because of the breadth of these laws and the limited safe harbors, it is possible that some of our commercial activities in the future could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business.

***If we seek regulatory approvals for our products in foreign jurisdictions, we may not obtain any such approvals.***

We may market our products outside the U.S., either with a commercial partner or alone. To market our products in foreign jurisdictions, we will be required to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and jurisdictions and can involve additional testing, and the time required to obtain foreign approvals may differ from that required to obtain FDA approval. We have no experience with obtaining any such foreign approvals. Additionally, the foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We may not be able to submit applications for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. The failure to obtain these approvals could materially adversely affect our business, financial condition and results of operations.

**Risks Related to Our Common Stock*****Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over our affairs.***

Our executive officers, current directors and holders of five percent or more of our common stock own a significant portion of our common stock. These stockholders significantly influence the composition of our Board of Directors, retain the voting power to approve some matters requiring stockholder approval and continue to have significant influence over our operations. The interests of these stockholders may be different than the interests of other stockholders on these matters. This concentration of ownership could also have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could reduce the price of our common stock.

***If our stock price is volatile, purchasers of our common stock could incur substantial losses.***

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

- results of our clinical trials;
- announcements of technological innovations or new products by us or our competitors
- delays in obtaining regulatory approvals for clinical trials or commercial marketing efforts;
- the success rate of our discovery efforts, animal studies and clinical trials;

**Table of Contents**

developments or disputes concerning patents or proprietary rights, including announcements of infringement, interference or other litigation regarding these rights;  
the willingness of collaborators to commercialize our products and the timing of commercialization;  
ability to manufacture our products;  
changes in our strategic relationships which adversely affect our ability to acquire or commercialize products;  
announcements concerning our competitors or the health care industry in general;  
public concerns over the safety of our products or our competitors' products;  
changes in governmental regulation of the health care industry;  
litigation or other disputes with third parties;  
actual or anticipated fluctuations in our operating results from period to period;  
variations in our quarterly results;  
changes in financial estimates or recommendations by securities analysts;  
changes in accounting principles;  
the loss of any of our key personnel;  
sales or anticipated sales of our common stock;  
investors' perceptions of us;  
the loss of our ability to sell urokinase product if we are unsuccessful renegotiating our outstanding note with Abbott; and  
general economic, industry and market conditions.

A decline in the market price of our common stock could cause investors to lose some or all of their investment and may adversely impact our ability to attract and retain employees and raise capital. In addition, stockholders may initiate securities class action lawsuits if the market price of our stock drops significantly, which may cause us to incur substantial costs and could divert the time and attention of our management.

***We are at risk of securities class action litigation due to our stock price volatility.***

We are at risk of being subject to securities class action lawsuits if our stock price declines substantially. Securities class action litigation has often been brought against other companies following a decline in the market price of its securities. While no securities class action claims have been brought against us, it is possible that lawsuits will be filed based on such stock price declines naming our company, directors, and officers. Securities litigation could result in substantial costs, divert management's attention and resources, and seriously harm our business, financial condition and results of operations.

**Table of Contents**

***If there are substantial sales of common stock, our stock price could decline.***

If our existing stockholders sell a large number of shares of common stock or the public market perceives that existing stockholders might sell shares of common stock, the market price of our common stock could decline significantly.

***The financial reporting obligations of being a public company and other laws and regulations relating to corporate governance matters place significant demands on our management and cause increased costs.***

The laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and new rules adopted or proposed by the Securities and Exchange Commission, will result in ongoing costs to us as we comply with new and existing rules and regulations and respond to requirements under such rules and regulations. We are required to comply with many of these rules and regulations, and will be required to comply with additional rules and regulations in the future. With limited capital and human resources, management's time and attention will be diverted from our business in order to ensure compliance with these regulatory requirements. This diversion of management's time and attention as well as ongoing legal and compliance costs may have a material adverse effect on our business, financial condition and results of operations.

***Failure of our internal control over financial reporting could harm our business and financial results.***

Our management is responsible for establishing and maintaining effective internal control over financial reporting. Internal control over financial reporting is a process to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally accepted in the U.S. Internal control over financial reporting includes: (i) maintaining reasonably detailed records that accurately and fairly reflect our transactions; and (ii) providing reasonable assurance that we (a) record transactions as necessary to prepare the financial statements, (b) make receipts and expenditures in accordance with management authorizations, and (c) would timely prevent or detect any unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements. Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that we would prevent or detect a misstatement of our financial statements or fraud. Changes in our business will place additional pressure on our system of internal control over financial reporting. Any failure to maintain an effective system of internal control over financial reporting could limit our ability to report financial results accurately and timely or to detect and prevent fraud. A significant financial reporting failure could cause an immediate loss of investor confidence and our management and a sharp decline in the market price of our common stock.

***If we do not achieve our projected business goals in the time frames we announce and expect, our stock price may decline.***

From time to time, we estimate and publicly announce expectations for future financial results and the anticipated timing of the accomplishment of various clinical, regulatory and product development goals. These statements, which are forward-looking statements, include but are not limited to our estimates regarding cash use, operating losses, sales of Kinlytic, progress and timing of our clinical trials, when trial data will be publicly disclosed, and when we expect to obtain FDA approval for or begin to receive revenue from any of our products. These estimates are, and must necessarily be, based on a variety of assumptions. The timing of the actual achievement of these milestones may vary dramatically compared to our estimates, in some cases for reasons beyond our control. Our failure to meet any publicly-announced goals may be perceived negatively by the public markets, and, as a result, our stock price may decline.

**Table of Contents**

***Anti-takeover defenses that we have in place could prevent or frustrate attempts to change our direction or management.***

Provisions of our amended and restated certificate of incorporation and bylaws and applicable provisions of Delaware law may make it more difficult or impossible for a third party to acquire control of us without the approval of our Board of Directors. These provisions:

limit who may call a special meeting of stockholders;

establish advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted on at stockholder meetings;

prohibit cumulative voting in the election of our directors, which would otherwise permit holders of less than a majority of our outstanding shares to elect directors;

prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; and

provide our Board of Directors the ability to designate the terms of and issue new series of preferred stock without stockholder approval.

In addition, Section 203 of the Delaware General Corporation Law generally prohibits us from engaging in any business combination with certain persons who own 15% or more of our outstanding voting stock or any of our associates or affiliates who at any time in the past three years have owned 15% or more of our outstanding voting stock. These provisions may have the effect of entrenching our management team and may deprive stockholders of the opportunity to sell their shares to potential acquirers at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

***Failure to satisfy NASDAQ Capital Market listing requirements may result in our common stock being delisted from the NASDAQ Capital Market.***

Our common stock is currently listed on the NASDAQ Capital Market under the symbol IMRX. For continued inclusion on the NASDAQ Capital Market, we must maintain, among other requirements, stockholders' equity of at least \$2.5 million, a minimum bid price of \$1.00 per share and a market value of our public float of at least \$1.0 million; or market capitalization of at least \$35.0 million, a minimum bid price of \$1.00 per share and a market value of our public float of at least \$1.0 million. If we fail to meet a closing bid price of our common stock of \$1.00 for 30 consecutive business days, our common stock could be at risk of being delisted. The closing price of our common stock has been below \$1.00 since March 3, 2008. As of March 25, 2008, the closing price of our common stock was \$0.40 per share. In the event that we fail to satisfy any of the listing standards on a continuous basis, our common stock could be removed from listing on the NASDAQ Capital Market. If our common stock were delisted from the NASDAQ Capital Market, trading of our common stock, if any, may be conducted in the over-the-counter market in the so-called pink sheets or, if available, the National Association of Securities Dealers' Electronic Bulletin Board. Consequently, broker-dealers may be less willing or able to sell and/or make a market in our common stock. Additionally, an investor would find it more difficult to dispose of, or to obtain accurate quotations for the price of, our common stock. A delisting would likely also make it more difficult for us to raise funds through the sale of our securities.

***We do not intend to pay cash dividends on our common stock in the foreseeable future.***

We have never declared or paid any cash dividends on our common stock or other securities, and we do not anticipate paying any cash dividends in the foreseeable future. Accordingly, our stockholders will not realize a return on their investment unless the trading price of our common stock appreciates. Our common stock may not appreciate in value and may not maintain the price at which investors purchased shares.

**ITEM 2. Properties**

Our current facilities are located in four leased buildings in Tucson, Arizona. Our corporate headquarters is approximately 7,850 square feet and is subject to a five-year lease at approximately \$0.2 million per year that

terminates on December 31, 2012. One facility provides office, storage and laboratory space, is approximately 6,500 square feet, and is subject to a one-year lease at approximately \$0.1 million per year that terminates December 31, 2007. The third facility served as our corporate headquarters until February 18, 2007 and is currently unutilized. It is approximately 6,200 square feet and is subject to a six-year lease at approximately \$65,000 per year that terminates on October 31, 2008. This lease may be extended at our option for up to four additional six-year periods. Our previous headquarters facility is owned by a partnership whose beneficial owners include two of our officers and several of our stockholders. Our fourth facility is a temporary modular office space which was used for our expanded administrative staff, and is subject to a month-to-month lease. We are no longer utilizing this facility and are in the process of decommissioning the modular space.

**Table of Contents****ITEM 3. Legal Proceedings**

From time to time, we may be involved in litigation relating to claims arising out of our operations. We are not currently subject to any material legal proceedings and are also not aware of any pending legal, arbitration or governmental proceedings against us that may have material effects on our financial position or results of operations.

**ITEM 4. Submission of Matters to a Vote of Security Holders**

No matters were submitted to a vote of security holders during the fourth quarter of 2007.

**PART II****ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

Our common stock has been quoted on the NASDAQ Capital Market under the symbol **IMRX** since July 26, 2007. Prior to that time, there was no public market for our common stock. The following table sets forth, for the periods indicated, the quarterly high and low sales prices per share of our common stock as reported on the NASDAQ Capital Market.

	<b>High</b>	<b>Low</b>
<b>2007</b>		
Fourth Quarter	\$ 3.45	\$ 1.51
Third Quarter (beginning July 26, 2007)	4.90	3.25

At March 25, 2008, there were 363 stockholders of record.

We have never declared or paid cash dividends on capital stock. We intend to retain any future earnings to finance growth and development and therefore do not anticipate paying cash dividends in the foreseeable future.

**Use of Proceeds.**

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-142646), which was declared effective by the Securities and Exchange Commission on July 25, 2007. We received net proceeds of \$12.4 million from the offering. As of December 31, 2007, all of the net proceeds from the initial public offering remain invested in short-term, interest-bearing, investment-grade securities. We expect to use the offering proceeds in the following manner:

to repay a portion of the Abbott Laboratories note;

to fund exploration of strategic alternatives to continue the development of our SonoLysis program;

to fund urokinase commercialization activities; and

working capital and other general corporate purposes.

**Table of Contents****ITEM 6. Selected Financial Data**

The selected financial data for each of the five years in the period ended December 31, 2007 is derived from our audited financial statements. The following selected data should be read in conjunction with our financial statements located elsewhere in this Annual Report on Form 10-K and Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

	<b>Years Ended December 31,</b>				
	<b>2003</b>	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>2007</b>
	<b>(in thousands, except share data)</b>				
<b>Consolidated Statements of Operations Data:</b>					
Product sales, research and development revenue	\$ 224	\$ 575	\$ 619	\$ 1,328	\$ 8,360
Total operating expenses (1)	3,741	5,859	31,915	17,020	17,029
Operating loss	(3,517)	(5,284)	(31,296)	(15,692)	(8,669)
Gain on extinguishment of debt (2)			3,835	16,127	219
Net loss	(3,820)	(5,724)	(27,926)	(699)	(8,764)
Accretion of dividends on preferred stock	(1,287)	(301)	(601)	(1,167)	(867)
Reversal of accretion of dividends on preferred stock not paid					4,919
Deemed dividend from beneficial conversion feature for Series F redeemable convertible preferred stock					(13,842)
Net loss attributable to common stockholders	\$ (5,107)	\$ (6,025)	\$ (28,527)	\$ (1,866)	\$ (18,554)
Net loss attributable to common stockholders per share Basic and diluted	\$ (8.71)	\$ (5.37)	\$ (15.11)	\$ (0.72)	\$ (3.16)
Weighted average shares outstanding Basic and diluted	586,396	1,122,881	1,888,291	2,599,425	5,868,131
	<b>At December 31,</b>				
	<b>2003</b>	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>2007</b>
	<b>(in thousands, except share data)</b>				

**Consolidated Balance Sheet Data:**

Cash and cash equivalents	\$ 736	\$ 1,538	\$ 8,513	\$ 4,256	\$ 12,861
Working capital (deficit)	(1,440)	739	(8,111)	2,657	7,383
Total assets	1,298	2,122	9,516	25,293	30,707
Long-term notes payable, less current portion	4,002	4,282			



Redeemable convertible preferred stock (3)	20,826	21,127	21,727	35,863	
Total stockholders equity (deficit)	(26,003)	(24,529)	(29,327)	(30,008)	10,205

(1) Research and development expense for the year ended December 31, 2005 includes the purchase of in-process research and development operations valued at \$24.0 million in accordance with the Asset Purchase Agreement entered into with Abbott Laboratories in September 2005 related to our acquisition of certain recombinant thrombolytic drug technologies. In December 2006, our Board of Directors decided not to complete payment for these technologies under the non-recourse debt we had issued to Abbott Laboratories, and decided to allow the acquired technologies to be repossessed

by Abbott  
Laboratories.

- (2) An extinguishment of debt payable to a development partner in a joint development agreement entered into in 2001 resulted in a gain on extinguishment of note of \$3.8 million in March 2005. Extinguishment of the non-recourse debt issued to Abbott Laboratories as partial payment for the 2005 purchase of recombinant thrombolytic drug technologies resulted in a gain on extinguishment of debt of \$16.1 million in December 2006. An extinguishment of a debt payable to a third party for patent costs resulted in a gain on extinguishment of debt of \$0.2 million in May 2007.
- (3) Upon the completion of the initial public

offering in  
July 2007, all of  
the previously  
outstanding  
preferred shares  
were converted  
into shares of  
common stock.

**Table of Contents****ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*The following discussion and analysis should be read in conjunction with our audited financial statements and notes thereto that appear elsewhere in this report. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those set forth in the section entitled "Risk Factors" and elsewhere in this report.*

The statements contained in this Annual Report on Form 10-K, including statements under this section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including, without limitation, statements regarding our or our management's expectations, hopes, beliefs, intentions or strategies regarding the future. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "plan," and similar expressions may identify forward-looking statements but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements contained in this Annual Report on Form 10-K are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include those factors described in greater detail in Item 1A of Part I, "Risk Factors." Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those anticipated in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

**Overview**

We are 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 four 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.

