IMARX THERAPEUTICS INC Form 10-K March 09, 2009

### 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, 2008

 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.)

12277 134<sup>th</sup> Court NE, Suite 202, Redmond, WA (Address of Principal Executive Offices) 98052 (Zip Code)

### (425) 821-5501

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

None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, \$0.0001 par value

(Title of Each Class)

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

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

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 b NO o

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

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):

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Large Accelerated Filer o Accelerated Filer o Non-accelerated filer o Smaller reporting company þ (Do not check if a smaller reporting company) Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

YES o NO þ

As of February 24, 2009, there were 10,165,733 shares of the Registrant s Common Stock outstanding. As of the last day of the most recently completed second fiscal quarter (June 30, 2008), the aggregate market value of the Common Stock of the Registrant held by non-affiliates was approximately \$1.4 million, based on the closing price per share of the Registrant s Common Stock on such date. This amount excludes an aggregate of 1,516,847 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.

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### PART I

### **ITEM 1. BUSINESS**

### Overview

ImaRx Therapeutics, Inc., is a development stage biopharmaceutical company whose research and development efforts have focused on the development of therapies for stroke and other vascular disorders, using our proprietary microsphere technology together with ultrasound. Our lead program, SonoLysis, involves the administration of our proprietary MRX-801 microspheres and ultrasound to break up blood clots and restore blood flow to oxygen deprived tissues. We were previously engaged in the commercialization of one drug approved by the Food and Drug Administration or FDA, urokinase. Urokinase is an FDA-approved thrombolytic, or clot-dissolving agent, indicated for the treatment of acute massive pulmonary embolism. We purchased the product from Abbott Laboratories and had been selling the product since 2006 until we sold all rights to that product to Microbix Biosystems, Inc., or Microbix, in the third quarter of 2008.

On June 11, 2008, in order to preserve capital resources, we announced a restructuring that included a significant workforce reduction in which all of our employees other than Bradford Zakes, our president and chief executive officer, and one additional employee were terminated. In furtherance of the June 2008 restructuring we discontinued substantially all research and development activity and are now exploring strategic alternatives for our clinical-stage SonoLysis program and other Company assets.

On September 23, 2008, we divested our urokinase business to Microbix. Under the terms of the agreement, Microbix acquired the remaining urokinase inventory and related assets and assumed full responsibility for ongoing commercial and regulatory activities associated with the product. Microbix paid to us an upfront payment of \$2.0 million and assumed up to \$0.5 million in chargeback and other liabilities for commercial product currently in the distribution channel. If the assumed chargeback and other liabilities paid by Microbix are less than \$0.5 million, Microbix will issue payment to us for the difference. An additional \$2.5 million payment will be made to us upon release by the FDA of three lots of urokinase that are currently subject to a May 2008 Approvable Letter. Microbix is presently working with the FDA to secure the release of the three lots of urokinase. There can be no assurances that Microbix will be successful in securing such release in a timely manner or at all. If Microbix is unable to secure the release of the three lots we will not entitled to the additional \$2.5 million payment.

We are seeking strategic alternatives that would enable the continued development of our SonoLysis program and are preserving our cash resources in order to provide sufficient resources to accomplish this objective. Historically, one of our primary sources of cash has been the sale of our urokinase product. Due to the sale of the urokinase asset to Microbix, we do not currently have any significant source of cash.

### **Our Development Stage Programs**

*SonoLysis Program.* Our SonoLysis program involves the administration of our proprietary MRX-801 microspheres and ultrasound to break up blood clots and restore blood flow to oxygen deprived tissues. Our MRX-801 microspheres are a proprietary formulation of a lipid shell encapsulating an inert biocompatible gas. We believe the sub-micron size of our MRX-801 microspheres 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 ischemic stroke as well as a broad variety of other vascular disorders associated with blood clots.

Our initial therapeutic focus for our SonoLysis program has been ischemic stroke. Approximately 795,000 adults in the U.S., or one every 40 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 \$68.9 billion was spent in the U.S. in 2009 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 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

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of ischemic stroke patients receiving such treatment. We believe that our SonoLysis program, which involves the administration of our proprietary MRX-801 microspheres and ultrasound to break up blood clots and restore blood flow to oxygen deprived tissues, has the potential to expand this narrow treatment window, thus increasing the number of stroke patients eligible to receive this therapy.

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 microspheres 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 microspheres 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 microspheres 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-801microspheres 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 microspheres 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.

In furtherance of the June 2008 restructuring we discontinued substantially all research and development activity and are now evaluating strategic alternatives for funding and continuation of our clinical-stage SonoLysis program and for our other Company assets.

Additional Research Stage Opportunities. Following our recent restructuring and significant workforce reduction, we suspended all ongoing research stage programs and are also evaluating strategic alternatives for the funding and continuation of these programs.

### **Our Business Strategy**

Our goal is to become a leading provider of therapies for vascular disorders. In order to achieve this objective, our business strategy includes the following key elements:

Obtain additional funding and/or enter into strategic partnerships to gain access to the required operating capital to continue the development of our SonoLysis program, and;

Execute on our development plan to incrementally advance our SonoLysis program towards commercialization.

### **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 is essential. *Ischemic Stroke* 

Approximately 795,000 adults in the U.S., or one every 40 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 \$68.9 billion will be spent in the U.S. in 2009 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, 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.

### 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 and is the only thrombolytic drug currently approved for the treatment of ischemic stroke.

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 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.

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 procedure. 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

We have contracted with a third party to produce the necessary quantities of our MRX-801 microspheres for clinical research purposes.

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. 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 product candidates could be interrupted, which could result in substantial delays, and additional costs.

### Competition

The market for therapies to treat vascular disorders associated with blood clots is highly competitive. Numerous companies are developing competing treatments for ischemic stroke. Many of these competitors have significantly greater financial reserves than we do, and have access to greater resources. We expect that our competitors will continue to pursue the development of new or improved treatments for ischemic stroke.

Although we are unaware of any other companies that are developing microsphere technologies for therapeutic use in vascular disorders, 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.

### Thrombolytic Drug Competitors

The U.S. market for thrombolytic drugs is dominated by Genentech, Inc., which manufactures tPA, the most widely used thrombolytic drug. Whereas, we are aware that other thrombolytic drugs have been under development for the treatment of ischemic stroke, Genentech s tPA is currently the only thrombolytic drug that has been approved by the FDA for this indication. 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

One of the primary device-based treatments for ischemic stroke 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 which is also used for 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 aspirated out of intracranial vessels.

### **Patents and Proprietary Rights**

Our success depends in part on our ability to develop a competitive advantage in the market through the use of microspheres 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 microspheres 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.

The U.S. patents that we own cover certain applications related to microsphere compositions and methods of making and using such microspheres 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 microsphere 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 microsphere 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.

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 some cases, our product candidates may fall into multiple categories and require regulatory approval in more than one category. For example, 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 microspheres, 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 or medical devices, and must meet similar regulatory hurdles as in the U.S. to gain approval and reach the market.

Drug Regulation

The process required by the FDA before drug 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.

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 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 <u>www.clinicaltrials.gov</u>. 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

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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. The submission of an NDA 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 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.

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 microspheres.

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 Investigational Device Exemption, or 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.

### 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, 510(k) clearance or PMA that have already been granted; and

criminal prosecution.

### Employees

We have two full-time employees who are engaged in executive, administrative, accounting and business development functions. None of our employees is covered by a collective bargaining agreement.

### **Available Information**

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

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### 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, 2008, we had an accumulated deficit of \$91.3 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, 2008 and 2007 were \$10.1 million and \$18.6 million, respectively. We currently do not have sufficient cash resources to further product development activities. However, if and when we are successful in obtaining such resources, we expect our product development expenses to increase in connection with our ongoing and future product development initiatives. 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.