Since our inception, we have devoted substantially all of our efforts toward commercializing our FDA approved product, planning, conducting and funding the various stages of development for our product candidates, researching potential new product opportunities based upon our proprietary technologies, and acquiring technology and potential products.

**Product Sales, Research and Development Revenue**

Our primary source of revenue is derived from sales of our urokinase product currently sold as Abbokinase and being re-branded as Kinlytic. We commenced sales of urokinase in October 2006 and have been generating revenue from

sales of this product since that date. Future revenues from sales of urokinase may also be impacted by our ability to extend the expiration dating of the currently unlabeled vials. In addition to our commercial product sales, we also generate a limited amount of revenue by providing research services for projects funded under various government grants.

**Table of Contents**

All product sales recorded to date relate to sales of urokinase in the United States, which we commenced in October 2006. Due to the lack of returns history and the fact that customers may return expired urokinase product that is in its original, unopened cartons within 12 months past the product expiration date, we currently account for these product shipments using a deferred revenue recognition model. We do not recognize revenue upon product shipment to a wholesale distributor but rather, we defer the recognition of revenue until the right of return no longer exists or when the product is sold to the end user as is stipulated by SFAS No. 48, *Revenue Recognition When the Right of Return Exists*. We record product sales net of chargebacks, distributor fees, discounts paid to wholesale distributors, and administrative fees paid to Group Purchasing Organizations (GPOs). The allowances are based on historical information and other pertinent data. As of December 31, 2007, we had deferred revenue of \$5.4 million.

***Cost of Product Sales***

Cost of product sales is determined using a weighted-average method and includes the acquisition cost of the inventory as well as additional labeling costs we incur to bring the product to market. Our product pricing is fixed, but could include a variable sales or cash discount depending on the nature of the sale. Our gross margins are affected by chargebacks, discounts and administrative fees paid to the wholesalers and GPOs.

***Research and Development Expenses***

We classify our research and development expenses into four categories of activity, namely; research, development, clinical and regulatory. To date, our research and development efforts have been focused primarily on product candidates from our SonoLysis program. Because we do not expect to expend significant resources on this program until a strategic alternative is identified that would provide sufficient financing to continue the development of the program we expect our research and development expenses to decrease significantly with our efforts to find a strategic alternative for our SonoLysis program and the wind-down of our Phase I/II clinical trial in ischemic stroke patients.

***General and Administrative Expenses***

General and administrative expenses consist primarily of personnel-related expenses and other costs and fees associated with our general corporate activities, such as sales and marketing, administrative support, business development, intellectual property protection, public reporting and corporate compliance, as well as a portion of our overhead expenses. Our selling expenses have increased and may continue to increase should we decide to expand our infrastructure to support commercialization efforts relating to urokinase. We have incurred and will continue to incur additional expenses in the areas of legal, accounting and corporate governance as a public company.

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

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosed amounts of contingent assets and liabilities and our reported revenue and expenses. Significant management judgment is required to make estimates in relation to clinical trial costs and previous costs associated with transitioning to a public reporting company. We evaluate our estimates, and judgments related to these estimates, on an ongoing basis. We base our estimates of the carrying values of assets and liabilities that are not readily apparent from other sources on historical experience and on various other factors that we believe are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

We believe that the following accounting policies are critical to a full understanding of our reported financial results. Our significant accounting policies are more fully described in Note 1 of our consolidated financial statements.

**Table of Contents*****Inventory and Inventory Subject to Return***

Inventory of urokinase, our only commercially available FDA approved product, is comprised of finished goods and is stated at the lower of cost or market value. We currently sell urokinase under the name Abbokinase and are re-branding the product to be sold under the name Kinlytic. Inventory value was determined as a result of the purchase price allocation from the acquisition of this product from Abbott Laboratories in 2006. We periodically review the composition of inventory in order to identify obsolete, slow-moving or otherwise un-saleable inventory. As of December 31, 2007, 24% of the vials in inventory held by us or our wholesale distributors, or \$3.3 million in inventory value, were labeled and will expire at various times up to September 2009. The remaining 76% of the vials or \$10.4 million in inventory value, were unlabeled and based on current stability data will expire September 2009. We have an ongoing stability program to support future expiration date extensions for the unlabeled vials. We have submitted to the FDA lot release requests for inventory to be labeled with the new expiration dates and received lot release approval from the FDA in the first quarter of 2008. We intend to continue the stability program to potentially enable further expiration extensions for unlabeled vials of inventory. We will continue to monitor these efforts and evaluate the adequacy of our inventory obsolescence reserves.

***Clinical Trial Accrued Expenses***

We record accruals for clinical trial costs associated with clinical research organizations, investigators and other vendors based upon the estimated amount of work completed on each clinical trial. All such costs are charged to research and development expenses based on these estimates. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, correspondence and discussions with our contract research organizations and review of contractual terms in order to make these estimates accurate. To date, we have not experienced material changes in these estimates.

***Revenue Recognition***

Revenue from product sales is recognized pursuant to Staff Bulletin No. 104 (SAB 104), *Revenue Recognition in Financial Statements*. Accordingly, revenue is recognized when all four of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products has occurred; (iii) the selling price is both fixed and determinable; and (iv) collectibility is reasonably assured. We apply SFAS No. 48, *Revenue Recognition When the Right of Return Exists*, which among other criteria requires that future returns can be reasonably estimated in order to recognize revenue. The amount of future returns is uncertain due to the insufficiency of returns history data. Due to the uncertainty of returns, we are accounting for these product shipments to wholesale distributors using a deferred revenue recognition model. Under this model, we do not recognize revenue upon product shipment to wholesale distributors; therefore, recognition of revenue is deferred until the product is sold by the wholesale distributor to the end user.

Our customers consist primarily of large pharmaceutical wholesaler distributors who sell directly to hospitals and other healthcare providers. Provisions for product returns and exchanges, sales discounts, chargebacks, managed care and Medicaid rebates and other adjustments are established as a reduction of product sales revenues at the time such revenues are recognized. These deductions from gross revenue are established by us as our best estimate at the time of sale adjusted to reflect known changes in the factors that impact such reserves.

We provide research services under certain grant agreements, including federal grants from the National Institutes of Health. We recognize revenue for these research services as the services are performed. Revenue from grants is recognized over the contractual period of the related award.

***Stock-Based Compensation***

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards, or SFAS, No. 123R, *Share-Based Payment* or SFAS 123R, which revises SFAS 123, *Accounting for Stock-Based Compensation*, and supersedes Accounting Principles Board Opinion, or APB, No. 25, *Accounting for Stock Issued to Employees*. SFAS 123R requires that share-based payment transactions with employees be recognized in the financial statements based on their value and recognized as compensation expense over the requisite service period. Prior to SFAS 123R, we disclosed the pro forma effects of SFAS 123 under the minimum value method. We adopted SFAS 123R effective January 1, 2006, prospectively for new equity awards issued subsequent to December 31, 2005.





**Table of Contents**

Pursuant to SFAS 123R, our estimate of share-based compensation expense requires a number of complex and subjective assumptions including our stock price volatility, employee exercise patterns, and future forfeitures. The value of a stock option is derived from its potential for appreciation. The more volatile the stock, the more valuable the option becomes because of the greater possibility of significant changes in stock price. The most significant assumptions are our estimates of the expected volatility and the expected term of the award. Because we recently completed our IPO in July 2007, we have limited historical information on our stock price volatility. In accordance with the implementation guidance in SFAS 123R, we have therefore calculated expected volatility based on the average volatilities of similar companies that are transitioning from newly public to more mature companies with more stock price history. For purposes of identifying similar entities, we have considered factors such as industry, company age, stage of life cycle, and size. The expected term of options granted represents the periods of time that options granted are expected to be outstanding. The expected option term also has a significant effect on the value of the option. The longer the term, the more time the option holder has to allow the stock price to increase without a cash investment and thus, the more valuable the option. Furthermore, lengthier option terms provide more opportunity to exploit market highs. However, historical data demonstrates that employees, for a variety of reasons, typically do not wait until the end of the contractual term of a nontransferable option to exercise. When establishing an estimate of the expected term of an award, we have elected to use the simplified method of determining expected term as permitted by SEC Staff Accounting Bulletin 107. As a result of using estimates, when factors change and we use different assumptions, our share-based compensation expense could be materially different in the future. We review our valuation assumptions at each grant date and, as a result, from time to time we will likely change the valuation assumptions we use to estimate the value of share-based awards granted in future periods.

**Results of Operations*****Twelve Months Ended December 31, 2006 Compared to 2007***

*Product Sales, Research and Development Revenue.* Our revenue-producing activities during 2006 and 2007 consisted of sales of our urokinase product, which commenced in October 2006, and services provided under research grants and contracts. Our total revenues increased from \$1.3 million in 2006 to \$8.4 million in 2007, primarily as a result of our commencement of sales of urokinase product which accounted for \$0.5 million of our revenue in 2006 and \$7.8 million in 2007. The \$7.3 million increase in urokinase sales from 2006 to 2007 is due to having one full year of sales in 2007 as opposed to just three months of sales in 2006. Our grant and other revenue decreased from \$0.8 million in 2006 to \$0.5 million in 2007, primarily due to the completion of one grant in the first quarter of 2007.

*Cost of Product Sales.* Cost of product sales was \$0.2 million in 2006 and \$3.5 million in 2007. The increase in cost of product sales was due to the fact we did not commence sales of urokinase until October of 2006. The cost of product sales includes the price paid to acquire the product as well as labeling costs that are directly incurred in bringing the product to market.

*Research and Development Expenses.* Research and development expenses decreased from \$9.1 million in 2006 to \$7.4 million in 2007. This decrease was principally a result of our focus on development of our more advanced SonoLysis programs and a reduction in early stage research activities, that resulted in a reduction in headcount of \$0.8 million and third party consulting expenses of \$0.9 million and the elimination of expenses associated with the recombinant thrombolytic drug assets that were relinquished to Abbott Laboratories in December 2006, offset partially by an increase in clinical trial costs related to our Phase I/II clinical trial of \$1.0 million incurred in 2007. We have concluded the Phase I/II clinical trial in patients with ischemic stroke and we are currently exploring strategic alternatives to continue the development of our SonoLysis program. We will not incur significant expenses in this program until a strategic alternative is identified. To this effect, in February 2008, we notified approximately 20 employees, approximately 60% of our workforce, that their employment would be terminated unless we were successful in securing an alternative funding source for the SonoLysis program. As of March 27, 2008, eight of those notified employees have left the employ of the Company.

**Table of Contents**

*General and Administrative Expenses.* General and administrative expenses decreased from \$7.7 million in 2006 to \$6.1 million in 2007. This decrease was principally a result of a \$1.9 million decrease in legal and consulting expenses that were capitalized upon the completion of the IPO in 2007 whereas in 2006 similar expenses were expensed after the unsuccessful initial public offering in 2006.

*Interest and Other Income.* Interest and other income increased from \$0.4 million in 2006 to \$0.5 million in 2007, as a result of a higher cash balance throughout the year and higher interest rates.

*Interest Expense.* Interest expense decreased from \$1.5 million in 2006 to \$0.9 million in 2007, due to the extinguishment of a note payable in December 2006.

*Gain on Extinguishment of Debt.* In December 2006, we extinguished a non-recourse debt that had been issued as partial consideration for the acquisition of recombinant thrombolytic drug technologies, resulting in a gain of \$16.1 million. In May 2007, we extinguished a debt for patent costs that resulted in a gain of \$0.2 million.

**Twelve Months Ended December 31, 2005 Compared to 2006**

*Product Sales, Grant and Other Revenue.* Our revenue-producing activities during 2005 and 2006 consisted of providing services under research grants and contracts, and sales of urokinase which commenced in October 2006. Our total revenues increased from \$0.6 million in 2005 to \$1.3 million in 2006, primarily as a result of our commencement of sales of urokinase product which accounted for \$0.5 million of our revenue in 2006. Our grant and other revenue increased from \$0.6 million in 2005 to \$0.8 million in 2006, primarily due to the receipt of an additional grant.

*Cost of Product Sales.* Cost of product sales was \$0.2 million in 2006. There was no cost of product sales for the year ending December 31, 2005 as we did not acquire our commercialized product until April 2006 and did not commence product sales until October 2006. The cost of product sales includes the price paid to acquire the asset as well as labeling costs that are directly incurred in bringing the product to market.

*Research and Development Expenses.* Research and development expenses increased from \$3.7 million in 2005 to \$9.1 million in 2006. This increase was principally a result of our continuing transition from a research organization to a clinical development organization, which required the expansion of both clinical and regulatory departments. The main components of increased cost were: \$1.7 million in compensation associated with increased headcount; \$0.9 million in increased expenses for the initiation of a clinical trial in stroke which began in August 2006 as well as other clinical trial activities; \$0.3 million in preclinical study costs related to our SonoLysis product candidates; \$0.1 million in expense for storing our commercial inventory of urokinase and related assets and \$1.4 million in third party service costs and other expenses. Of the \$9.1 million in expenses for 2006, \$0.5 million were costs related to the recombinant thrombolytic drug assets that we decided to relinquish to Abbott Laboratories in December 2006.

*General and Administrative Expenses.* General and administrative expenses increased from \$4.2 million in 2005 to \$7.7 million in 2006. This increase was principally a result of our expansion of financing and selling activities, which required additional headcount and third party services. The main components of increased cost were \$2.0 million in increased third party service costs, principally legal and accounting expenses related to financing matters, asset acquisitions and matters associated with becoming a public company; \$0.7 million in additional compensation expense to support increased headcount, and stock-based compensation expense including the expense under SFAS 123R; and \$0.2 million in third party service costs associated with marketing and sales of urokinase.

*Interest and Other Income.* Interest and other income increased from \$0.1 million in 2005 to \$0.4 million in 2006, as a result of a higher cash balance throughout the year and higher interest rates.

*Interest Expense.* Interest expense increased from \$0.6 million in 2005 to \$1.5 million in 2006, due to the interest accrued on a note payable issued in April 2006 and the payment of a full year of interest in 2006 on a note payable issued in September 2005.

**Table of Contents**

*Gain on Extinguishment of Debt.* In March 2005, we repurchased a note from a former development partner at a discount. The outstanding principal and accrued interest, totaling \$4.3 million, was settled in cash for \$0.5 million resulting in a non-recurring gain of \$3.8 million. In December 2006, we extinguished a non-recourse debt that had been issued as partial consideration for the acquisition of recombinant thrombolytic drug technologies, resulting in a non-recurring gain of \$16.1 million.