## 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 \$91.3 million at December 31, 2008 raises substantial doubt about our ability to continue as a going concern.

# We will need additional capital to fund our present operations beyond the third quarter 2009. If we are unable to identify or consummate an attractive strategic transaction for our SonoLysis program or our other assets in a timely manner we may be forced to delay, reduce or eliminate these activities and we may be unable to timely pay our debts.

We do not currently have sufficient cash resources to fund any product development activities. Our current activities are directed toward securing an attractive strategic transaction for our SonoLysis program and our other assets. We believe that our cash and cash equivalents will be sufficient to fund these activities and other demands and commitments into the third quarter 2009. Our funding requirements will, however, depend on numerous factors, including:

whether Microbix is successful in obtaining lot release from the FDA with respect to the three lots currently subject to an FDA Approvable Letter:

the timing and amount of revenue from a strategic transaction for our clinical-stage SonoLysis program and our other assets;

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.

We cannot be certain that we will generate any additional funding. We may be forced to accept terms on a strategic transaction that are highly dilutive or otherwise disadvantageous to our existing stockholders. If we are unable to secure adequate financing, we could be required to liquidate the remaining assets.

*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.

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 candidate, we may not generate sufficient revenue to continue our business.

The process to develop, obtain regulatory approval for and commercialize potential drug candidates is long, complex and costly. Our proprietary SonoLysis microsphere technology has not been used in clinical trials other than our concluded Phase I/II clinical trial. As a result, our business in the near term is substantially dependent upon our ability to complete development, obtain regulatory approval for and commercialize our SonoLysis product candidate in a timely manner. If we are unable to 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 manufactures 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.

### 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 payers, even if necessary regulatory approvals are obtained. We believe that recommendations by physicians and other health care providers and payers 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 microspheres currently being commercialized as contrast agents for use in echocardiography were revised by the FDA to include warnings with respect to certain serious cardiopulmonary reactions, including fatalities observed when the bubbles were administered during echocardiography. One of the microspheres marketed under the brand name Definity<sup>®</sup> is similar in composition to our MRX-801 microsphere. As a result, our MRX-801 microsphere, if approved, may receive a similar warning that 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;

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. If we eventually succeed at obtaining regulatory approval for commercial sale of our product candidate, competitive developments may 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 our MRX-801 and other proprietary microspheres;

conducting clinical trials;

conducting preclinical studies;

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 agreements in place for all of these services. Although we use a third party manufacturer to produce MRX-801 microspheres for our research purposes on a purchase order basis, that third party may not have the capacity to produce the volume of MRX-801 microspheres necessary for commercial sales. To the extent that we are unable to maintain the relationships we have in place or to enter into any one or more of the additional relationships necessary to conduct 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 microspheres 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 have only two full-time employees and consulting relationships with certain key consultants to provide necessary services. We may not have sufficient personnel to effectively identify or consummate an attractive strategic transaction for our clinical-stage SonoLysis program and other Company assets in a timely manner, or at all.* 

Our success depends substantially on the services of our two employees and key consultants. The loss of the services of one or more of these persons could have a material adverse effect on our business. Each of these persons may terminate his or her relationship with us without notice and without cause or good reason. Our ability to identify or consummate an attractive strategic transaction for our clinical-stage SonoLysis program and other Company assets is substantially dependent on these persons and without them we cannot be certain that we will be able to do accomplish our business objectives.

### 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 may 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.

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 microspheres-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.

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.

## 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, microspheres 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.

## 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 microspheres that we are developing for breaking up blood clots, as well as a new generation of MRX-802 microspheres 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. 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 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.

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. 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.

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.

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 payer. 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 officer, 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; 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;

### 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.

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. As a result of the restructuring plan initiated in June 2008 management believes that there have been changes in our internal control environment that have materially affected our internal control over financial reporting. Based on that evaluation, our principal executive officer and principal financial officer concluded that our internal control over financial reporting was ineffective as of the end of the period covered by this report.

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. 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 in 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, 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.

## 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.

# 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 price has depreciated significantly since our initial public offering and may continue to depreciate in value. The price of our common stock may never appreciate and our stockholders may never realize gain on their purchase of shares of our common stock.

# **ITEM 2. Properties**

Our current facilities are located in a leased building in Redmond, Washington. Our corporate headquarters is 3,335 square feet, is subject to a ten-month lease at approximately \$31,250 and terminates on October 31, 2009. We also lease approximately 900 square feet of laboratory space at the same facility as the corporate headquarters for a total of \$2,640 until October 31, 2009.

#### **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 2008.

#### PART II

# ITEM 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is currently quoted on the Over the Counter Bulletin Board under the symbol IMRX.OB . From July 2007 to October 2008, our common stock was traded on the NASDAQ Capital Market under the symbol IMRX . 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 by NASDAQ through October 22, 2008 and the Over the Counter Bulletin Board after October 22, 2008.

	I	High	]	Low
2008				
Fourth Quarter	\$	0.10	\$	0.04
Third Quarter		0.33		0.04
Second Quarter		0.84		0.16
First Quarter		2.17		0.36
2007				
Fourth Quarter	\$	3.45	\$	1.51
Third Quarter (beginning July 26, 2007)		4.90		3.25

At February 24, 2009, there were 258 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, 2008, all of the net proceeds were used to fund SonoLysis development and urokinase commercialization activities, pay the non-recourse note to Abbott Laboratories and working capital and other general corporate purposes.

#### 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. expect, plan, and similar expressions may identify forward-looking stat estimate, continue, anticipate. intend, 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 IA 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 whose research and development efforts have focused on the development of therapies for stroke and other vascular disorders, using our proprietary microsphere technology together with ultrasound. Our lead program, SonoLysis, involves the administration of our proprietary MRX-801 microspheres and ultrasound to break up blood clots and restore blood flow to oxygen deprived tissues. We were previously engaged in the commercialization of one drug approved by the Food and Drug Administration or FDA, urokinase. Urokinase is an FDA-approved thrombolytic, or clot-dissolving agent, indicated for the treatment of acute massive pulmonary embolism. We purchased the product from Abbott Laboratories and had been selling the product since 2006 until we sold all rights to that product to Microbix Biosystems, Inc., or Microbix, in the third quarter of 2008. On June 11, 2008, in order to preserve capital resources, we announced a restructuring that included a significant workforce reduction in which all of our employees other than Bradford Zakes, our president and chief executive officer, and one additional employee were terminated. In furtherance of the June 2008 restructuring we discontinued substantially all research and development activity and are now exploring strategic alternatives for our clinical-stage SonoLysis program and other assets.

On September 23, 2008, we divested our urokinase business to Microbix. Under the terms of the agreement, Microbix acquired the remaining urokinase inventory and related assets and assumed full responsibility for ongoing commercial and regulatory activities associated with the product. Microbix paid to us an upfront payment of \$2.0 million and assumed up to \$0.5 million in chargeback and other liabilities for commercial product currently in the distribution channel. If the assumed chargeback and otherliabilities paid by Microbix are less than the \$0.5 million assumed, Microbix will issue payment to us for the difference. An additional \$2.5 million payment will be made to us upon release by the FDA of the three lots of urokinase that are currently subject to a May 2008 Approvable Letter. Microbix is presently working with the FDA to secure the release of the three lots of urokinase. There can be no assurances that Microbix will be successful in securing such release in a timely manner or at all. If Microbix is unable to secure the release of the three lots we will not entitled to the additional \$2.5 million payment.

We are seeking strategic alternatives that would enable the continued development of our SonoLysis program and are preserving our cash resources in order to provide sufficient resources to accomplish this objective. Historically, one of our primary sources of cash has been the sale of our urokinase product. Due to the sale of the urokinase asset to

Microbix, we do not currently have any significant source of cash.

#### Product Sales, Research and Development Revenue

Our primary source of revenue was derived from sales of our urokinase product which commenced in October 2006 upon our purchase from Abbott Laboratories and will be eliminated as the product was sold to Microbix on September 23, 2008. As a result of the sale of the urokinase assets and inventory to Microbix, future revenues will no longer be recognized once the product currently held at the wholesale distributors is sold through to the end user. In addition to our commercial product sales, we also generated a limited amount of revenue by providing research services for projects funded under various government grants. We currently have no outstanding grants under which we are receiving revenue. We may apply for similar government grants in future periods.

All product sales recorded-to-date relate to sales of urokinase in the United States. Due to our limited 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, 2008, we had deferred revenue of \$0.2 million which will be recognized as the limited amount of inventory at our wholesale distributors is pulled through and then there will be zero.

# **Cost of Product Sales**

Cost of product sales had been 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. Due to the divestiture of our urokinase product, we will cease to have cost of product sales once all vials at the wholesale distributors have been sold to a hospital or other end user or have expired.

#### **Research and Development Expenses**

We classify our research and development expenses into four categories of activity, namely: research, development, clinical and regulatory. Our research and development efforts were focused primarily on product candidates from our SonoLysis program. As part of our restructuring effort announced in June 2008, we have ceased substantially all research related activities.

# 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 business development, public reporting and corporate compliance, as well as a portion of our overhead expenses. Although these expenses will be at reduced levels, we have incurred and will continue to incur expenses in the areas of legal compliance, 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 financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these 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 was previously required to make estimates in relation to inventory and intangible asset valuation, chargebacks and administrative fee accruals, clinical trial costs and 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 financial statements.

#### Inventory and Inventory Subject to Return

Inventory of urokinase was comprised of finished goods and is stated at the lower of cost or market value. Inventory value was initially determined as a result of the purchase price allocation from the acquisition of this product from Abbott Laboratories in 2006.

On September 23, 2008, we divested the urokinase assets and sold the entire remaining urokinase inventory to Microbix. As such, the inventory value at September 30, 2008 was zero.

As of December 31, 2008, all of the vials in inventory held by our wholesale distributors, or \$12,596 in inventory value will expire at various times up to September 2009. Once labeled inventory expires it cannot be relabeled and sold.

#### Long-lived and Intangible Assets

We account for long-lived assets in accordance with the provisions of SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS 144). SFAS 144 addresses financial accounting and reporting for the impairment or disposal of long-lived assets. This Statement requires that long-lived assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparing the carrying amount of an asset to the expected future net cash flows generated by the asset. If it is determined that the asset may not be recoverable and if the carrying amount of an asset exceeds its estimated fair value, an impairment charge is recognized to the extent of the difference. SFAS 144 requires companies to separately report discontinued operations, including components of an entity that either have been disposed of (by sale, abandonment or in a distribution to owners) or classified as held for sale. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

At June 30, 2008, we evaluated our intangible assets for impairment due to the receipt of the Approvable Letter from the FDA and determined that all of the intangible assets were impaired. As such, these intangibles were written off by recording a \$1.3 million impairment. We also initiated a plan to sell a portion of our laboratory equipment, which we valued at fair value and recorded a \$0.5 million impairment. The assets were classified as held for sale. We completed the sale of \$152,000 of assets held for sale for cash of \$115,000 and the termination of a lease agreement, which resulted in a reduction of future lease payments of \$16,000. We recorded an additional loss on the sale of equipment in this transaction in the amount of \$21,000.

# **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) collectability 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 consisted 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 have been established as a reduction of product sales revenues at the time such revenues are recognized. These deductions from gross revenue have been established by us as our best estimate at the time of sale adjusted to reflect known changes in the factors that impact such reserves.

Historically, we provided research services under certain grant agreements, including federal grants from the National Institutes of Health. We recognized revenue for these research services as the services were performed. Revenue from grants was 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. 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 initial public offering, or 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, 2007 Compared to 2008

*Product Sales, Research and Development Revenue.* Our revenue-producing activities during 2007 and 2008 consisted of sales of our urokinase product and services provided under research grants and contracts. Our total revenues decreased from \$8.4 million in 2007 to \$6.7 million in 2008, primarily as a result of the decline in revenue recognized which accounted for \$7.8 million of our revenue in 2007 and \$6.5 million in 2008. The \$1.3 million decrease in urokinase sales from 2007 to 2008 is due to a decrease in inventory in the channel and the lack of current dated inventory to replenish the channel.

Our grant and other revenue decreased from \$0.5 million in 2007 to \$0.2 million in 2008, primarily due to the wind down of research and development activities in 2008.

*Cost of Product Sales.* Cost of product sales was \$3.5 million in 2007 and \$3.1 million in 2008. The decrease in cost of product sales was due to the decrease in inventory in the channel and the lack of current dated inventory to replenish the channel. 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.

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*Research and Development Expenses.* Research and development expenses decreased from \$7.4 million in 2007 to \$3.0 million in 2008. This decrease was principally a result of lower clinical trial costs and consulting costs associated with the wind down of our clinical trial and reduced salaries and pre-clinical trial costs as a result of restructuring activities.

*General and Administrative Expenses.* General and administrative expenses increased from \$6.1 million in 2007 to \$6.4 million in 2008. This increase is principally a result of severance costs associated with our June 2008 restructuring, an increase in costs associated with maintaining public company infrastructure and increased marketing costs associated with the rebranding of the urokinase asset offset partially by a decrease in patent maintenance, board of director expenses and amortization.

*Asset Impairment*. The asset impairment of \$10.0 million includes a \$9.5 million impairment related to the write-down and sale of our urokinase assets and a \$0.5 million impairment of all laboratory equipment that was classified as available for sale in the second quarter of 2008.

*Interest and Other Income.* Interest and other income decreased from \$0.5 million in 2007 to \$0.1 million in 2008, as a result of a lower cash balance throughout the year.

*Interest Expense*. Interest expense decreased from \$0.9 million in 2007 to \$0.2 million in 2008, due to the extinguishment of a note payable in April 2008.

*Gain on Settlement of Accounts Payable.* In the fourth quarter of 2008, we settled various accounts payable for amounts less than those invoiced for a total gain of \$0.2 million.

*Gain on Extinguishment of Debt.* In May 2007, we extinguished a debt for patent costs that resulted in a gain of \$0.2 million. In April 2008, we extinguished a note payable to Abbott for the purchase of the urokinase assets that resulted in a gain of \$5.6 million.

# Liquidity and Capital Resources

# Sources of Liquidity

We have incurred losses since our inception. At December 31, 2008, we had an accumulated deficit of \$91.3 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 of urokinase, which commenced in October 2006. During the year ended December 31, 2007, we received net proceeds of \$12.4 million from the issuance of shares of our common stock. At December 31, 2008, we had \$0.8 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 with an initial maturity date of December 31, 2007, which was extended to March 31, 2008. On April 17, 2008, we entered into a satisfaction, waiver and release agreement with Abbott Laboratories regarding payment of the note. Under the terms of the agreement, we were required to pay Abbott Laboratories \$5.2 million in cash and upon payment of the funds, the debt obligation was deemed to be indefeasibly paid in full by us and the note was cancelled and returned to us.

On September 23, 2008, we divested our urokinase business to Microbix. Through this transaction, Microbix acquired the remaining urokinase inventory and related assets and assumed full responsibility for ongoing commercial and regulatory activities associated with the product. Microbix paid to us an upfront payment of \$2.0 million and assumed up to \$0.5 million in chargeback and other liabilities for commercial product currently in the distribution channel. If the assumed chargeback and other liabilities paid by Microbix are less than the \$0.5 million assumed, Microbix will issue payment to us for the difference. An additional \$2.5 million payment will be made to us upon release by the

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FDA of the three lots of urokinase that are currently subject to a May 2008 Approvable Letter.