**Liquidity and Capital Resources*****Sources of Liquidity***

We have incurred losses since our inception. At December 31, 2007, we had an accumulated deficit of \$81.2 million. We have historically financed our operations principally through the public offering and private placement of shares of our common and preferred stock and convertible notes, government grants, and, more recently, product sales, which commenced in October 2006. During the years ended December 31, 2005, 2006 and 2007, we received net proceeds of \$17.9 million, \$13.0 million, \$12.4 million, respectively, from the issuance of shares of our common and preferred stock and convertible notes. These amounts do not include the \$15.0 million secured non-recourse note and \$4.0 million of Series E preferred stock that we issued as partial consideration for an acquisition of recombinant thrombolytic drug technologies in September 2005, or the \$15.0 million secured non-recourse note that we issued to acquire urokinase and related assets in April 2006. At December 31, 2007, we had \$12.9 million in cash and cash equivalents.

On July 25, 2007, 3,000,000 shares of common stock were sold on the Company's behalf at an initial public offering price of \$5.00 per share, resulting in aggregate cash proceeds of approximately \$12.4 million, net of underwriting discounts commissions and offering expenses. Upon the completion of the Company's initial public offering in July 2007, all of the Company's previously outstanding preferred shares converted into an aggregate of 4,401,129 shares of the Company's common stock.

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. The purchase price for the assets was \$20.0 million, which was paid in the form of \$5.0 million in cash and the issuance of a \$15.0 million non-recourse promissory note which was originally due December 31, 2007 and is now due 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 a final agreement with Abbott Laboratories will be completed in the second quarter of 2008.

We commenced selling urokinase in October 2006. Since the initiation of sales in October 2006, as of December 31, 2007, we had received aggregate net proceeds of \$15.4 million from sales of urokinase to our wholesale distributors and customers. Our agreement with Abbott Laboratories requires us to place 50% of the proceeds from all sales of urokinase after the initial \$5.0 million of sales is reached into an escrow account until the \$15.0 million note from the initial purchase from Abbott Laboratories is repaid. On October 25, 2007, we signed a Note Extension and Amendment Agreement with Abbott Laboratories. In this Agreement, Abbott Laboratories agreed to extend the due date of the note to March 31, 2008, and we instructed the escrow agent to transfer the funds held in escrow of \$4.8 million to Abbott representing \$1.4 million of accrued interest and principal of \$3.4 million. The principal amount outstanding on the note upon completion of this transaction was \$11.6 million. As of December 31, 2007, the remaining balance of the note including accrued interest was \$11.7 million and we paid \$0.4 million into the escrow account as of December 31, 2007 and another \$0.7 million has been placed into the escrow account from January 1, 2008 through March 25, 2008. We do not currently have sufficient resources to pay the balance of the note when due and at the same time continue the operations of our business. 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 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 which aggregate \$15.3 million at December 31, 2007. In that event we would no longer generate revenue from sales of urokinase and we would be forced to discontinue our commercial efforts with this program, which could significantly limit our ability to continue as a going concern, and we may not have

sufficient funds available past the third quarter of 2008. We would then be required to obtain additional funding and would seek to do so through collaborative arrangements, public offerings or private financings.

**Table of Contents**

The exact timing and amount of future sales of urokinase will depend on a number of external factors, such as our ability to renegotiate the payments terms on the non-recourse note with Abbott Laboratories, our ability to obtain an extension of the expiration dates for the urokinase inventory beyond September 2009, our ability to establish additional sales relationships with customers for that product, our inventory levels at the wholesale distributors that are currently stocking the product, and other competitive and regulatory factors. Based on current stability data as of December 31, 2007, all vials of our urokinase inventory expire at various times up to September 2009. We have an ongoing stability program to support expiration date extensions for the unlabeled vials. Once product is labeled, we cannot extend the expiration date of the labeled vials. If the FDA objects to the methods or results of the stability testing program, we estimate that 76% of inventory held by us or our wholesale distributors that we expect hospitals to purchase, or \$10.4 million in inventory value out of the total of \$13.7 million carried at December 31, 2007, is at risk of expiring. Based on the testing to date, which has shown that the product changes very little from year to year, we believe that the stability data supports extension of the inventory expiration dates, that we will be able to sell this inventory and that we will recover the initial cost of this inventory. We submitted a lot release request for inventory to be labeled with the new expiration dates in the fourth quarter 2007 and received lot release approval from the FDA in the first quarter of 2008. We submitted two additional lot release extension requests for inventory to be labeled with the new expiration dates in the first quarter of 2008 and received lot release approval from the FDA in the first quarter of 2008. We intend to continue the stability program to potentially enable further expiration extensions for unlabeled vials of inventory.

***Cash Flows***

*Net Cash Used in or provided by Operating Activities.* Net cash used in operating activities was \$11.1 million and \$16.0 million for the years ended December 31, 2005 and 2006, respectively, and net cash provided by operating activities was \$1.9 million for the year ended December 31, 2007. The net cash used in 2005 and 2006 primarily reflects the net loss for those periods, offset in part by depreciation, amortization of warrant expense and debt discount, and non-cash gain on extinguishment of debt, stock-based compensation and changes in working capital. The cash provided by operations in 2007 primarily reflects an increase in revenue, depreciation, amortization and accrued expenses and other liabilities and an decrease in inventory, offset in part by the net loss.

*Net Cash Used in or provided by Investing Activities.* Net cash used in investing activities was \$0.6 million, \$1.3 million and \$0.6 million for the years ended December 31, 2005, 2006 and 2007, respectively. Net cash used in investing activities primarily reflects purchases of property and equipment, including manufacturing, information technology, laboratory and office equipment and intangible assets.

*Net Cash Provided by Financing Activities.* Net cash provided by financing activities was \$18.7 million, \$13.0 million and \$7.2 million for the years ended December 31, 2005, 2006 and 2007. Net cash provided by financing activities was primarily attributable to the issuance of common stock totaling \$17.9 million in 2005; the issuance of preferred stock totaling \$13.0 million net of issuance costs in 2006; and \$12.4 million net cash proceeds from the initial public offering offset partially by a \$4.8 million payment on the note payable to Abbott Laboratories in 2007.

***Operating Capital and Capital Expenditure Requirements***

Based on our existing liquid assets, including the proceeds of our sales of urokinase product and the IPO, our decision to reduce expenditures related to our SonoLysis program while we search for strategic alternatives to fund the program, and the tentative agreement we have reached with Abbott Laboratories revising the payment terms of our outstanding promissory note, we believe we have sufficient capital to fund our operating needs for at least the next 12 months. Our operating needs include the planned costs to operate our business and the amount required to fund our working capital and capital expenditures. At the present time, we have no material commitments for capital expenditures.

Our ability to repay the \$11.6 million principal balance on the secured non-recourse note due to Abbott Laboratories on March 31, 2008 is our most significant near term financing requirement. Our ability to fund the repayment of the note as well as fund our other business activities will depend on our ability to successfully renegotiate the payment terms of the note. In the event we are not successful in renegotiating the payment terms of the note, Abbott may elect to foreclose on the urokinase assets. In that event we would no longer generate revenue from sales of urokinase and we would be forced to discontinue our commercial efforts with this program.



**Table of Contents**

We expect to continue to fund our operations primarily from our current cash resources, from sales of urokinase, provided we finalize the tentative agreement we have reached with Abbott Laboratories on the revised payment terms of our outstanding note, and from revenue or payments received under grants. We may also seek additional funds through issuance of our equity securities or through debt financings. We may not be successful in commercializing urokinase or in gaining restructured repayment terms on the Abbott note or in obtaining such additional proceeds or revenue. We cannot be sure that our existing cash and cash equivalents will be adequate, or that additional financing will be available when needed, or that, if available, such financing will be obtained on terms favorable to us or our stockholders. Failure to obtain adequate financing may adversely affect our ability to operate as a going concern. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders will likely result. If we raise additional funds by incurring debt obligations, the terms of the debt will likely involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

**Contractual Obligations**

The following table summarizes our outstanding contractual obligations as of December 31, 2007 (in thousands):

<b>Total</b>	<b>Total</b>	<b>Payments Due By Period</b>			<b>More than 5 Years</b>
		<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>3-5 Years</b>	
Operating leases	\$ 1,119	\$ 307	\$ 600	\$ 212	
Secured non-recourse note(1)	11,572	11,572			
<b>Total</b>	<b>\$ 12,691</b>	<b>\$ 11,879</b>	<b>\$ 600</b>	<b>\$ 212</b>	

(1) Includes only the principal balance.

We also have contractual payment obligations that are contingent on future events.

If we or our sublicensees sell products or processes that utilize the intellectual property we license from UNEMED Corporation, we will be obligated pay a royalty to UNEMED of 2% of such net sales.

If we or our sublicensees sell products or processes that utilize the intellectual property we license from the University of Arkansas, we will be obligated to pay, in addition to a one-time fee of \$25,000, royalties to the University of Arkansas of (i) 4% of net sales up to \$1.0 million; (ii) 3% of net sales between \$1.0 million and \$10.0 million; and (iii) 2% of net sales greater than \$10.0 million, subject to minimal royalty thresholds and a maximum aggregate royalty of \$20.0 million.

If we or our sublicensees sell products or processes that utilize the intellectual property that we license from Dr. Schlieff, we will be obligated to pay a royalty to Dr. Schlieff of 2% of such net sales by us and 3% of any net sales by sublicensees.

**Off-Balance Sheet Transactions**

At December 31, 2006 and 2007, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

**Recently Issued Accounting Pronouncements**

In September 2006, the FASB issued SAFS No. 157, *Fair Value Measurements*. SFAS 157 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 applies under other accounting pronouncements that require or permit fair value measurements, the FASB having

previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, SFAS 157 does not require any new fair value measurements, but may change current practice for some entities. SFAS 157 is effective for fiscal years beginning after December 15, 2006. The adoption of SFAS No. 157 will not have an effect on our financial position or results of operations.



**Table of Contents**

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The standard requires that unrealized gains and losses on items for which the fair value option has been elected be reported in earnings. SFAS 159 is effective for the fiscal years beginning after November 15, 2007. The adoption of SFAS No. 159 is not expected to have a material effect on our financial position or results of operations.

In December 2007, the FASB issued SFAS No. 141 (revised 2007) ( SFAS 141R ), *Business Combinations* and SFAS No. 160 ( SFAS 160 ), *Noncontrolling Interests in Consolidated Financial Statements, an amendment of Accounting Research Bulletin No. 51*. SFAS 141R will change how business acquisitions are accounted for and will impact financial statements both on the acquisition date and in subsequent periods. SFAS 160 will change the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. SFAS 141R and SFAS 160 are effective beginning in the first fiscal period ending after December 15, 2008. Early adoption is not permitted. We believe the adoption of these new standards, SFAS 141R and SFAS 160, will not have an impact on our consolidated financial statements.

**ITEM 7A. Quantitative and Qualitative Disclosure About Market Risk**

**Interest Rate Risk.** Our exposure to market risk is confined to our cash and cash equivalents. We invest in high-quality financial instruments, primarily money market funds, which we believe are subject to limited credit risk. We currently do not hedge interest rate exposure. The effective duration of our portfolio is less than three months and no security has an effective duration in excess of three months. Due to the short-term nature of our investments, we do not believe that we have any material exposure to interest rate risk arising from our investments.

**Foreign Currency Risk.** Most of our transactions are conducted in U.S. dollars, although we do have some development and clinical trial agreements with vendors located outside the U.S. Transactions under certain of these agreements are conducted in U.S. dollars while others occur in the local currency. If the exchange rate were to change by ten percent, we do not believe that it would have a material impact on our results of operations or cash flows.

**ITEM 8. Financial Statements and Supplementary Data**

The information required by this item is incorporated herein by reference to the financial statements and schedule listed in Item 15 (a)1 and (a)2 of Part IV and included in this Form 10-K Annual Report.

**ITEM 9A(T). Controls and Procedures*****Evaluation of Disclosure Controls and Procedures***

We maintain disclosure controls and procedures that are designed to ensure that material information required to be disclosed in our periodic reports filed under the Securities Exchange Act of 1934, as amended, or 1934 Act, is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and to ensure that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer as appropriate, to allow timely decisions regarding required disclosure. During the quarter ended December 31, 2007 we carried out an evaluation, under the supervision and with the participation of our management, including the chief executive officer and the chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the 1934 Act. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of December 31, 2007, our disclosure controls and procedures were effective.

**Table of Contents**

***Management's Report on Internal Control over Financial Reporting***

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

**PART III**

**ITEM 10. Directors, Executive Officers, and Corporate Governance**

The information required by this item concerning our directors and director nominees is incorporated by reference to our definitive Proxy Statement for our 2008 Annual Meeting of Shareholders under the captions Election of Directors and Corporate Governance. Information regarding Section 16(a) beneficial ownership reporting compliance is incorporated by reference to the material under the heading Security Ownership of Certain Beneficial Owners and Management in our 2008 Proxy Statement. Information relating to our executive officers is contained in Item 1 of this Annual Report on Form 10-K. Information relating to our audit committee is incorporated by reference to our 2008 Proxy Statement under the caption Audit Committee Report.

We have adopted a written code of conduct that applies to all employees, including our Chief Executive Officer, Chief Financial Officer and Controller, which is a code of ethics as defined by applicable rules of the SEC. This code of conduct is publicly available on our website at [www.imarx.com](http://www.imarx.com) in the Investor Relations/Corporate Governance section. The information contained on our website is not incorporated by reference into this Annual Report on Form 10-K. If we make any amendments to this code of conduct other than technical, administrative or other non-substantive amendments, or grant any waivers, including implicit waivers, from a provision of this code to our Chief Executive Officer, Chief Financial Officer, or Controller, we will disclose the nature of the amendment or waiver, its effective date and to whom it applies on our website or in a report on Form 8-K filed with the SEC.

**ITEM 11. Executive Compensation**

Information concerning executive compensation is incorporated by reference from the sections entitled Executive Compensation and Other Information contained in our definitive Proxy Statement for our 2008 Annual Meeting of Stockholders.

**ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

Information concerning the security ownership of certain beneficial owners and management is incorporated by reference from the section entitled Ownership of Securities contained in our 2008 Proxy Statement. Information regarding our equity compensation plans is incorporated by reference to our 2008 Proxy Statement under the caption Equity Compensation Plan Information.

**ITEM 13. Certain Relationships and Related Transactions, and Director Independence**

Information concerning certain relationships and related transactions is incorporated by reference from the sections entitled Proposal One: Election of Directors, Executive Compensation and Other Information and Certain Transactions contained in our 2008 Proxy Statement. Information regarding corporate governance is incorporated by reference to our 2008 Proxy Statement under the caption Proposal One: Election of Directors.