## Cash Flows

*Net Cash Used in or provided by Operating Activities.* Net cash provided by operating activities was \$1.9 million for the year ended December 31, 2007 and net cash used in operating activities was \$8.4 million for the year ended December 31, 2008. The cash provided by operations in 2007 primarily reflects our cash from product sales and changes in working capital. Net cash used in 2008 primarily reflects the net loss offset in part by the gain on extinguishment of debt, asset impairment charges and changes in woking capital.

*Net Cash Used in or provided by Investing Activities.* Net cash used in investing activities was \$0.6 million for the year ended December 31, 2007 and net cash provided by investing activities was \$2.2 million in 2008. Net cash used in investing activities in 2007 primarily reflects purchases of property and equipment, including manufacturing, information technology, laboratory and office equipment and intangible assets. Net cash provided by investing activities in 2008 primarily reflects the cash received in the sale of the urokinase assets and proceeds from the sale of property and equipment.

*Net Cash Provided by or used in Financing Activities.* Net cash provided by financing activities was \$7.2 million for the year ended December 31, 2007 and net cash used in financing activities was \$5.9 million in 2008. Net cash provided by financing activities in 2007 was primarily attributable to the \$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. In 2008, net cash used in financing activities was attributable to the \$6.3 million payment on the note payable to Abbott Laboratories offset partially by the \$0.4 million change in the restricted cash balance.

# **Operating Capital and Capital Expenditure Requirements**

Historically, our primary source of liquidity has been the public offering and private placement of shares of our common and preferred stock and convertible notes, government grants, and, more recently, product sales of urokinase. We do not currently have a significant source of cash.

In furtherance of the June 2008 restructuring we are now exploring strategic alternatives for our clinical-stage SonoLysis program and other Company assets, which may involve the disposition of substantially all of these assets. As a result of the sale of all of our urokinase assets to Microbix on September 23, 2008, we have sufficient capital to fund our operating needs into the third quarter 2009. 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.

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 cash resources may adversely affect our ability to operate as a going concern. If we raise additional funds by issuing equity securities, or enter into a strategic transaction, 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.

#### **Off-Balance Sheet Transactions**

At December 31, 2007 and 2008, 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 May 2008, the FASB issued SFAS No. 162 (SFAS 162), *The Hierarchy of Generally Accepted Accounting Principles*. SFAS 162 sets forth the level of authority to a given accounting pronouncement or document by category. Where there might be conflicting guidance between two categories, the more authoritative category will prevail. SFAS 162 becomes effective 60 days after the SEC approves the PCAOB s amendments to AU Section 411 of the AICPA Professional Standards. SFAS 162 will not have an impact on our financial statements.

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 have an impact on our financial statements.

#### **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, 2008 we carried out an evaluation, under the supervision and with the participation of our management, including the principal executive officer and the principal 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 that evaluation and due to the restructuring plan initiated in June 2008 including the significant reduction in personnel in the accounting and finance function, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were ineffective as of the end of the period covered by this report.

# Management s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. The Company s internal control over financial reporting is designed to provide reasonable assurances regarding the reliability of financial reporting and the preparation of the financial statements of the Company in accordance with U.S. generally accepted accounting principles, or GAAP. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree or compliance with the policies or procedures may deteriorate.

With the participation of our Chief Executive Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2008 based on the framework in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation and the material weaknesses described below, management concluded that the Company did not maintain effective internal control over financial reporting as of December 31, 2008 based on the specified criteria. Management has identified control deficiencies regarding the lack of segregation of duties and the need for a stronger internal control environment. Management of the Company believes that these material weaknesses are due to the small size of the Company s accounting staff, which stemmed from the significant work force reduction that resulted from our June 11, 2008 restructuring. The small size of the Company s accounting staff may prevent adequate controls in the future, such as segregation of duties, due to the cost/benefit of such remediation. Due to the lack of financial resources available to the company we do not expect to retain additional personnel to remediate these control deficiencies in the near future, if ever.

These control deficiencies could result in a misstatement of account balances that would result in a reasonable possibility that a material misstatement to our financial statements may not be prevented or detected on a timely basis. Accordingly, we have determined that these control deficiencies as described above together constitute a material weakness.

In light of this material weakness, we performed additional analyses and procedures in order to conclude that our financial statements for the year ended December 31, 2008 included in this Annual Report on Form 10-K were fairly stated in accordance with US GAAP. Accordingly, management believes that despite our material weaknesses, our financial statements for the year ended December 31, 2008 are fairly stated, in all material respects, in accordance with US GAAP.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management s report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management s report in this Annual Report on Form 10-K.

# PART III

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

The names, ages and positions of our directors and officers as of December 31, 2008, are set forth below. Biographical information for each of these persons also is presented below.

Name	Age	Position Held
Richard L. Love	65	Chairman of Board
Bradford A. Zakes	43	President and Chief Executive Officer
Richard E.Otto	59	Director
James M. Strickland	66	Director
Philip C. Ranker	49	Director
Thomas W. Pew	70	Director
	c	11 1/

There are no family relationships between any of our directors and/or any executive officer.

# **Richard L. Love** Chairman of Board

Richard Love has served as a director since March 2006 and as Chairman of the Board of Directors since September 2007. Since September 2007 to present, Mr. Love has served as Manager of TVP Management, LLC, an Arizona-based venture capital investment firm and since January 2007, Mr. Love has served as a partner of Translational Accelerator Venture Fund (TRAC), an investment fund. From January 2005 to January 2007 Mr. Love served as Managing Director of TGEN Accelerator LLC for his employer Translational Genomics Research Institute. From January 2003 to January 2005, Mr. Love served as Chief Operating Officer for Translational Genomics Research Institute and from June 1993 to January 2002 Mr. Love served as Chief Executive Officer and a director of ILEX Oncology, Inc., a biotechnology company evaluating cancer therapeutics. Mr. Love also serves as a director for Parexel International, Medical Consultant Services, Cell Therapeutic Inc, and Medtrust, LLC. Mr. Love holds B.S. and M.S. degrees in Chemical Engineering from the Virginia Polytechnic Institute.

# Bradford A. Zakes President and Chief Executive Officer

Bradford Zakes has served as our President and Chief Executive Officer since October 2006, prior to that he served ImaRx as Chief Operating Officer. From December 2001 to August 2005, Mr. Zakes served as Director, Business Management at ICOS Corporation, a biotechnology company. Mr. Zakes currently serves on the Board of The BioIndustry Organization of Southern Arizona and on the Emerging Company Section Governing Body of The Biotechnology Industry Organization (BIO). Mr. Zakes holds a B.S. in Biology from Oregon State University, a M.S. degree in Toxicology from American University and a M.B.A. from Duke University s Fuqua School of Business.

# **Richard E. Otto** Director

Richard Otto has served as a director since July 2004. From February 2003 to December 2006, Mr. Otto served as President and Chief Executive Officer of Corautus Genetics, Inc., a gene therapy company. Mr. Otto founded Clique Capital, a venture capital company, in January 1999, where he was employed until January 2002. Mr. Otto serves on the board of directors of Medi-Hut Co., Inc. Mr. Otto holds a B.S. in Chemistry and Zoology from the University of Georgia and engaged in graduate studies in Biochemistry at Medical College of Georgia.

# James M. Stickland Director

James Strickland has served as a director since August 2000. Since February 2004, Mr. Strickland has served as the Chief Executive Officer of Thayer Medical Corporation, a medical device company. Since March 1998,

Mr. Strickland has served as the General Partner and Managing Director of the Coronado Venture Funds, a group of venture investing partnerships formed in 1988. Mr. Strickland holds B.S. and M.S. degrees in Electrical Engineering from the University of New Mexico and an M.S. in Industrial Administration from Carnegie Institute of Technology (now Carnegie-Mellon University).