**ITEM 14. Principal Accountant Fees and Services**

Information concerning principal accounting fees and services is incorporated by reference from the sections entitled Proposal Two: Ratification of Independent Auditors contained in our 2008 Proxy Statement.

**Table of Contents****PART IV****ITEM 15. Exhibits and Financial Statement Schedules**

a) The following documents are filed as a part of this report:

(1) *Consolidated Financial Statements*: The financial statements required by this item are submitted in a separate section beginning on page F-1 of this annual report.

	<b>Page</b>
Index to Consolidated Financial Statements	F-1
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2006 and 2007	F-3
Consolidated Statements of Operations for the years ended December 31, 2005, 2006, and 2007	F-5
Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2005, 2006 and 2007	F-6
Consolidated Statements of Cash Flows for the years ended December 31, 2005, 2006 and 2007	F-7
Notes to Consolidated Financial Statements	F-8

(2) The information for financial statement schedules has been omitted since they are not applicable.

(b) Exhibits

<b>Exhibit No</b>	<b>Exhibit Title</b>	<b>Filed Herewith</b>	<b>Form</b>	<b>Incorporated by Reference</b>		
				<b>Exhibit No.</b>	<b>File No.</b>	<b>Filing Date</b>
3.1	Fourth Amended and Restated Certificate of Incorporation of the registrant		S-1	3.1	333-142646	5/4/2007
3.2	Amendment to Certificate of Incorporation of the registrant to effect a six-for-ten reverse stock split		S-1	3.2	333-142646	5/4/2007
3.3	Second Amendment to Certificate of Incorporation of the registrant to effect a one-for-three reverse stock split		S-1	3.3	333-142646	5/4/2007
3.4	Amended and Restated Certificate of Incorporation of the registrant		S-1	3.4	333-142646	5/4/2007

Edgar Filing: IMARX THERAPEUTICS INC - Form 10-K

3.5	Bylaws of the registrant, as amended	S-1	3.5	333-142646	5/4/2007
3.6	Amended and Restated Bylaws of the registrant	S-1	3.6	333-142646	5/4/2007
4.1	Specimen certificate evidencing shares of common stock	S-1	4.1	333-142646	5/4/2007
10.1*	Form of Indemnification Agreement entered into between the registrant and each of its directors and officers	S-1	10.1	333-142646	5/4/2007

**Table of Contents**

<b>Exhibit No</b>	<b>Exhibit Title</b>	<b>Filed Herewith</b>	<b>Form</b>	<b>Incorporated by Reference</b>		
				<b>Exhibit No.</b>	<b>File No.</b>	<b>Filing Date</b>
10.2	Second Amended and Restated Investors Rights Agreement, dated April 14, 2006, by and among the registrant and certain stockholders		S-1	10.2	333-142646	5/4/2007
10.3*	2000 Stock Plan and related agreements		S-1	10.3	333-142646	5/4/2007
10.4*	2007 Performance Incentive Plan and related agreements		S-1	10.4	333-142646	5/4/2007
10.5*	Bonus Plan		S-1	10.5	333-142646	5/4/2007
10.6	License Agreement, dated January 4, 2005, between the registrant and Dr. med. Reinhard Schlieff		S-1	10.6	333-142646	5/4/2007
10.7	Exclusive Sublicense Agreement, dated October 10, 2003, between the registrant and UNEMED Corporation		S-1	10.7	333-142646	5/4/2007
10.8	Assignment, Assumption and License Agreement, dated October 7, 1999, between the registrant and Bristol-Myers Squibb Medical Imaging, Inc. (as successor to DuPont Contrast Imaging, Inc.) dated October 7, 1999, and amendments thereto		S-1	10.8	333-142646	5/4/2007
10.9	License Agreement, dated February 10, 2006, between the registrant and the University of Arkansas for Medical Sciences		S-1	10.9	333-142646	5/4/2007
10.10			S-1	10.10	333-142646	5/4/2007

Edgar Filing: IMARX THERAPEUTICS INC - Form 10-K

Asset Purchase Agreement,  
dated April 10, 2006,  
between the registrant and  
Abbott Laboratories, and  
amendments thereto

10.11	Escrow Agreement, dated April 14, 2006, between the registrant and Abbott Laboratories	S-1	10.11	333-142646	5/4/2007
10.12	Inventory Trademark License Agreement, dated April 14, 2006, between the registrant and Abbott Laboratories	S-1	10.12	333-142646	5/4/2007
10.13	Security Agreement, dated April 14, 2006, between the registrant and Abbott Laboratories	S-1	10.13	333-142646	5/4/2007
10.14	Secured Promissory Note, dated April 14, 2006, between the registrant and Abbott Laboratories	S-1	10.14	333-142646	5/4/2007
10.15	Second Amended Executive Employment Agreement, dated May 15, 2006, between the registrant and Evan C. Unger	S-1	10.15	333-142646	5/4/2007

**Table of Contents**

<b>Exhibit No</b>	<b>Exhibit Title</b>	<b>Filed Herewith</b>	<b>Form</b>	<b>Incorporated by Reference</b>		
				<b>Exhibit No.</b>	<b>File No.</b>	<b>Filing Date</b>
10.16	Consulting Agreement, dated October 20, 2006, between the registrant and Evan C. Unger		S-1	10.16	333-142646	5/4/2007
10.17	Confidential Separation Agreement and Mutual General Release of All Claims, dated November 28, 2006, between the registrant and Evan C. Unger		S-1	10.17	333-142646	5/4/2007
10.18*	Consulting Agreement, dated April 11, 2005, between the registrant and Greg Cobb		S-1	10.18	333-142646	5/4/2007
10.19*	Amended Executive Employment Agreement, dated February 1, 2007, between the registrant and Greg Cobb		S-1	10.19	333-142646	5/4/2007
10.20*	Amended Executive Employment Agreement, dated February 1, 2007, between the registrant and Bradford A. Zakes		S-1	10.20	333-142646	5/4/2007
10.21	Agreement, dated March 31, 2006, by and among the registrant, John A. Moore and Edson Moore Healthcare Ventures		S-1	10.21	333-142646	5/4/2007
10.22	Subscription Agreement and Investor Questionnaire, dated March 2004, between the registrant and each of the signatory investors, offering price \$2.00 per share		S-1	10.22	333-142646	5/4/2007
10.23	Subscription Agreement and Investor Questionnaire,		S-1	10.23	333-142646	5/4/2007

dated December 2004,  
between the registrant and  
each of the signatory  
investors, offering price  
\$3.00 per share

10.24	Subscription Agreement and Investor Questionnaire, dated September and October 2004, between the registrant and each of the signatory investors, offering price \$4.00 per share	S-1	10.24	333-142646	5/4/2007
10.25	Commercial Lease Triple Net, dated November 1, 2002, between the registrant and ImaRx Investments L.L.C.	S-1	10.25	333-142646	5/4/2007
10.26	Standard Commercial Industrial Lease, dated December 30, 1997, between the registrant and Tucson Tech Park and addenda thereto	S-1	10.26	333-142646	5/4/2007



**Table of Contents**

Exhibit No	Exhibit Title	Filed Herewith	Form	Incorporated by Reference		
				Exhibit No.	File No.	Filing Date
10.27	Note Extension and Amendment Agreement, dated October 25, 2007, between the registrant and Abbott Laboratories		8-K	10.1	001-33043	10/26/2007
10.28*	Amendment No. 2 to Executive Employment Agreement dated as of January 1, 2008 by and between the Company and Bradford A. Zakes		8-K	10.1	001-33043	2/7/2008
10.29*	Amendment No. 2 to Executive Employment Agreement dated as of January 1, 2008 by and between the Company and Greg Cobb		8-K	10.2	001-33043	2/7/2008
10.30*	Executive Employment Agreement dated as of January 1, 2008 by and between the Company and Garen Manvelian		8-K	10.3	001-33043	2/7/2008
10.31*	Executive Employment Agreement dated as of January 1, 2008 by and between the Company and Kevin Ontiveros		8-K	10.4	001-33043	2/7/2008
10.32	Commercial Lease dated December 10, 2007, between the registrant and Cambric Partners	X				
23.1	Consent of Independent Registered Public Accounting Firm	X				
24.1	Power of Attorney (included in the signature page hereto)	X				

31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X

\* Denotes a compensatory plan, contract or arrangement, in which the Registrant's directors or executive officers may participate.

c) Financial Statements and Schedules See Item 15(a)(1) and 15(a)(2) above.

**Table of Contents****SIGNATURES**

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

IMARX THERAPEUTICS, INC.

By: /s/ Bradford A. Zakes

Bradford A. Zakes  
President and Chief Executive Officer

March 31, 2008

Date

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Bradford A. Zakes, Greg Cobb, and Kevin J. Ontiveros, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file, any and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their and his or her substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

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

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Bradford A. Zakes	President, Chief Executive Officer and	
Bradford A. Zakes	Director ( <i>principal executive officer</i> )	March 31, 2008
/s/ Greg Cobb	Chief Financial Officer	March 31, 2008
Greg Cobb	( <i>principal financial and accounting officer</i> )	
/s/ Richard Love	Director	March 31, 2008
Richard Love		
/s/ Richard Otto	Director	March 31, 2008
Richard Otto		
/s/ Thomas W. Pew	Director	March 31, 2008
Thomas W. Pew		
/s/ Philip Ranker	Director	March 31, 2008

Philip Ranker

/s/ James M. Strickland

Director

March 31, 2008

James M. Strickland

**Table of Contents**

**IMARX THERAPEUTICS, INC.  
INDEX TO FINANCIAL STATEMENTS**

	<b>Page</b>
<u>Index to Consolidated Financial Statements</u>	F-1
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets as of December 31, 2006 and 2007</u>	F-3
<u>Consolidated Statements of Operations for the years ended December 31, 2005, 2006, and 2007</u>	F-5
<u>Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2005, 2006 and 2007</u>	F-6
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2005, 2006 and 2007</u>	F-7
<u>Notes to Consolidated Financial Statements</u>	F-8

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

Board of Directors and Stockholders

ImaRx Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of ImaRx Therapeutics, Inc. as of December 31, 2006 and 2007, and the related consolidated statements of operations, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of ImaRx Therapeutics, Inc. at December 31, 2006 and 2007, and the results of its operations and its cash flows for the three year period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the consolidated financial statements, effective January 1, 2006, the Company adopted the provisions of Statement of Financial Accounting Standards No. 123R (revised 2004), *Share-Based Payments*. The accompanying financial statements have been prepared assuming that ImaRx Therapeutics, Inc. will continue as a going concern. As more fully described in Note 1, the Company has recurring losses, which has resulted in an accumulated deficit of \$81.2 million at December 31, 2007. In addition, the Company has a note payable principal balance of \$11.6 million due on March 31, 2008. This condition, among others, raises substantial doubt about the Company's ability to continue as a going concern. Management plans in regards to these matters are also described in Note 1. The financial statements do not include any adjustments to reflect possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Phoenix, Arizona

March 25, 2008

**Table of Contents**

**ImaRx Therapeutics, Inc.**  
**Consolidated Balance Sheets**  
**(in thousands, except share data)**

	<b>December 31</b>	
	<b>2006</b>	<b>2007</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 4,256	\$ 12,861
Restricted cash		388
Accounts receivable	576	349
Inventory	16,060	11,138
Inventory subject to return	445	2,560
Prepaid expenses and other	539	589
Total current assets	21,876	27,885
Long-term assets:		
Property and equipment, net	917	1,170
Intangible assets, net	2,500	1,633
Other		19
Total assets	\$ 25,293	\$ 30,707
<b>Liabilities and stockholders equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 1,413	\$ 1,277
Accrued expenses	851	837
Accrued chargebacks and administrative fees	385	1,317
Deferred revenue	955	5,373
Notes payable and accrued interest	15,615	11,698
Total current liabilities	19,219	20,502
Other	219	
Total liabilities	19,438	20,502
Redeemable convertible preferred stock:		
Series A 8% Redeemable Convertible Preferred Shares, \$.0001 par, at carrying value including accrued dividends, 2,302,053 shares authorized and 2,291,144 shares issued and outstanding at December 31, 2006 and no shares authorized, issued or outstanding at December 31, 2007	9,329	
Series B 7% Mandatorily Redeemable Convertible Preferred Shares, \$.0001 par, at carrying value, 593,226 shares authorized, issued and outstanding at December 31, 2006 and no shares authorized, issued or outstanding at December 31, 2007	9,492	
Series C Mandatorily Redeemable Convertible Preferred Shares, \$.0001 par, at carrying value, 285,714 shares authorized, issued and outstanding at December 31, 2006 and no shares authorized, issued or outstanding at December 31, 2007	1,945	
	1,562	

Edgar Filing: IMARX THERAPEUTICS INC - Form 10-K

Series D 8% Redeemable Convertible Preferred Shares, \$.0001 par, at carrying value including accrued dividends, 438,232 authorized, issued and outstanding at December 31, 2006 and no shares authorized, issued or outstanding at December 31, 2007

Series F 8% Redeemable Convertible Preferred Shares, \$.0001 par, at carrying value including accrued dividends, 4,000,000 shares authorized and 2,835,000 shares issued and outstanding at December 31, 2006 and no shares authorized, issued and outstanding at December 31, 2007

	13,535
Total redeemable convertible preferred stock	35,863

F-3

---



**Table of Contents**

	<b>December 31</b>	
	<b>2006</b>	<b>2007</b>
Stockholders' equity (deficit):		
Series E Redeemable Convertible Preferred Shares, \$.0001 par 1,000,000 shares authorized, issued and outstanding at December 31, 2006 and no shares authorized, issued and outstanding at December 31, 2007	4,000	
Common stock, \$.0001 par 70,000,000 shares authorized and 2,606,739 shares issued and outstanding at December 31, 2006 and 100,000,000 shares authorized and 10,046,683 shares issued and outstanding at December 31, 2007		1
Additional paid-in capital	28,620	91,386
Accumulated deficit	(62,628)	(81,182)
Total stockholders' equity (deficit)	(30,008)	10,205
Total liabilities and stockholders' equity (deficit)	\$ 25,293	\$ 30,707

See accompanying notes.