## Philip C. Ranker Director

Philip Ranker has served as a director since February 2006. Since January 2008, Mr. Ranker has served as the Vice President of Finance for Amylin Pharmaceuticals, Inc. From September 2004 to January 2008, Mr. Ranker served as the Chief Financial Officer and Vice President of Finance of Nastech Pharmaceutical Company, Inc. From September 2001 to August 2004, Mr. Ranker served as Director of Finance for ICOS Corporation. Prior to working at ICOS, Mr. Ranker spent nearly 15 years in various positions with Aventis and its predecessor companies. Mr. Ranker holds a B.S. in Accounting from the University of Kansas.

# Thomas W. Pew Director

Thomas Pew has served as a director since January 2004. Since 1994, Mr. Pew has been a private investor in formative-stage biotechnology companies. He holds a B.A. in Economics from Cornell University.

# **Responsibilities of the Board**

Our Board of Directors is elected by the stockholders to oversee the stockholders interest in the Company and the overall success of our business. Among other things, the Board, directly and through its committees, establishes corporate policies; oversees compliance and ethics; reviews the performance of the Chief Executive Officer and other executives; establishes our executive compensation policies and objectives; reviews and approves total compensation paid to our named executive officers; reviews and approves significant transactions or transactions involving related persons; and reviews our long-term strategic plans.

In accordance with general corporate legal principles applicable to corporations organized under the laws of Delaware, the Board of Directors does not control the day-to-day management of ImaRx. Members of the Board keep informed about our business by participating in Board and committee meetings, by reviewing analyses and reports and through discussions with the Chief Executive Officer.

The Board meets throughout the year and holds special meetings and acts by written consent from time to time as needed. Directors are expected to attend Board meetings and meetings of committees on which they serve, and to devote the time needed and meet as frequently as necessary to discharge their responsibilities properly. During the fiscal year ended December 31, 2008, the Board of Directors held 20 meetings. At certain meetings for limited periods of time and for limited considerations, the Board met in executive session where only the independent directors were present. Each Board member standing for re-election attended 75% or more of the aggregate of the meetings held by the Board and by the respective committees on which such Board member served during the period for which he or she was a director or a member of such committee.

# **Committees of the Board**

The Board has elected to use Board committees in furtherance of the discharge of its duties and for the conduct of its work. All major decisions of such committees are reviewed and, where appropriate, ratified by the Board. In furtherance of its decision to employ committees and consistent with applicable laws and regulations, the Board has established an Audit Committee, a Compensation Committee, and a Nominating and Corporate Governance Committee. Information regarding each committee is provided below. *Audit Committee* 

The Board has a separately-designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act of 1934, as amended (the Exchange Act ), the purpose of which includes: overseeing ImaRx s accounting and financial reporting processes and audits of ImaRx s financial statements; reviewing evaluations of ImaRx s system of internal controls; engaging and monitoring the independence and performance of ImaRx s independent registered public accounting firm; providing a forum for communication among the independent registered public accounting firm, management, and the Board; and providing such additional information and materials the Audit Committee may deem necessary to make the Board aware of significant financial matters that require the Board s attention. The Audit Committee also submits the Audit Committee Report included in this proxy statement. The Audit Committee met five times during the fiscal year ended December 31, 2008.

The Audit Committee is presently composed of three directors, Philip Ranker, Richard Otto and James Strickland. Our Board has determined that each member of the Audit Committee is independent under our independence criteria described above. Our Board has also determined that Mr. Ranker qualifies as an Audit Committee Financial Expert as defined in the applicable SEC rules. The Board has adopted a written charter for the Audit Committee and this charter is available on the corporate governance section of our web site at <u>www.imarx.com</u>.

Compensation Committee

The Board has delegated to the Compensation Committee the responsibility for implementing, reviewing and monitoring adherence with ImaRx s compensation policies and objectives. The Compensation Committee is responsible for establishing, approving and recommending to the Board for final approval ImaRx s compensation programs. The Compensation Committee s functions include: (i) establishing, reviewing, and overseeing base salaries, incentive compensation, equity compensation, retention compensation and other forms of compensation paid to our executive officers; (ii) administering our incentive compensation and equity plans; and (iii) performing such other functions regarding compensation as the Board may delegate. In connection with annual adjustments to named executive officer compensation recommendations of the CEO and the compensation studies and data it has available to it and then renders a final compensation recommendation for each of our named executive officers to the Board for approval. The Compensation Committee has the final authority to hire and terminate any compensation consultant engaged by ImaRx.

The Compensation Committee is currently composed of three directors, James Strickland, Richard Love and Thomas Pew. The Compensation Committee met three times during the fiscal year ended December 31, 2008.

Our Board has determined that each member of the Compensation Committee is independent under our independence criteria described above. In addition, all members of the Compensation Committee are outside directors as defined by Rule 162(m) of the Internal Revenue Code and are nonemployee directors as defined by Rule 16b-3 promulgated by the SEC under the Securities Exchange Act of 1934. The Board has adopted a written charter for the Compensation Committee and the charter is available on the corporate governance section of our web site at <u>www.imarx.com</u>. *Nominating and Corporate Governance Committee* 

The Nominating and Corporate Governance Committee s functions include: evaluating director performance on at least an annual basis; providing advice, information and materials relating to the nomination of directors; interviewing, nominating, and recommending individuals for membership on the Board and its committees; developing and overseeing the Board s Corporate Governance Principles and a Code of Business Conduct and Ethics applicable to members of the Board, officers and employees of ImaRx; and assessing and monitoring the independence of the Board. The Committee will, at least on an annual basis, consider the mix of skills and experience that the then-current directors bring to the Board to assess whether the Board has the necessary membership and resources to perform its oversight function effectively. The qualifications of any non-incumbent director candidates brought to the attention of the Committee by directors, management, stockholders or third parties will be evaluated from time to time in light of the Committee s determination of the Board s needs, and under the same criteria as set forth below. The Committee will consider nominees for directors nominated by stockholders upon submission in writing to the Secretary of ImaRx of the names of such nominees, together with their qualifications for service as a director of ImaRx. Our bylaws set forth the procedures a stockholder must follow to nominate candidates for director. The Committee does not distinguish between nominees suggested by stockholders and other nominees. To date, the committee has not received a director nominee from a stockholder or stockholders holding more than five percent of our common stock.

In evaluating the suitability of candidates for Board membership, the Committee takes into account many factors, including whether the persons is independent; the individual s personal qualities and characteristics, accomplishments and reputation in the business community; the person s current knowledge and contacts in the communities in which ImaRx does business and in ImaRx s industry or other industries relevant to ImaRx s business; the person s ability and willingness to commit adequate time to Board and committee matters; the fit of the individual s skills and personality with those of other directors and potential directors in building a Board that is effective and responsive to the needs of ImaRx; and the need for the Board to have a diversity of viewpoints, background, experience and other factors. The Committee has not established any specific minimum qualification standards for nominees to the Board.

The Nominating and Corporate Governance Committee is currently composed of four directors, Mr. Love, Mr. Otto, Mr. Pew and Mr. Ranker.

Our Board has determined that each member of the Nominating and Corporate Governance Committee is independent under our independence criteria described above. The Board has adopted a written charter for the Nominating and Corporate Governance Committee and the charter is available on the corporate governance section of our web site at <u>www.imarx.com</u>. The Nominating and Corporate Governance Committee did not meet during the fiscal year-ended December 31, 2008.