F-4

---

**Table of Contents**

**ImaRx Therapeutics, Inc.**  
**Consolidated Statements of Operations**  
(in thousands, except share data)

	Years Ended December 31		
	2005	2006	2007
Revenues:			
Product sales, net	\$	\$ 480	\$ 7,841
Research and development	619	848	519
Total operating revenue	619	1,328	8,360
Costs and expenses:			
Cost of product sales		204	3,518
Research and development	3,669	9,067	7,424
General and administrative	4,246	7,749	6,087
Acquired in-process research and development	24,000		
Total cost and expenses	31,915	17,020	17,029
Operating loss	(31,296)	(15,692)	(8,669)
Other income (expense):			
Interest and other income	122	381	548
Interest expense	(587)	(1,515)	(862)
Gain on extinguishment of debt	3,835	16,127	219
Net loss	(27,926)	(699)	(8,764)
Deemed dividend from beneficial conversion feature for Series F redeemable convertible preferred stock			(13,842)
Accretion of dividends on preferred stock	(601)	(1,167)	(867)
Reversal of accretion of dividends on preferred stock not paid			4,919
Net loss attributed to common stockholders	\$ (28,527)	\$ (1,866)	\$ (18,554)
Net loss attributed to common stockholders per share			
Basic and diluted	\$ (15.11)	\$ (0.72)	\$ (3.16)
Weighted-average shares outstanding			
Basic and diluted	1,888,291	2,599,425	5,868,131

See accompanying notes.

**Table of Contents**

**ImaRx Therapeutics, Inc.**  
**Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders Equity (Deficit)**  
**(in thousands, except share data)**

	Redeemable Convertible Preferred Stock						Series E Redeemable Convertible Preferred Shares		Common Stock	
	Series B	Series C	Series D	Series F	Series E	Common Stock	Shares	Amount	Shares	Amount
	Shares	Carrying Value	Shares	Carrying Value	Shares	Carrying Value	Shares	Amount	Shares	Amount
2021	593,226	\$ 9,492	285,714	\$ 1,945	438,232	\$ 1,369		\$	1,301,040	\$
										277,999
										188,664
									1,000,000	4,000
										531,750
										218,250

04

97

3,506

63,454

25

593,226

9,492

285,714

1,945

438,232

1,466

1,000,000

4,000

2,584,663

2,835,000

12,968

04

96

567

22,076

29 593,226 9,492 285,714 1,945 438,232 1,562 2,835,000 13,535 1,000,000 4,000 2,606,739

52

48

567

3,000,000

81) (593,226) (9,492) (285,714) (1,945) (438,232) (1,610) (2,835,000) (14,102) (1,000,000) (4,000) 4,401,129

38,500

315

\$

\$

\$

\$

\$

10,046,683 \$

See accompanying notes.

F-6

---

**Table of Contents**

**ImaRx Therapeutics, Inc.**  
**Consolidated Statements of Cash Flows**  
(in thousands)

	<b>Years Ended December 31</b>		
	<b>2005</b>	<b>2006</b>	<b>2007</b>
<b>Operating activities</b>			
Net loss	\$ (27,926)	\$ (699)	\$ (8,764)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation and amortization	194	1,049	1,174
Stock-based compensation	207	955	700
Warrant amortization expense	36	174	
Amortization of debt discount	273		
Gain on extinguishments of debt	(3,835)	(16,127)	(219)
Note issued for acquisition of technology expensed to operations	15,000		
Preferred stock issued for acquisition of technology expensed to operations	4,000		
Loss on disposal of property and equipment		3	19
Changes in operating assets and liabilities:			
Inventory	36	(3,873)	4,922
Inventory subject to return		(107)	(2,115)
Accounts receivable		(576)	227
Prepaid expenses and other	(27)	(266)	(49)
Other assets			(19)
Accounts payable	386	637	(136)
Accrued expenses and other liabilities	541	1,857	1,781
Deferred revenue		955	4,417
Net cash (used in) provided by operating activities	(11,115)	(16,018)	1,938
<b>Investing activities</b>			
Purchase of property and equipment, net	(564)	(439)	(577)
Purchase of intangibles		(825)	
Net cash used in investing activities	(564)	(1,264)	(577)
<b>Financing activities</b>			
Deferred financing costs	(58)		
Change in restricted cash			(388)
Payment upon extinguishments of note	(500)		
Payment on note payable			(4,780)
Proceeds from sale of common stock	17,854	56	12,412
Issuance of promissory note for acquisition of technology	4,000		
Payment of promissory note for acquisition of technology	(4,000)		
Issuance of warrants	1,358		
Net proceeds from issuance of preferred stock		12,969	
Net cash provided by financing activities	18,654	13,025	7,244
Net increase (decrease) in cash and cash equivalents	6,975	(4,257)	8,605

Edgar Filing: IMARX THERAPEUTICS INC - Form 10-K

Cash and cash equivalents at the beginning of the year	1,538	8,513	4,256
Cash and cash equivalents at the end of the year	\$ 8,513	\$ 4,256	\$ 12,861

**Supplemental schedule of cash flow information**

Cash paid for interest	\$ 117	\$	\$ 1,351
------------------------	--------	----	----------

**Supplemental Schedule of Noncash Investing and Financing Activities:**

Accretion of undeclared dividends on Series A/D/F redeemable convertible preferred stock	\$ 601	\$ 1,167	\$ 867
Reversal of accretion of undeclared dividends on Series A/D/F redeemable convertible preferred stock not paid			4,919
Deemed dividend from beneficial conversion feature for Series F redeemable convertible preferred stock			13,842
Conversion of convertible preferred stock to common stock upon initial public offering			35,811
Fair value of stock warrants issued in connection with Company s initial public offering			1,179
Fair value of stock warrants issued for consulting services and placement agreement amendment		174	
Fair value of stock warrants issued for patents	36		
Fair value of stock warrants issued for bridge notes	273		
Fair value of stock warrants issued in connection with private placement	1,358		
Note issued for acquisition of technology and related inventory and intangibles	15,000	15,000	
Preferred stock issued for acquisition of technology	4,000		

See accompanying notes.

F-7

---



**Table of Contents**

**ImaRx Therapeutics, Inc.  
Notes to Consolidated Financial Statements**

**1. The Company and Significant Accounting Policies**

*The Company*

We are a biopharmaceutical company focused on developing and commercializing therapies for vascular disorders. We have devoted substantially all of our efforts towards the research and development of our product candidates and the commercialization of our currently marketed product, Abbokinase<sup>®</sup> currently being rebranded as Kinlytic<sup>™</sup>. During September 2006, we began selling the Abbokinase product to wholesale distributors and exited the development stage, as defined by Statement of Financial Accounting Standards (SFAS) No. 7, *Accounting and Reporting by Development Stage Enterprises*.

***Consolidation***

The consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America and include the accounts of ImaRx Therapeutics, Inc. and ImaRx Europe Limited (IEL) a wholly owned subsidiary created in 2005 by us to facilitate clinical trials in Europe. It was later determined that the European subsidiary was not required and IEL was dissolved in December 2006 with no activity reported for any period. All significant intercompany accounts and transactions have been eliminated.

***Basis of Presentation***

Our ability to continue as a going concern depends on the successful future sales of the urokinase product acquired in 2006 and marketed under the name Abbokinase and re-branded under the name Kinlytic, and the commercialization or licensing of our technologies. We have had recurring losses, which have resulted in an accumulated deficit of \$81.2 million at December 31, 2007. In addition, we have a note payable principal balance of \$11.6 million due on 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 a final binding agreement with Abbott Laboratories will be completed in the second quarter of 2008. These conditions, among others, raise substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments relating to the recoverability and classification of recorded assets, or the amounts and classification of liabilities that might be necessary in the event we cannot acquire additional financing.

We may require additional funding in the future and may seek to do so through collaborative arrangements and/or public or private financings. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail certain of our sales and marketing efforts, our development efforts with respect to our product candidates and may be required to limit, scale back or cease our operations.

***Estimates and Assumptions***

Preparing financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, and expenses. Examples include estimates of stock-based compensation forfeiture rates; assumptions such as the potential outcome of future tax consequences of events that have been recognized in our financial statements or tax returns; and, estimating the fair value and/or goodwill impairment for our reporting units. Actual results and outcomes may differ from management's estimates and assumptions.

***Reclassifications***

Certain prior year amounts have been reclassified to conform to current year presentation.

**Table of Contents**

***Cash Equivalents and Restricted Cash***

We consider all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash equivalents are recorded at cost, which approximates market value. Our cash equivalents are comprised mainly of marketable bank obligations, commercial paper, and corporate notes and bonds.

The restricted cash is the amount of cash held in the escrow account for the repayment of the note payable with Abbott Laboratories.

***Fair Value of Financial Instruments***

The carrying amounts of financial instruments, including cash and cash equivalents, accounts payable, accrued expenses and notes payable, approximate fair value based on the liquidity or on the short-term maturities of these financial instruments.

***Accounts Receivable***

Accounts receivable consist of amounts due from wholesalers for the purchase of urokinase product and are recorded net of allowances for sales discounts and prompt payment discounts. To date we have not recorded a bad debt allowance because the majority of our product revenue comes from sales to a limited number of established wholesale distributors. The need for bad debt allowance is evaluated each reporting period based on our assessment of the creditworthiness of our customers.

***Inventory and Inventory Subject to Return***

Inventory is comprised of finished goods and is stated at the lower of cost or market value. Inventory subject to return is comprised of finished goods, stated at the lower of cost or market value, and represents the amount of inventory that has been sold to wholesale distributors. When product is sold by the wholesale distributor to a hospital or other health care provider, a reduction in this account occurs and cost of sales is recorded.

Abbokinase (urokinase), rebranded under the name Kinlytic, is our only commercially available FDA approved product. Abbokinase is a thrombolytic or clot-dissolving agent approved for the treatment of acute massive pulmonary embolism. In the acquisition of Abbokinase, we received 111,000 vials that we determined could be sold and assigned a portion of the purchase price to these vials. As of December 31, 2007, \$3.3 million of vial inventory was labeled and the remaining \$10.4 million of vial inventory was unlabeled. Based on current stability data all vials are not saleable after September 2009.

In the fourth quarter of 2007, we submitted to the FDA a lot release request for \$1.6 million in vial inventory to be labeled with the new expiration dates and received lot release approval from the FDA with respect to that request. In the first quarter of 2008, we submitted two additional lot release requests for vials representing \$3.0 million in inventory to be labeled with new expiration dates and have received lot release approval from the FDA.

We have an ongoing stability program to support expiration date extensions for the unlabeled vials. Since we recently have been successful in extending the expiration dates of our unlabeled inventory, we intend to continue the stability program to potentially enable further expiration extensions for unlabeled vials of inventory.

We periodically review the composition of inventory in order to identify obsolete, slow-moving or otherwise un-saleable inventory. We will write down inventory for estimated obsolete or un-saleable inventory in an amount equal to the difference between the cost of the inventory and the estimated market value based upon assumptions about future demand and market conditions.

Costs related to shipping and handling are charged to general and administrative expense as incurred.

**Table of Contents*****Property and Equipment***

All property and equipment are recorded at cost and depreciated over their estimated useful lives, ranging from three to seven years, using the straight-line method. Leasehold improvements are amortized using the straight-line method over the lesser of the lease term or the estimated useful life.

***Intangible Assets***

Intangible assets include customer relationships, trade name, contracts and technology and are accounted for based on SFAS No. 142, *Goodwill and Other Intangible Assets*. Intangible assets with finite useful lives are amortized over the estimated useful lives from the date of acquisition, ranging from one to four years, using the straight-line method. The Abbokinase trade name has an estimated life of one year.

In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, if indicators of impairment exist, we assess the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, we measure the future discounted cash flows associated with the use of the asset and adjust the value of the asset accordingly. We specifically evaluated the intangible assets and concluded there is no impairment as of December 31, 2007.

***Revenue Recognition***

Revenue from product sales is recognized pursuant to SEC Staff Bulletin No. 104 (SAB 104), *Revenue Recognition in Financial Statements*. Accordingly, revenue is recognized when all four of the following criteria are met:

(i) persuasive evidence that an arrangement exists; (ii) delivery of the products has occurred; (iii) the selling price is both fixed and determinable; and (iv) collectibility is reasonably assured. We apply SFAS No. 48, *Revenue Recognition When the Right of Return Exists*, which amongst other criteria, requires that future returns be reasonably estimated in order to recognize revenue. The amount of future returns is uncertain due to the insufficiency of returns history data. Due to the uncertainty of returns from our wholesale distributors, we are accounting for product shipments to wholesale distributors using a deferred revenue recognition model. Under this model, we do not recognize revenue upon product shipment to wholesale distributors; therefore, recognition of revenue is deferred until the product is sold by the wholesale distributor to the end user. Our returns policy allows end users to return product within 12 months after expiration, but current practice by wholesalers and end users is generally a just in time purchasing methodology, meaning that the product is purchased by the end user on an as-needed basis, typically on a daily or weekly basis. Although the product was previously marketed by Abbott Laboratories, we were unable to obtain historical returns data for the product from Abbott Laboratories at the time of our acquisition of Abbokinase. Based on input from our wholesale distributors, current purchasing practices and the estimated amount of product in the channel, we anticipate immaterial product returns from end users.

Our customers consist primarily of large established pharmaceutical wholesale distributors who sell directly to hospitals and other healthcare providers. Provisions for product returns and exchanges, sales discounts, chargebacks, managed care and Medicaid rebates and other adjustments are established as a reduction of product sales revenues at the time such revenues are recognized. These deductions from gross revenue are established by management as its best estimate at the time of sale adjusted to reflect known changes in the factors that impact such reserves.

Our top three customers accounted for 93% of our total product revenue in 2007. AmerisourceBergen and Cardinal each accounted for 34% of our 2007 revenues and McKesson Corporation accounted for 25% of our 2007 revenues. One customer, AmerisourceBergen, accounted for 100% of our total 2006 product revenues.

***Stock-Based Compensation***

We maintain performance incentive plans under which incentive and non-qualified stock options are granted primarily to employees and non-employee directors. Prior to January 1, 2006, we accounted for stock-based compensation in accordance with Accounting Principles Board Opinion No. 25 (APB No. 25), *Accounting for Stock Issued to Employees*, SFAS No. 123, *Accounting for Stock Based Compensation*, and related interpretations. Our policy is to grant all stock options at the fair market value of the underlying stock at the date of grant. Accordingly, no compensation expense was required to be recognized for the stock options at the date of grant prior to January 1, 2006. For non-employee grants issued prior to January 1, 2006, the calculation of expense was determined using the Black-Scholes option pricing model. We calculated the expense using the exercise price of the option, the fair market

value of the underlying stock at the date of the grant, the expected volatility of the stock price, the life of the option and the risk-free interest rate. The expense was recorded in accordance with the vesting period of the option.

F-10

---

**Table of Contents**

Effective January 1, 2006, we adopted SFAS 123(R), requiring measurement of the cost of employee services received in exchange for all equity awards granted, based on the fair market value of the award as of the grant date. We currently use the Black-Scholes option pricing model to estimate the fair value of our share-based payments. The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by our stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The Company uses guideline companies and, to a limited extent, experiences of the Company since becoming publicly traded, to determine volatility. The expected life of the stock options is based on historical data and future expectations. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of our stock options. The dividend yield assumption is based on our history and expectation of dividend payouts. Stock-based compensation expense recognized in our financial statements in 2006 and thereafter is based on awards that are ultimately expected to vest. The amount of stock-based compensation expense in 2006 and thereafter will be reduced for estimated forfeitures. Forfeitures are required to be estimated at the time of the grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We will evaluate the assumptions used to value stock awards on a quarterly basis. If factors change and we employ different assumptions, stock-based compensation expense may differ significantly from what has previously been recorded. To the extent that we grant additional equity securities to employees, the stock-based compensation expense will be increased by the additional compensation resulting from those additional grants. We adopted SFAS 123(R) using the prospective application method of adoption which requires recording compensation cost related to awards granted on or after January 1, 2006 based on the fair value related to stock options at the grant dates.

The weighted-average expected option term for the years ending December 31, 2006 and 2007 reflects the application of the simplified method set out in SEC Staff Accounting Bulletin No. 107 (SAB 107). The simplified method defines the life as the average of the contractual term of the options and the weighted-average vesting period for all option tranches.

Pro forma information regarding net loss was required by SFAS No. 123 which required that the information be determined as if we had accounted for our employee stock options granted during the year ended December 31, 2005, under the fair value method of SFAS 123. The deemed fair value for options granted was estimated at the date of grant using the minimum value option valuation model, which assumes the stock price has no volatility since the common stock was not publicly traded. The following assumptions were used to calculate the deemed fair value of the option awards at the date of grant: no dividend payout expected, expected option life of five years and a risk-free interest rate averaging 3% for the year ended December 31, 2005. The weighted-average estimated fair value of stock options granted with an exercise price equal to the fair value of the underlying common stock on the date of the grant 2005 was \$1.03.

***Research and Development Expenses***

Research and development costs primarily consist of salaries and related expenses for personnel, fees paid to consultants and outside service providers, facilities costs, and the costs associated with clinical trials and research and development. The Company charges all research and development expenses to operations as incurred.

***Income Taxes***

We account for income taxes under the liability method pursuant to SFAS No. 109, *Accounting for Income Taxes*. Under the liability method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when we determine that it is more likely than not that some portion or all of a deferred tax asset will not be realized.

**Table of Contents**

We adopted the Financial Accounting Standards Board's Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109* (FIN 48), effective January 1, 2007. FIN 48 contains a two-step approach to recognizing and measuring uncertain tax positions accounted for in accordance with SFAS No. 109, *Accounting for Income Taxes*. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation process, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement.

**Net Loss Attributable to Common Stockholders per Share**

Basic and diluted net loss attributable to common stockholders per share is calculated by dividing the net loss applicable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is the same as basic net loss per common share for all periods presented. The effects of potentially dilutive securities are antidilutive in the loss periods.

The following potential common shares have been excluded from the computation of diluted net loss per share since their effect would be antidilutive in each of the loss periods presented. The shares have been revised to account for the six-for-ten reverse stock split that was affected in September 2006 as well as the one-for-three reverse stock split that occurred in May 2007. Herein all shares presented in this annual report on Form 10-K have been adjusted to reflect these stock splits.

	<b>Years Ended December 31,</b>		
	<b>2005</b>	<b>2006</b>	<b>2007</b>
Convertible preferred stock	1,065,796	3,448,189	
Stock options	534,143	630,351	1,534,269
Warrants	337,324	352,324	1,023,913

**Recently Issued Accounting Pronouncements**

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurement* (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 applies under other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, SFAS 157 does not require any new fair value measurements, but may change current practice for some entities. SFAS 157 is effective for fiscal years beginning after December 15, 2006. The adoption of SFAS No. 157 is not expected to have a material effect on our financial position or results of operations.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The standard requires that unrealized gains and losses on items for which the fair value option has been elected be reported in earnings. SFAS 159 is effective for the fiscal years beginning after November 15, 2007. The adoption of SFAS No. 159 will not have a material effect on our financial position or results of operations.

In December 2007, the FASB issued SFAS No. 141 (revised 2007) (SFAS 141R), *Business Combinations* and SFAS No. 160 (SFAS 160), *Noncontrolling Interests in Consolidated Financial Statements, an amendment of Accounting Research Bulletin No. 51*. SFAS 141R will change how business acquisitions are accounted for and will impact financial statements both on the acquisition date and in subsequent periods. SFAS 160 will change the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. SFAS 141R and SFAS 160 are effective beginning in the first fiscal period ending after December 15, 2008. Early adoption is not permitted. We do not believe the adoption of these new standards, SFAS 141R and SFAS 160, will not have an impact on our consolidated financial statements.



**Table of Contents****2. Balance Sheet Data*****Property and Equipment***

Property and equipment consist of the following:

	<b>December 31,</b>	
	<b>2006</b>	<b>2007</b>
	<b>(in thousands)</b>	
Leasehold improvements	\$ 628	\$ 652
Laboratory equipment	1,557	2,212
Computer and communications equipment	374	279
Office furniture and equipment	224	157
Construction in progress		43
	2,783	3,343
Less accumulated depreciation	1,866	2,173
	\$ 917	\$ 1,170

For the years ended December 31, 2005, 2006 and 2007, we recorded depreciation expense of \$0.2 million, \$0.2 million and \$0.3 million, respectively.

***Intangible Assets***

Intangibles consist of the following (in thousands):

		<b>December 31, 2006</b>		<b>December 31, 2007</b>	
	<b>Weighted average life</b>	<b>Gross carrying amount</b>	<b>Accumulated amortization</b>	<b>Gross carrying amount</b>	<b>Accumulated amortization</b>
Customer lists	4 years	\$ 2,700	\$ (450)	\$ 2,700	\$ (1,125)
Trade name	1 year	500	(333)	500	(500)
Cell technology	4 years	100	(17)	100	(42)
		\$ 3,300	\$ (800)	\$ 3,300	\$ (1,667)

As of December 31, 2007, we expect the future amortization of the intangible to be as follows (in thousands):

2008	\$ 700
2009	700
2010	233
2011	
	\$ 1,633

***Accrued Expenses***

Accrued expenses consist of the following:

	<b>December 31,</b>	
	<b>2006</b>	<b>2007</b>
	<b>(in thousands)</b>	



Edgar Filing: IMARX THERAPEUTICS INC - Form 10-K

Accrued compensation	\$	250	\$	528
Accrued contract services		176		181
Accrued severance		212		
Other accrued expenses		213		128
	\$	851	\$	837

F-13

---

**Table of Contents****3. Income Taxes**

The provision for income taxes consists of the following (in thousands):

	<b>Years Ended December 31,</b>		
	<b>2005</b>	<b>2006</b>	<b>2007</b>
	<b>(in thousands)</b>		
Current:			
Federal	\$	\$	\$
State			
Total current provision			
Deferred:			
Federal	(8,981)	(187)	(3,246)
State	(1,328)	57	(328)
Total deferred provision			
Total tax provision	\$	\$	\$

A reconciliation of the U.S. federal statutory income tax rate to the effective rate follows.

	<b>Years Ended December 31,</b>		
	<b>2005</b>	<b>2006</b>	<b>2007</b>
	<b>(in thousands)</b>		
Tax benefit at statutory rate	\$ (9,245)	\$ (237)	\$ (2,980)
State taxes (net of federal benefit)	(1,328)	57	(328)
Net benefit from research and development credits	(129)	(23)	(547)
Stock compensation		118	96
Other, net	393	15	184
Valuation allowance	10,309	70	3,575
Tax benefit at statutory rate	\$	\$	\$

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Our deferred tax assets and liabilities are attributed to the following temporary differences:

	<b>December 31,</b>	
	<b>2006</b>	<b>2007</b>
	<b>(in thousands)</b>	
Current deferred tax assets:		
Reserves and accrued liabilities	\$ 55	\$ 47
Other	5	5
	60	52
Noncurrent deferred tax assets:		
Property and equipment	203	110
Deferred revenue	257	2,004
Intangibles	3,501	2,301

Stock compensation		448
Research and development credits	1,324	2,188
Net operating loss carryforward	12,156	13,973
	17,441	21,024
Total deferred tax assets	17,501	21,076
Valuation allowance	(17,501)	(21,076)
Net deferred tax assets	\$	\$

At December 31, 2007, we had net operating loss carryforwards of \$36.8 million for federal tax purposes that begin to expire in the year 2020. For state income tax purposes, we had net operating loss carryforwards at December 31, 2007 of \$30.5 million that expire within five years of being incurred and will begin to expire for state purposes in 2008. Additionally, we have research and development credit carryforwards of \$1.5 million for federal purposes and \$1.1 million for state purposes that begin to expire in 2020 and 2015 for federal and state purposes, respectively. For financial reporting purposes, a valuation allowance of \$17.5 million and \$21.1 million has been established at December 31, 2006 and 2007, respectively, to offset deferred tax assets relative to the net operating loss carryforwards and other deferred tax assets. The gross deferred tax assets resulted from accumulated net operating loss carryforwards since inception. We will not recognize any tax benefit until we are in a tax paying position, and therefore, more likely to realize the tax benefit. Our valuation allowance changed by \$10.3 million, \$0.1 million and \$3.6 million during the years ended December 31, 2005, 2006 and 2007, respectively.

**Table of Contents**

We adopted the Financial Accounting Standards Board's Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109* (FIN 48), effective January 1, 2007. FIN 48 contains a two-step approach to recognizing and measuring uncertain tax positions accounted for in accordance with SFAS No. 109, *Accounting for Income Taxes*. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation process, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement.

We file U.S. Federal tax returns and U.S. State tax returns. We have identified our US Federal tax return as our major tax jurisdiction. For the U.S. Federal return, years 2003 through 2006 are subject to tax examination by the U.S. Internal Revenue Service. We do not currently have any ongoing tax examinations. We believe that our income tax filing positions and deductions will be sustained on audit and do not anticipate any adjustments that will result in a material change to our financial position. Therefore, no reserves for uncertain income tax positions have been recorded pursuant to FIN 48. In addition, we did not record a cumulative effect adjustment related to the adoption of FIN 48. We do not anticipate that the total amount of unrecognized tax related to any particular tax benefit position will change significantly within the next 12 months.

Our policy for recording interest and penalties associated with audits is to record such items as a component of income before taxes.

Our net operating losses and tax credit carryforwards are subject to limitation under Internal Revenue Code Sections 382 and 383. Based on the most current analysis, it appears that a greater than 50% change in ownership occurred in July 2007 in conjunction with our public offering. This analysis indicates the annual limitation on the use of losses would be \$1.5 million per year (pre-tax). However, we can avail ourselves of certain elections to increase the annual limitation by certain recognized built-in gains on assets that existed at the date of change. Furthermore, we continue to study whether we could alter the date on which the ownership change was deemed to occur by making one or more elections permitted under Section 382 which could reduce the net operating losses subject to limitation and eliminate the risk of expiration. We are continuing to study each of these issues. Until such time as it is conclusively determined that a portion of net operating loss or credit carryforward has been permanently impaired, we will continue to reflect these attributes in our deferred tax assets and maintain an offsetting valuation allowance. When the analysis is finalized, we plan to update our unrecognized tax benefits under FIN 48. We expect the Section 382 and 383 analysis to be completed within the next 12 months. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate.

At December 31, 2007 and 2006, our deferred tax assets do not include \$0.3 million of excess tax benefits from employee stock option exercises that are a component of our net operating loss carryforward. Additional paid in capital will be increased by \$0.3 million if and when such excess tax benefits are realized.

**4. Investment in ImaRx Oncology, Ltd.**

During 2001, we entered into a joint venture agreement with a development partner to form ImaRx Oncology, Ltd. (IOL) for the development of certain patents and technology. Upon the formation of IOL, we acquired an 80.1% interest in IOL by purchase of 100% of IOL's voting common shares for \$5.0 million and 60.2% of IOL's preferred shares for \$3.0 million, representing a total of 80.1% of IOL's outstanding shares. The development partner acquired the remaining 39.8% of IOL's preferred shares for \$2.0 million, representing a total of 19.9% of IOL's outstanding shares.

On October 2, 2002, we entered into a termination agreement (Termination Agreement) of the joint venture with the development partner whereby we acquired the remaining 19.9% interest in IOL in exchange for consideration equal to \$0.1 million plus future contingent consideration in the form of a net royalty interest in the sale, licensing or other commercialization proceeds, as defined in the Termination Agreement, of all IOL operations. This acquisition cost was expensed to research and development in 2002 at the time we entered into the Termination Agreement. IOL received funding pursuant to a convertible promissory note (Development Note) with the development partner for funding of the development partner's pro rata share of the development costs.



**Table of Contents**

Under the Termination Agreement, the Development Note was amended and restated (Restated Development Note) to provide for funding by the development partner up to a maximum principal amount of \$3.6 million. The Restated Development Note was extinguished in full in March 2005, which resulted in a gain on the debt extinguishment. We completed the dissolution of IOL on March 9, 2007.

**5. Related Party Transactions**

We lease an office facility from a partnership whose beneficial owners include a former member of the Board of Directors of the Company. Rent expense related to this lease, which expires on October 31, 2008, amounted to \$0.1 million in 2005, 2006 and 2007.

In October 2006, the Company entered into a separation agreement with the former CEO and member of the Board of Directors. The separation agreement provided for a severance payment of \$0.3 million, which was charged to expense in 2006.

**6. Notes Payable*****Note Payable to Development Partner***

On March 6, 2005, we executed a Securities Purchase Agreement with our former development partner whereby the outstanding principal and accrued interest totaling \$4.3 million as of that date was purchased by us for \$0.5 million, resulting in a gain on the extinguishment of \$3.8 million. No other consideration was given by us in connection with the Securities Purchase Agreement.

***Secured Promissory Notes Payable***

In September 2005, \$4.0 million in secured promissory notes were issued for cash. The notes were secured by all assets other than those represented by research and development stage technologies acquired by us during September 2005 from Abbott. In October 2005, the Company repaid the notes in full.

***Note Payable for Technology Acquisition***

In September 2005, we entered into an agreement with Abbott to acquire certain assets related to Abbott's development of recombinant pro-urokinase (rproUK) and recombinant urokinase (rUK) (Abbott Agreement). The total purchase price under the Abbott Agreement of \$24.0 million included a payment of \$5.0 million in cash, a \$15.0 million note payable to Abbott and the issuance of 1,000,000 shares of Series E preferred stock valued at \$4.00 per share.