# Section 16(a) Beneficial Ownership Reporting

Section 16(a) of the Exchange Act requires ImaRx s directors and executive officers, and persons who own more than 10% of ImaRx s common stock, to file with the Commission reports of ownership and changes in ownership of ImaRx common stock. Officers, directors, and greater than 10% stockholders are required by the Commission to furnish ImaRx with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such reports furnished to ImaRx or written representations that no other reports were required, during the fiscal year ended December 31, 2008, we believe that all of these filing requirements were satisfied by our directors, officers and 10% holders.

#### **Code of Ethics**

We have adopted a corporate Code of Business Conduct and Ethics that applies to all of our directors, officers (including our chief executive and accounting officers) and employees. We require that all of our directors, officers, employees and agents certify on an annual basis that they are in compliance with the code. A copy of the Code of Business Conduct and Ethics is available on the corporate governance section of our web site at <u>www.imarx.com</u>. **ITEM 11. Executive Compensation** 

# SUMMARY COMPENSATION TABLE

The table below summarizes the total compensation paid to or earned by each of our named executive officers for the fiscal years ended December 31, 2008 and 2007.

		Salary		Nonequity Incentive Plan Compensation	-	Total
Name and Principal Position	Year	(\$)	(\$)(1)	(\$)(2)	(\$)(3)	(\$)
Bradford A. Zakes	2008	272,731	254,767	318,125(4	)	845,623
President and Chief Executive Officer	2007	227,308	76,012	63,281		366,601
Greg Cobb (6)	2008	129,423	9,162	25,000	119,689	283,274
Chief Financial Officer	2007	192,306	74,685	56,250		323,242
Kevin J. Ontiveros (7)	2008	303,008	13,895	39,250	110,449	446,601
Vice President, Legal Affairs and General Counsel	2007	139,327	16,912	52,500	15,000(5)	223,739

(1) The amounts in this column represent the compensation expenses recognized in 2008 and 2007, respectively, related to stock option awards pursuant to **SFAS** No. 123(R). A discussion of the valuation assumptions used to determine the expense is included in Note 8 of our audited financial statements included in this Form 10-K. (2) The amounts shown in this column constitute the quarterly cash incentive bonuses made to each named executive officer based on the attainment of certain pre-established performance criteria established by our Board of Directors.

(3) Amounts consist of severance

payments including benefits.

- (4) Amounts include a retention bonus.
- (5) Amounts consist of relocation expenses.
- (6) 177,249 options were forfeited in 2008 upon separation with the Company. Also upon separation, 94,000 shares were accelerated.
- (7) 65,501 options were forfeited in 2008 upon separation with the Company. Also upon separation, 60,165 shares were accelerated.

#### **Employment Agreements**

*Bradford A. Zakes.* On June 27, 2008, pursuant to the recommendation of the Compensation Committee and approval of the our Board of Directors, we entered into an amendment to the Executive Employment Agreement (the

Agreement ) with Mr. Bradford Zakes. Pursuant to the terms of the Agreement, we agreed to pay to Mr. Zakes a retention bonus in the amount of \$290,000. In consideration for such payment, Mr. Zakes agreed to remain in our employ for a period of 12 months from the date of the Agreement. In the event that Mr. Zakes employment is terminated prior to the expiration of such 12-month period and such termination is not incident to a change-in-control, disability, death, or is not for good reason or is by us without cause, then Mr. Zakes is required to repay us a ratable portion of the bonus. We will continue to pay Mr. Zakes an annual base salary of \$275,000. Furthermore, Mr. Zakes is eligible to receive bonus awards aggregating up to 50% of his base salary.

The Agreement removes any obligation we had to make cash severance payments to Mr. Zakes or to pay on Mr. Zakes behalf any premiums for medical, dental and vision insurance coverage upon termination of his employment with us. Furthermore, if Mr. Zakes is terminated without cause or he resigns for good reason, Mr. Zakes will receive accelerated vesting for 12 months from the date of his termination of employment for all stock options granted by us to Mr. Zakes before or after the date of the Agreement, and extension of the option exercise period for an additional 12 months beyond the period set forth in the governing option documents for such exercise. Finally, in the event a change-in-control transaction occurs and Mr. Zakes or by Mr. Zakes for good reason, 100% of Mr. Zakes unvested

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options shall automatically vest and the exercise period for all such options shall be extended an additional 12 months. Greg Cobb. Effective June 11, 2008, in connection with a general workforce reduction, Greg Cobb left us and no longer serves as our chief financial officer or treasurer. We entered into a Separation and Release of Claims Agreement with Mr. Cobb. The Separation and Release of Claims Agreement provided for a lump sum severance payment in an amount equal to Mr. Cobb s salary for six months totaling \$112,500. In addition, we agreed to pay on Mr. Cobb s behalf his COBRA benefits for six months totaling approximately \$7,200. Additionally, Mr. Cobb provided a general release of all claims he may have against us other than rights to indemnification he may have under the terms of an Indemnification Agreement dated July 12, 2007 entered into with us in connection with the our initial public offering of common stock. We entered into a Consultant Services Agreement with Mr. Cobb. Under the Consulting Agreement Mr. Cobb will provide general business development services and assistance on the review, maintenance and prosecution of its patent estate and patent applications on an as-needed basis and as requested by us from time-to-time. Mr. Cobb shall be paid \$165 per hour for services rendered under the agreement. The term of the agreement is 9 months and either party may terminate the agreement upon the provision of 30 days advance notice. Kevin Ontiveros. Effective June 11, 2008, in connection with a general workforce reduction, Kevin Ontiveros left us. We entered into a Separation and Release of Claims Agreement with Mr. Ontiveros. The Separation and Release of Claims Agreement provided for a lump sum severance payment in an amount equal to Mr. Ontiveros s salary for six months totaling \$103,260. In addition we agreed to pay on Mr. Ontiveros s behalf his COBRA benefits for six months totaling approximately \$7,200. Additionally, Mr. Ontiveros provided a general release of all claims he may have against us other than rights to indemnification he may have under the terms of an Indemnification Agreement dated July 12, 2007 entered into with us in connection with our initial public offering of common stock.

# OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

	Number of Securities Underlying Unexercised Options	Option Awards Number of Securities Underlying Unexercised Options	<b>Option</b> Exercise	Option
	(#)	(#)	Price	Expiration
Name	Exercisable(1)	Unexercisable (2)	(\$)	Date
Bradford A. Zakes	24,000		15.00	8/22/2015
	4,000		20.00	12/14/2015
	30,333		15.00	12/12/2016
	41,666		5.00	7/31/2017
	16,667		4.05	9/07/2017
	56,250	168,750	2.10	12/18/2017
Greg Cobb	30,000		15.00	4/18/2015
-	6,750		20.00	12/14/2015
	9,000		25.00	5/16/2016
	2,000		15.00	12/12/2016
	10,417		5.00	7/31/2017
	16,667		4.05	9/07/2017
	46,250		2.10	12/18/2017
Kevin J. Ontiveros	30,665		5.00	7/31/2017
	21,834		2.10	12/18/2017

(1) Stock options with expiration dates after July 31, 2007 were granted under the 2000 Stock Plan and are immediately exercisable, and, when and if exercised, will be subject to a repurchase right held by the company, which lapses in accordance with the respective

vesting schedules for such options.

(2) Stock options with expiration dates after July 31, 2007 were granted under the 2007 Performance Incentive Plan and vest and generally vest at the rate of 28% of the total option grant vests one year from the anniversary date of the grant and remainder vests at the rate of 2%per month thereafter.

# **Pension Benefits**

None of our named executive officers participates in or has account balances in qualified or non-qualified defined benefit plans sponsored by us.

# Nonqualified Deferred Compensation

None of our named executive officers participates in or has account balances in non-qualified defined contribution plans or other deferred compensation plans maintained by us. The compensation committee, which will be comprised solely of outside directors as defined for purposes of Section 162(m) of the Internal Revenue Code, may elect to provide our officers and other employees with non-qualified defined contribution or deferred compensation benefits if the compensation committee determined that doing so is in our best interests.

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#### **Director Compensation**

Each non-employee member of our board of directors receives the following compensation:

\$1,500 for each board and committee meeting attended in person;

\$250 for each board and committee meeting attended via tele-conference;

\$15,000 annual retainer for each non-employee director payable in cash if our cash balance exceeds \$10 million on the date of payment, or in stock valued at the fair market value on the date of payment; Annual grant of an option to purchase 3,333 shares of common stock with an exercise price equal to fair market value of our common stock on the date of grant; and

Reimbursement of actual, reasonable travel expenses incurred in connection with attending board or committee meetings;

In addition, the following additional compensation will be paid annually, generally, immediately following the annual meeting of stockholders:

\$10,000 to the chairman of the Board;

\$7,500 to the chairman of our audit committee;

\$2,500 to each audit committee member other than the chairman;

\$5,000 to the chairman of our compensation committee;

\$1,500 to each compensation committee member other than the chairman;

\$5,000 to the chairman of our nomination and governance committee; and

\$1,500 to each nomination and governance committee member other than the chairman. The following table sets forth a summary of the compensation we paid to our non-employee directors for the fiscal year ended December 31, 2008:

# 2008 DIRECTOR COMPENSATION

Name	 ned or Paid in 'ash (\$)	Stoc	ck Awards (\$)	Option vards (\$)	Т	otal (\$)
Richard Otto (1)	\$ 23,750	\$	15,000	\$ 1,614	\$	40,364
James M. Strickland (2)	\$ 23,375	\$	15,000	\$ 1,614	\$	39,989
Thomas W. Pew (3)	\$ 17,750	\$	15,000	\$ 1,614	\$	34,364
Richard Love (4)	\$ 29,375	\$	15,000	\$ 1,614	\$	45,989
Philip Ranker (5)	\$ 21,625	\$	15,000	\$ 1,614	\$	38,239

 Mr. Otto owned 28,810 shares of common stock awards and 17,666 option shares as of December 31, 2008.

- Mr. Strickland directly owned 32,810 shares of common stock awards, indirectly owned 79,095 shares of common stock awards and 17,666 option shares as of December 31, 2008.
- (3) Mr. Pew owned 98,231 shares of common stock awards and 17,666 option shares as of December 31, 2008.
- (4) Mr. Love owned 48,810 shares of common stock awards and 17,666 option shares as of December 31, 2008.
- (5) Mr. Ranker owned 28,810 shares of common stock awards and 17,666 option shares as of December 31, 2008.

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

#### EQUITY COMPENSATION PLAN INFORMATION

The following table sets forth information regarding outstanding awards and shares reserved for future issuance under our equity compensation plans as of December 31, 2008.

				Number of securities remaining available for future issuance under equity
Plan Category	Number of securities to be issued upon exercise of outstanding awards (a)	Weighted-average exercise price of outstanding awards (b)		compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders Equity compensation plans not approved by security holders	732,079 None	\$	6.93 None	885,600 None

# Total732,079\$ 6.93885,600SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding the ownership of our common stock as of (or options and warrants exercisable within 60 days of) February 1, 2009, by: (a) all those known by us to be beneficial owners of more than five percent of our common stock; (b) each current director and nominee for director; (c) each of the named executive officers referenced in the Summary Compensation Table; and (d) all of our executive officers and directors as a group. This table lists applicable percentage ownership based on 10,165,733 shares of common stock outstanding as of February 1, 1009.

Beneficial ownership is determined according to the rules of the SEC. Beneficial ownership means that a person has or shares voting or investment power of a security, and includes shares underlying options and warrants that are currently exercisable or exercisable within 60 days after the measurement date. This table is based on information supplied by officers, directors and principal stockholders. Except as otherwise indicated, we believe that the beneficial owners of the common stock listed below, based on the information each of them has given to us or that is otherwise publicly available, have sole investment and voting power with respect to their shares, except where community property laws may apply.

Options and warrants to purchase shares of our common stock that are exercisable within 60 days after February 1, 2009 are deemed to be beneficially owned by the persons holding these options and warrants for the purpose of computing percentage ownership of that person, but are not treated as outstanding for the purpose of computing any other person s ownership percentage.

Beneficial Ownership					
Number of	Percent of				
Shares	Total				

Name and Address of Beneficial Owner

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5% Stockholders		
Saints Capital Everest, L.P. (1)	1,176,471	11.6%
475 Sansome Street, Suite 1850		
San Francisco, CA 94111		
Berg & Berg Enterprises, LLC (2)	570,588	5.6%
10050 Bandley Drive		
Cupertino, CA 95014		
Directors and Named Executive Officers (12)		
Richard Love (3)	66,476	*
Richard Otto (4)	46,476	*
Thomas W. Pew (5)	128,586	1.3%
Philip Ranker (6)	46,476	*
James M. Strickland (7)	130,571	1.3%
Bradford A. Zakes (8)	186,979	1.8%
Greg Cobb (9)	121,084	1.2%
Kevin J. Ontiveros (10)	52,499	*
All Directors and Executive Officers as a Group (9 persons) (11)	779,147	7.1%

- \* Less than one percent.
- The number of shares of common stock for Saints Capital Everest, L.P. is based solely on the information contained in the Schedule 13G filed with the Commission on September 17, 2008.
- (2) The reporting person disclosed that Mr. Carl E. Berg is the manager and a member of Berg & Berg Enterprises LLC and that he may be deemed to have shared voting and dispositive power with respect to the shares held by such entity.
- (3) Includes 17,666 shares of common stock issuable to Mr. Love upon exercise of options.
- (4) Includes 17,666 shares of common stock

issuable to Mr. Otto upon exercise of options.

(5) Includes 17,666 shares of common stock issuable to Mr. Pew upon exercise of options and 12,689 shares of common stock issuable upon exercise of warrants.

 (6) Includes 17,666 shares of common stock issuable to Mr. Ranker upon exercise of options.

(7) Includes 17,666 shares of common stock issuable to Mr. Strickland upon exercise of options, 1,000 shares of common stock issuable upon exercise of warrants and 79,095 shares of common stock held by Coronado Venture Fund IV, LP. With regard to Coronado Venture Fund IV, LP, Coronado Venture Management

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LLC is the sole general partner of and may be deemed to have voting and dispositive power over shares held by Coronado Venture Fund IV, LP. Mr. Strickland is a managing director of Coronado Venture Management LLC. Mr. Strickland disclaims beneficial ownership of the shares held by Coronado Venture Fund IV, LP, except to the extent of his direct pecuniary interest therein.

(8) Includes

177,604 shares of common stock issuable to Mr. Zakes upon exercise of options and rights to acquire 9,375 shares of common stock within 60 days.

(9) Includes

121,084 shares of common stock issuable to Mr. Cobb upon exercise of options.

- (10) Includes 52,499 shares of common stock issuable to Mr. Ontiveros upon exercise of options.
- (11) Includes shares described in Footnotes
  (4) through
  (10) above.
- (12) The address for the officers and directors listed is c/o ImaRx Therapeutics, Inc., 12277 134th Court NE, Suite 202, Redmond, Washington.

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

We maintain various policies and procedures relating to the review, approval or ratification of transactions in which ImaRx is a participant and in which any of our directors, executive officers, 5% stockholders or their family members have a direct or indirect material interest. We refer to these individuals and entities in this proxy statement as related persons. Our Code of Business Conduct and Ethics, which is available on our website at www.imarx.com, prohibits our directors, executive officers, and employees and in some cases, their family members, from engaging in specified activities without prior written consent from the General Counsel. These activities typically relate to situations where an ImaRx employee, and in some cases, an immediate family member, may have significant financial or business interests in another company competing with or doing business with ImaRx, or who stands to benefit in some way from such a relationship or activity. Members of our Board of Directors are also required to disclose potential conflicts of interest to us for evaluation.