The purchase of these assets did not constitute the purchase of a business as defined in EITF No. 98-3, *Determining Whether a Nonmonetary Transaction Involves Receipt of Productive Assets or of a Business*. Assets included in the purchase, among others, were rproUK and rUK drug substance and drug product inventories, raw materials including master and working cell banks, intellectual property related to these drug products, rights under existing contractual agreements and all related applications and supplements filed with the U.S. Food and Drug Administration (FDA). Although these product candidates may have significant future importance, the Company determined that, since they had not yet received FDA approval and presented no alternative future use, they did not meet established guidelines for technological feasibility sufficiently to be recorded as assets. As a result, the full amount of the purchase price of \$24.0 million was expensed as acquired in-process research and development expense in September 2005.

In November 2006, we made the decision to return these assets to Abbott. We notified Abbott on December 13, 2006 of our intent to default on the note and return the purchased assets. On December 31, 2006, we received a default notice from Abbott confirming receipt of our intent and plan for the return of assets. The outstanding principal and accrued interest as of December 31, 2006 totaling \$16.1 million was written-off, resulting in an extinguishment of debt of the entire amount. The default had no impact on our ownership of the Abbokinase inventory and rights purchased in April 2006 from Abbott for cash and a separate \$15.0 million note.

**Table of Contents*****Note Payable for Asset Acquisition***

In connection with an Asset Purchase Agreement dated April 25, 2006 with Abbott for the purchase of inventory and related intangibles, we issued a \$15.0 million secured promissory note payable, which accrues simple interest at an annual rate of 6.0%. On October 25, 2007, we signed a Note Extension and Amendment Agreement with Abbott and the escrow agent. In this Agreement, Abbott agreed to extend the due date of the note to March 31, 2008, and we instructed the escrow agent to transfer the funds held in escrow of \$4.8 million to Abbott in payment of accrued interest through the transaction date of \$1.4 million and principal of \$3.4 million. The principal amount outstanding on the note upon completion of this transaction was \$11.6 million. In addition, we are required to place 50% of the gross proceeds from all future sales of Abbokinase into the escrow account as required by our escrow agreement with Abbott until the \$11.6 million note is repaid. The balance outstanding at December 31, 2007 including principal and interest is \$11.7 million.

**7. Equity Transactions*****Reverse Stock Splits***

The Company's Board of Directors and stockholders approved in September 2006 a reverse stock split. On September 12, 2006, a six-for-ten reverse stock split of the Company's common stock became effective. The Company's Board of Directors and stockholders further approved in May 2007 a reverse stock split. On May 4, 2007, a one-for-three reverse stock split of the Company's common stock became effective. All common share, per share and stock option data information in the accompanying financial statements and notes thereto has been retroactively restated for all periods to reflect the reverse stock splits.

***Initial Public Offering (IPO)***

On July 25, 2007, 3,000,000 shares of common stock were sold at an initial public offering price of \$5.00 per share, resulting in aggregate net cash proceeds of \$12.4 million. Upon the completion of the initial public offering in July 2007, all of the previously outstanding preferred shares converted into an aggregate of 4,401,129 shares of the common stock. All accrued and unpaid dividends relating to applicable preferred stock did not convert into shares of common stock upon the IPO and were reversed. These shares combined with 2,607,054 shares of common stock outstanding immediately before the initial public offering and the 3,000,000 shares sold in the initial public offering resulted in 10,008,183 shares of common stock outstanding upon completion of the initial public offering in July 2007.

***Common Stock***

In January and February 2005, we completed two closings of a \$7.0 million private placement offering at \$15.00 per share for the issuance of 466,663 shares of common stock. Net proceeds were \$5.5 million including offset of the value of warrants issued to the placement agent in the offering of \$0.4 million.

In October and November 2005, we completed two closings of a private placement of \$15.0 million at \$20.00 per share for the issuance of 750,000 shares of common stock. Net proceeds were \$12.0 million, including offset of the value of warrants issued to the placement agent in the offering of \$0.9 million.

***Restricted Stock Awards***

On July 31, 2007, members of the Board of Directors were issued a total of 38,500 shares of restricted common stock at a grant date fair value of \$5.00 per share for services previously rendered for the Board. These shares vest upon the member's departure from the Board of Directors. We recognized compensation expense of \$0.2 million in 2007.

**Table of Contents*****Preferred Stock***

In connection with the effective closing of the IPO in July 2007, shares of Series A, B, C, D and E redeemable convertible preferred stock then outstanding were converted into an aggregate of 1,632,835 shares of our common stock.

We entered into a Series F Preferred Stock (Series F) Purchase Agreement in April 2006. We issued a total of 2,835,000 shares of Series F and received net proceeds of \$13.0 million in 2006. The per share conversion rate of Series F was variable and was determined by dividing \$5.00 by the lesser of (a) \$25.00 (as adjusted for any stock dividends, combinations, splits, recapitalizations and the like with respect to such shares) or (b) 85% of the price per share paid in an initial public offering. The price per share of the initial public offering was \$5.00, therefore, the holders of the Series F have converted to shares of common stock at a rate of 1.176 per share of Series F. The beneficial conversion as determined under the provisions of EITF Issue No. 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments*. Effectively on the completion of the IPO, a deemed dividend on the conversion of preferred stock of \$13.8 million was recorded. The exchange of common shares of stock for shares of Series F preferred stock resulted in the issuance of 2,768,294 shares of common stock on July 25, 2007.

Cumulative undeclared dividends of \$4.9 million on Series A, D and F were reversed upon the IPO and no dividends were paid.

In September 2005, we entered into an Asset Purchase Agreement (September Abbott Agreement) with Abbott to acquire certain assets. As partial consideration related to the September Abbott Agreement, we issued 1,000,000 shares of Series E preferred stock (Series E) valued at \$4.00 per share.

***Warrants to Purchase Common Stock***

A warrant to purchase 4,000 shares of common stock with a fair value of \$35,870 at date of issue was issued in connection with a licensed patent in January 2005. The exercise price of this warrant is \$15.00 per share and has not been exercised.

A warrant to purchase 46,664 shares of common stock exercisable at any time at \$16.50 per share on a cashless basis was issued on February 28, 2005, for a term of five years as provided in the placement agent agreement relative to the \$7.0 million common stock offering. The fair value of the warrant at the date of issue of \$0.4 million was offset against proceeds of the offering.

In September 2005, warrants to purchase 20,000 shares of common stock were issued in connection with the issuance of \$4.0 million in secured promissory notes. The warrants are exercisable at any time for a period of ten years at a price of \$20.00 per share. The value of the warrants were recorded as debt discount and amortized to interest expense over the expected maturity of the notes. The fair value of the warrants outstanding at September 30, 2005 of \$0.3 million was amortized to interest as the expected maturity date of the notes was less than one month. The warrants were fully expensed in October 2005.

A warrant to purchase 74,996 shares of common stock exercisable at any time at \$21.25 per share on a cashless basis was issued on November 8, 2005, for a term of seven years as provided in the placement agent agreement relative to the \$15.0 million common stock offering. The fair value of the warrant at the date of issue of \$0.4 million was offset against proceeds of the offering.

In connection with a consulting agreement, warrants to purchase 15,000 shares of common stock were issued on February 1, 2006. The warrants are exercisable at any time at \$20.00 per share on a cashless basis for a term of seven years. The fair value of the warrant at the date of issue of \$0.2 million has been recorded as expense.

In connection with the initial public offering, warrants to purchase 671,589 shares of common stock were issued on July 31, 2007. The warrants are exercisable up to five years on a cashless basis at \$5.75 per share. The fair value of the warrants at the date of issuance of \$1.2 million was recorded against additional paid in capital as a cost of the initial public offering.



**Table of Contents**

The following table summarizes the warrants that were outstanding as of December 31, 2007:

**Warrants Issued**

<b>Exercise Price</b>	<b>Warrants Outstanding</b>	<b>Weighted-Average Remaining Life in Years</b>	<b>Warrants Exercisable</b>
\$ 5.75	671,589	9.58	671,589
10.00 - 13.75	91,050	1.61	91,050
15.00 - 16.50	150,664	1.55	150,664
20.00 - 21.25	109,996	5.41	109,996
35.00	614	3.18	614
	1,023,913	7.24	1,023,913

A summary of activity of warrants is as follows:

	<b>Warrants</b>	<b>Weighted-Average Exercise Price</b>
Balance at January 1, 2005	195,169	\$ 12.63
Granted	145,660	19.39
Exercised	(3,505)	10.00
Canceled		
Balance at December 31, 2005	337,324	15.61
Granted	15,000	20.00
Exercised		
Canceled		
Balance at December 31, 2006	352,324	15.79
Granted	671,589	5.75
Exercised		
Canceled		
Balance at December 31, 2007	1,023,913	\$ 9.21

**8. Stock Options**

We have two equity incentive plans; the 2000 Stock Plan ( 2000 Plan ) and the 2007 Performance Incentive Plan ( 2007 Plan ). The 2000 Stock Plan was terminated immediately following the closing of the initial public offering on July 31, 2007. No additional grants will be issued from the 2000 Stock Plan; however, there are grants currently outstanding under this plan. The 2007 Plan became effective July 25, 2007, the effective date of the Company's initial public offering. As of December 31, 2007, the total compensation cost related to non-vested options not yet recognized is \$2.4 million, which will be charged to expense over the next 3.1 years.

Prior to January 1, 2006, we accounted for stock-based compensation in accordance with Accounting Principles Board Opinion No. 25 (APB No. 25), *Accounting for Stock Issued to Employees*, SFAS No. 123, *Accounting for Stock Based Compensation*, and related interpretations. Our policy is to grant all stock options at the fair market value of the underlying stock at the date of grant. Accordingly, no compensation expense was required to be recognized for the stock options at the date of grant prior to January 1, 2006. For non-employee grants issued prior to January 1, 2006, the calculation of expense was determined using the Black-Scholes option pricing model. We calculated the expense using the exercise price of the option, the fair market value of the underlying stock at the date of the grant, the expected volatility of the stock price, the life of the option and the risk-free interest rate. The expense was recorded in accordance with the vesting period of the option.

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS No. 123R, *Share Based Payment*, using the prospective-transition method. Under this method, compensation cost during the year includes all share-based payments granted subsequent to December 31, 2005, based on the grant date fair value estimated using the Black-Scholes option-pricing model. We continue to account for the unvested portion of options that were granted prior to December 31, 2005 using the provisions of APB No. 25. Before adoption of SFAS 123R, pro forma disclosures reflected the fair value of each option grant estimated on the date of grant using the Black-Scholes option-pricing model.

**Table of Contents**

The pro forma amounts required by SFAS No. 123 was applied to the stock-based compensation during the year ended December 31, 2005. The pro forma effect on net loss was determined as if the fair value of the stock-based compensation had been recognized as compensation expense on a straight-line basis over the vesting period of the stock options in each period. If compensation for options granted under the plan had been determined based on the deemed fair value at the grant date consistent with the method provided under SFAS 123, then our net loss would have been as indicated in the pro forma amounts below (in thousands):

	<b>2005</b>
Net loss attributable to common stockholders:	
Net loss	\$ (28,527)
Stock-based compensation included in net loss	207
Stock-based compensation expense determined under the fair value method	(349)
Net loss pro forma	\$ (28,669)
Net loss attributable to common stockholders per share	
Basic and diluted	\$ (15.11)
Net loss attributable to common stockholders per share pro forma	
Basic and diluted	\$ (15.18)

The following assumptions were used to determine pro-forma and actual stock-based compensation expense:

	<b>Years Ended December 31,</b>		
	<b>2005<sup>1</sup></b>	<b>2006</b>	<b>2007</b>
Expected dividend yield	0.00%	0.00%	0.00%
Expected stock price volatility	0.00%	75.0%	75.0 - 82.17%
Risk free interest rate	3.00%	4.54 - 5.05%	3.78 - 4.93%
Expected life of option	5 years	7 years	7 years

<sup>1</sup> Prior to the adoption of SFAS 123R on January 1, 2006, we followed the minimum value method under SFAS 123, which assumes the stock price has no volatility since the common stock was not publicly traded.

A summary of activity under our stock option plans is as follows:

<b>Options</b>	<b>Exercise Price Per Share</b>	<b>Weighted-Average Exercise Price</b>
----------------	-------------------------------------	--

Edgar Filing: IMARX THERAPEUTICS INC - Form 10-K

Balance at January 1, 2005	393,552	\$ 2.50-15.00	\$ 9.00
Granted	350,978	15.00-20.00	16.22
Exercised	(63,454)	2.50-15.00	4.66
Canceled	(146,933)	2.50-15.00	14.34
Balance at December 31, 2005	534,143	2.50-20.00	13.11
Granted	210,772	15.00-30.00	21.64
Exercised	(22,076)	2.50-27.50	2.53
Canceled	(92,488)	2.50-30.00	16.64
Balance at December 31, 2006	630,351	2.50-30.00	18.15
Granted	1,094,607	2.10-5.00	2.86
Exercised	(315)	2.50	2.50
Canceled	(190,374)	2.50-27.50	13.71
Balance at December 31, 2007	1,534,269	\$ 2.50-30.00	\$ 6.81

There was no aggregate intrinsic value on the options outstanding at December 31, 2007 since the exercise price of all outstanding options was greater than the closing stock price on December 31, 2007.

**Table of Contents**

The following table summarizes information relating to currently outstanding and vested options at December 31, 2007:

Range of Exercise Prices	Options Outstanding		Options Exercisable		
	Options Outstanding	Weighted-Average Remaining Life (Years)	Options Vested	Options Exercisable	Weighted-Average Exercise Price
\$ 2.10-2.50	834,262	9.56	73,475	73,475	\$ 2.13
2.51-9.99	285,823	9.65	33,334	33,334	5.24
10.00-14.99	50,000	6.28	50,000	50,000	10.00
15.00-19.99	210,622	7.71	115,409	210,622	15.00
20.00-24.99	70,062	8.02	27,756	70,062	20.00
25.00-27.49	80,500	8.41	24,500	80,500	25.17
27.51-30.00	3,000	8.68	750	3,000	30.00
Total	1,534,269	9.08	325,224	520,993	\$ 6.81

The difference between the number of options vested and the number of options exercisable relates to the options outstanding under the 2000 Plan that have an early exercise provision.

In August 2005, we approved the acceleration of vesting in stock option awards previously granted to the former and retired Chief Financial Officer, who retired on April 27, 2005. The Board of Directors approved the acceleration of the vesting in the two option grants made previously effective as of the date of her retirement. Furthermore, the Board of Directors extended the post-termination of employment/service exercise period from July 26, 2005 (90 days after termination of employment/service) to April 27, 2006. We recorded a charge of \$0.1 million on the new measurement in 2005. In April 2006, these options were exercised, resulting in an additional charge of \$0.1 million to expense in the year ending December 31, 2006.

**9. Benefit Plan**

The Company has a 401(k) profit sharing benefit plan (401(k) Plan) covering substantially all employees who are at least 21 years of age and provide a certain number of hours of service. Under the terms of the 401(k) Plan, employees may make voluntary contributions, subject to Internal Revenue Code limitations. We match 25% of the employee's contributions up to a total of 15% of the employee's gross salary. Our contributions to the 401(k) Plan vest equally over five years. Our contributions to the 401(k) Plan were \$24,476, \$32,936 and \$45,421, for 2005, 2006 and 2007, respectively.

**10. Asset Acquisition**

In April 2006, we acquired from Abbott Laboratories the assets related to Abbokinase, 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, for a total purchase price of \$20.0 million. The purchase price was comprised of \$5.0 million in cash and a \$15.0 million secured promissory note. The original due date of the note was December 31, 2007 and was extended to March 31, 2008. The Note is secured by the right, title and interest in the purchased assets. The purchase of these assets did not constitute the purchase of a business as defined in EITF No. 98-3, *Determining Whether a Nonmonetary Transaction Involves Receipt of Productive Assets or of a Business*, since no employees, equipment, manufacturing facilities or arrangements, or sales and marketing organization were included in the transaction. Since the purchase was not a business, the purchase price has been allocated based upon fair value assessments as follows: inventory \$16.7 million, Abbokinase trade name \$0.5 million and other identifiable intangibles \$2.8 million. We commenced selling Abbokinase in October 2006. Of the total number of vials of Abbokinase inventory that we acquired from Abbott, we estimated that a certain number of such vials will not be sold and, consequently, these vials are carried with no book value assigned. Under the purchase agreement, after we receive cash proceeds of \$5.0 million from the

sale of Abbokinase, we are required to deposit 50% of the cash received from sales of Abbokinase into an escrow account securing the repayment of the \$15.0 million promissory note (See Note 6). If the promissory note is not repaid by its maturity date, Abbott Laboratories has the right to the amount held in the escrow account and to reclaim any remaining inventory of Abbokinase and related rights.

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 a 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 may elect to foreclose on the urokinase assets.

**Table of Contents****11. Segments**

The Company has determined that, in accordance with SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, it operates in one segment as it only reports operating results on an aggregate basis to the chief operating decision maker of the Company, our chief executive officer.

**12. Commitments and Contingencies*****Lease Commitments***

We have noncancelable operating leases for office and laboratory space that expire through 2012. Total rent expense was \$0.1 million in 2005, 2006 and 2007.

Future minimum lease commitments for operating leases at December 31, 2007 are as follows (in thousands):

Years Ending December 31,

2008	\$	307
2009		194
2010		200
2011		206
2012		212
	\$	1,119

***Clinical Research Agreement***

On December 11, 2006, we entered into a clinical research and related services agreement with INC RESEARCH, Inc., (INC), pursuant to which, in accordance with work orders entered into by INC and us from time to time, INC will assist us in conducting and managing clinical trials. We will be obligated to pay fees and to reimburse INC for direct and indirect costs incurred by them under the applicable work orders within 30 days after our receipt of invoices provided from time to time by INC. The agreement will terminate upon completion of the work orders, unless earlier terminated by either party upon 30 days written notice to the other party. In 2006, we made a non-refundable payment to INC of \$0.2 million that was expensed.

**13. Licensing Agreements*****License Agreement with UNEMED Corporation***

On October 10, 2003, UNEMED Corporation granted us an exclusive, worldwide license, with sublicense rights, to intellectual property and patents relating to the use of a thrombolytic agent together with microbubbles for the treatment of thrombosis. We are obligated to pay UNEMED a royalty on any future net sales of products or processes which utilize the licensed technology, of which there have been no sales to date. We are also obligated to pay maintenance fees and expenses related to the maintenance of one of the patents covered by the license. The license agreement will terminate contemporaneously with the expiration of the licensed patents. Warrants were issued for the purchase of 4,000 shares of common stock at \$10.00 per share with a fair value of \$3,000 to acquire these rights.

***License Agreement with Dr. med. Reinhard Schlieff***

On January 4, 2005, Dr. med. Reinhard Schlieff granted us an exclusive, worldwide license, with the right to sub-license, to intellectual property and patents relating to methods of destroying cells by applying ultrasound to them in the presence of microbubbles. We are obligated to pay Dr. Schlieff a royalty of 2% of net sales revenue derived from the sale of products that utilize the licensed technology. The license agreement will terminate contemporaneously with the expiration of the licensed patents. Warrants were issued for the purchase of 4,000 shares of common stock at \$15.00 per share with a fair value of \$36,000 to acquire these rights.

**Table of Contents*****License Agreement with University of Arkansas***

On February 14, 2006, the University of Arkansas granted us an exclusive, worldwide license, with the right to sublicense, intellectual property and patents relating to the use of a specific ultrasound device to be used in conjunction with bubbles, a thrombolytic, or a combination of bubbles and a thrombolytic to break up blood clots. To maintain this license, we must meet certain product development milestones. We are obligated to pay the University of Arkansas a one-time fee of \$25,000 within 30 days after the first commercial sale of a product incorporating the licensed technology, and varying royalties depending on the amount of net revenue derived from the sale of products using the licensed technology, of which there have been no sales to date. We are also obligated to pay a one-time success fee of \$250,000 in the first year that net revenue derived from the sale of products using the licensed technology exceeds \$10.0 million. The license will terminate upon expiration of the last patent to which it relates.

**14. Selected Quarterly Financial Data (unaudited)**

The following is a summary of the quarterly results of operations for the years ended December 31, 2007 and 2006 (in thousands, except for per share amounts):

	<b>Quarters Ended</b>			
	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>	<b>December 31</b>
<b>2007</b>				
Revenues	\$ 1,208	\$ 2,153	\$ 2,349	\$ 2,650
Operating Expenses	3,422	3,723	5,049	4,835
Net loss	(2,398)	(1,487)	(2,666)	(2,185)
Net loss attributable to common stockholders	\$ (2,831)	\$ (1,921)	\$ (11,589)	\$ (2,213)
Basic and diluted net loss attributable to common shareholders	\$ (1.09)	\$ (0.74)	\$ (1.43)	\$ (0.24)
<b>2006</b>				
Revenues	\$ 177	\$ 251	\$ 193	\$ 707
Operating Expenses	3,402	4,048	3,827	5,744
Net income (loss)	(3,345)	(4,075)	(3,982)	10,703
Net income (loss) attributable to common stockholders	\$ (3,495)	\$ (4,225)	\$ (4,408)	\$ 10,262
Basic and diluted net income (loss) attributable to common shareholders	\$ (1.35)	\$ (1.62)	\$ (1.69)	\$ 3.94

In the fourth quarter ended December 31, 2007, the revenues increased \$0.3 million based on a change in estimate primarily relating to lower costs experienced with chargebacks.

**15. Subsequent Events*****SonoLysis***

In January 2008, following a comprehensive review of our commercial and development programs as well as external market conditions the Board of Directors and management determined to seek strategic alternatives for the continued pursuit and financing of the SonoLysis program, while continuing our commercialization efforts around urokinase. In alignment with this decision and to reduce our use of cash, we notified approximately 20 employees, representing approximately 60% of our workforce, that their employment would likely be terminated. If a strategic alternative for our SonoLysis program is not secured, we anticipate the terminations to be completed by July 2008 and that we will incur severance expenses in the range of \$0.2 million and \$0.4 million.





**Table of Contents**

We have not finalized our course of action for the SonoLysis program, therefore, we cannot currently estimate whether additional cost will result or be incurred.

*Urokinase*

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 a 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 may elect to foreclose on the urokinase assets.

**Table of Contents****Exhibit Index**

Exhibit No	Exhibit Title	Filed Herewith	Form	Incorporated by Reference		
				Exhibit No.	File No.	Filing Date
3.1	Fourth Amended and Restated Certificate of Incorporation of the registrant		S-1	3.1	333-142646	5/4/2007
3.2	Amendment to Certificate of Incorporation of the registrant to effect a six-for-ten reverse stock split		S-1	3.2	333-142646	5/4/2007
3.3	Second Amendment to Certificate of Incorporation of the registrant to effect a one-for-three reverse stock split		S-1	3.3	333-142646	5/4/2007
3.4	Amended and Restated Certificate of Incorporation of the registrant		S-1	3.4	333-142646	5/4/2007
3.5	Bylaws of the registrant, as amended		S-1	3.5	333-142646	5/4/2007
3.6	Amended and Restated Bylaws of the registrant		S-1	3.6	333-142646	5/4/2007
4.1	Specimen certificate evidencing shares of common stock		S-1	4.1	333-142646	5/4/2007
10.1*	Form of Indemnification Agreement entered into between the registrant and each of its directors and officers		S-1	10.1	333-142646	5/4/2007
10.2	Second Amended and Restated Investors Rights Agreement, dated April 14, 2006, by and among the registrant and certain stockholders		S-1	10.2	333-142646	5/4/2007
10.3*	2000 Stock Plan and related agreements		S-1	10.3	333-142646	5/4/2007
10.4*	2007 Performance Incentive Plan and related agreements		S-1	10.4	333-142646	5/4/2007
10.5*	Bonus Plan		S-1	10.5	333-142646	5/4/2007
10.6	License Agreement, dated January 4, 2005, between the registrant and Dr. med. Reinhard Schlieff		S-1	10.6	333-142646	5/4/2007

Edgar Filing: IMARX THERAPEUTICS INC - Form 10-K

10.7	Exclusive Sublicense Agreement, dated October 10, 2003, between the registrant and UNEMED Corporation	S-1	10.7	333-142646	5/4/2007
10.8	Assignment, Assumption and License Agreement, dated October 7, 1999, between the registrant and Bristol-Myers Squibb Medical Imaging, Inc. (as successor to DuPont Contrast Imaging, Inc.) dated October 7, 1999, and amendments thereto	S-1	10.8	333-142646	5/4/2007

---

**Table of Contents****Exhibit Index**

<b>Exhibit No</b>	<b>Exhibit Title</b>	<b>Filed Herewith</b>	<b>Form</b>	<b>Incorporated by Reference</b>		
				<b>Exhibit No.</b>	<b>File No.</b>	<b>Filing Date</b>
10.9	License Agreement, dated February 10, 2006, between the registrant and the University of Arkansas for Medical Sciences		S-1	10.9	333-142646	5/4/2007
10.10	Asset Purchase Agreement, dated April 10, 2006, between the registrant and Abbott Laboratories, and amendments thereto		S-1	10.10	333-142646	5/4/2007
10.11	Escrow Agreement, dated April 14, 2006, between the registrant and Abbott Laboratories		S-1	10.11	333-142646	5/4/2007
10.12	Inventory Trademark License Agreement, dated April 14, 2006, between the registrant and Abbott Laboratories		S-1	10.12	333-142646	5/4/2007
10.13	Security Agreement, dated April 14, 2006, between the registrant and Abbott Laboratories		S-1	10.13	333-142646	5/4/2007
10.14	Secured Promissory Note, dated April 14, 2006, between the registrant and Abbott Laboratories		S-1	10.14	333-142646	5/4/2007
10.15	Second Amended Executive Employment Agreement, dated May 15, 2006, between the registrant and Evan C. Unger		S-1	10.15	333-142646	5/4/2007
10.16	Consulting Agreement, dated October 20, 2006, between the registrant and Evan C. Unger		S-1	10.16	333-142646	5/4/2007
10.17	Confidential Separation Agreement and Mutual General Release of All Claims, dated November 28, 2006, between the registrant and Evan C. Unger		S-1	10.17	333-142646	5/4/2007
10.18*			S-1	10.18	333-142646	5/4/2007

Consulting Agreement, dated  
April 11, 2005, between the  
registrant and Greg Cobb

10.19*	Amended Executive Employment Agreement, dated February 1, 2007, between the registrant and Greg Cobb	S-1	10.19	333-142646	5/4/2007
10.20*	Amended Executive Employment Agreement, dated February 1, 2007, between the registrant and Bradford A. Zakes	S-1	10.20	333-142646	5/4/2007

---

**Table of Contents****Exhibit Index**

Exhibit No	Exhibit Title	Filed Herewith	Form	Incorporated by Reference		
				Exhibit No.	File No.	Filing Date
10.21	Agreement, dated March 31, 2006, by and among the registrant, John A. Moore and Edson Moore Healthcare Ventures		S-1	10.21	333-142646	5/4/2007
10.22	Subscription Agreement and Investor Questionnaire, dated March 2004, between the registrant and each of the signatory investors, offering price \$2.00 per share		S-1	10.22	333-142646	5/4/2007
10.23	Subscription Agreement and Investor Questionnaire, dated December 2004, between the registrant and each of the signatory investors, offering price \$3.00 per share		S-1	10.23	333-142646	5/4/2007
10.24	Subscription Agreement and Investor Questionnaire, dated September and October 2004, between the registrant and each of the signatory investors, offering price \$4.00 per share		S-1	10.24	333-142646	5/4/2007
10.25	Commercial Lease Triple Net, dated November 1, 2002, between the registrant and ImaRx Investments L.L.C.		S-1	10.25	333-142646	5/4/2007
10.26	Standard Commercial Industrial Lease, dated December 30, 1997, between the registrant and Tucson Tech Park and addenda thereto		S-1	10.26	333-142646	5/4/2007
10.27	Note Extension and Amendment Agreement, dated October 25, 2007, between the registrant and Abbott Laboratories		8-K	10.1	001-33043	10/26/2007
10.28*	Amendment No. 2 to Executive Employment Agreement dated as of January 1, 2008 by and between the Company and Bradford A. Zakes		8-K	10.1	001-33043	2/7/2008

Edgar Filing: IMARX THERAPEUTICS INC - Form 10-K

10.29*	Amendment No. 2 to Executive Employment Agreement dated as of January 1, 2008 by and between the Company and Greg Cobb	8-K	10.2	001-33043	2/7/2008
10.30*	Executive Employment Agreement dated as of January 1, 2008 by and between the Company and Garen Manvelian	8-K	10.3	001-33043	2/7/2008

---



**Table of Contents****Exhibit Index**

Exhibit No	Exhibit Title	Filed Herewith	Form	Incorporated by Reference		
				Exhibit No.	File No.	Filing Date
10.31*	Executive Employment Agreement dated as of January 1, 2008 by and between the Company and Kevin Ontiveros		8-K	10.4	001-33043	2/7/2008
10.32	Commercial Lease dated December 10, 2007, between the registrant and Cambric Partners	X				
23.1	Consent of Independent Registered Public Accounting Firm	X				
24.1	Power of Attorney (included in the signature page hereto)	X				
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X				
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X				
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				