Each year, we require our directors and executive officers to complete a questionnaire, among other things, to identify any transactions or potential transactions with us in which a director or an executive officer or one of their family members or associated entities has an interest. We also require that directors and executive officers notify us of any changes during the course of the year to the information provided in the annual questionnaire as soon as possible. In addition, the Board annually determines the independence of directors based on a review by the Board and the Nominating and Governance Committee as described under Independence of Board above. The Audit Committee of our Board of Directors, pursuant to its charter, has responsibility for reviewing and approving in advance any related person transactions as defined under Securities and Exchange Commission regulations.

We believe that these policies and procedures collectively ensure that all related person transactions requiring disclosure under Securities and Exchange Commission rules are appropriately reviewed and approved. Since January 1, 2008, we have not engaged in any transactions involving amounts exceeding \$120,000 with our executive officers, directors and holders of 5% or more of our stock.

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

The Board of Directors has selected McKennon, Wilson & Morgan, LLP (McKennon) as our independent auditors for the fiscal year ending December 31, 2008. Stockholder ratification of the selection of McKennon as ImaRx s independent registered public accounting firm is not required by ImaRx s Bylaws or otherwise.

The following table sets forth the aggregate fees billed to ImaRx for the fiscal years ended December 31, 2008 by McKennon and Ernst & Young, LLP and for the fiscal year ended December 31, 2007 by Ernst & Young, LLP:

	Fiscal YearFiscal YearEndedEndedDecember 31,December 320082007				
Audit fees	\$ 113,697	\$	208,863		
Audit-related fees	\$	\$	424,500		
Tax fees	\$	\$			
All other fees	\$	\$			

Audit fees consist of fees for services billed by McKennon and Ernst & Young related to their audits of ImaRx s annual financial statements and their review of financial statements included in ImaRx s quarterly reports on SEC Form 10-Q. Audit-related fees consist primarily of fees rendered for services in connection with Ernst &Young s review of the Company s SEC filed registration statements and the related issuance of consents and comfort letters. Tax fees consist of fees rendered for services on tax compliance matters, including tax return preparation, claims for refund and assistance with tax audits of previously filed tax returns, tax consulting and advisory services consisting primarily of tax advice rendered by McKennon and Ernst & Young in connection with the formulation of ImaRx s tax strategy and assistance in minimizing custom, duty and import taxes.

All audit, audit-related, tax, and any other services performed for ImaRx by its independent registered public accounting firm are subject to pre-approval by the Audit Committee of our Board of Directors and were pre-approved by the Audit Committee prior to such services being rendered. The Audit Committee determined that the services provided by and fees paid to McKennon and Ernst & Young were compatible with maintaining the independent registered public accounting firm s independence.

# **Changes in Certifying Accountant**

*Former Independent Registered Public Accounting Firm.* On December 19, 2008, we dismissed Ernst & Young LLP (*Ernst & Young*) as our independent registered public accounting firm. and, upon the recommendation of the Audit Committee, the Board unanimously voted to engage McKennon, Wilson & Morgan LLP (McKennon) as our independent registered public accounting firm to audit our financial statements and internal control over financial reporting for the year ending December 31, 2008. Ernst & Young s reports on our financial statements as of and for the year ended December 31, 2007 did not contain an adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principle.

During the year ended December 31, 2007 and from January 1, 2008 through December 19, 2008, there were no disagreements with Ernst & Young on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Ernst & Young, would have caused Ernst & Young to make reference to the subject matter of the disagreement in connection with its reports on the financial statements for such years.

# PART IV

# ITEM 15. Exhibits and Financial Statement Schedules

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

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

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Notes to Financial Statements (2) The information for financial statement schedules has been omitted since they are not applicable.	F-8

(b) Exhibits

Exhibit		Incorporated by Reference Filed Exhibit				
No	Exhibit Title	Herewith	Form	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		<b>S-</b> 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
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Exhibit		Filed		Incorporated by Reference Exhibit		
No	Exhibit Title	Herewith	Form	No.	File No.	Filing Date
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 Schlief		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	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

# Edgar Filing: IMARX THERAPEUTICS INC - Form 10-K

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

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Exhibit		Filed		Incorpo Exhibit	ence		
No	Exhibit Title	Herewith	Form	No.	File No.	Filing Date	
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, 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,		S-1	10.24	333-142646	5/4/2007	

# Edgar Filing: IMARX THERAPEUTICS INC - Form 10-K

offering price \$4.00 per share

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

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Exhibit		Filed		Incorporated by Reference Exhibit			
No	Exhibit Title	Herewith	Form	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	Separation and Release of Claims Agreement with Greg Cobb		8-K	10.2	001-33043	6/10/2008	
10.33	Separation and Release of Claims Agreement with Kevin Ontiveros		8-K	10.4	001-33043	6/10/2008	
10.33	Consulting Agreement with Greg Cobb		8-K	10.3	001-33043	6/10/2008	
10.34	Amended Executive Employment Agreement with Brad Zakes		8-K	10.1	001-33043	6/27/2008	
10.35	Commercial Lease dated December 10, 2007, between the registrant and Cambric Partners		10-K	10.32	001-33043	8/31/2008	
10.36	Sublease Agreement dated December 29, 2008 between the Registrant and Koronis Pharmaceuticals, Inc	Х					

23.1	Consent of Independent Registered Public Accounting Firm McKennon, Wilson & Morgan, LLP	Х
23.2	Consent of Independent Registered Public Accounting Firm Ernst & Young, LLP	Х
24.1	Power of Attorney (included in the signature page hereto)	Х
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Exhibit		Filed		Incorpo Exhibit	rated by Refe	erence
No	Exhibit Title	Herewith	Form	No.	File No.	Filing Date
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	Х				
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	Х				
32	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	Х				
(c) Financi	ial Statements and Schedules See Item 15(	a)(1) and 15(a	.)(2) abov	ve.		

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#### 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 6, 2009 Date

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Bradford A. Zakes with full power of substitution and resubstitution and full power to act 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 agent full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agent 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.

Signature	Title	Date
/s/ Bradford A. Zakes	President, Chief Executive Officer and Director (principal executive officer and	March 6, 2009
Bradford A. Zakes	principal financial officer)	
/s/ Richard Love	Director	March 6, 2009
Richard Love		
/s/ Richard Otto	Director	March 6, 2009
Richard Otto		
/s/ Thomas W. Pew	Director	March 6, 2009
Thomas W. Pew		
/s/ Philip Ranker	Director	March 6, 2009
Philip Ranker		
/s/ James M. Strickland	Director	March 6, 2009
James M. Strickland		

# IMARX THERAPEUTICS, INC. (A Development Stage Company) INDEX TO FINANCIAL STATEMENTS

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#### **Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders

ImaRx Therapeutics, Inc.

We have audited the accompanying balance sheet of ImaRx Therapeutics, Inc., a development-stage company, as of December 31, 2008, the related statements of operations, stockholders equity, and cash flows for the year then ended, and the period from inception (September 23, 2008) through December 31, 2008. 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 audit.

We conducted our audit 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 audit 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 audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of ImaRx Therapeutics, Inc. at December 31, 2008, the results of their operations and their cash flows for the year then ended and for the period from inception (September 23, 2008) through December 31, 2008, in conformity with accounting principles generally accepted in the United States.

As discussed in Note 1 to the financial statements, effective September 23, 2008, the Company re-entered the development stage, as a result of the sale of all rights to the product urokinase to Microbix Biosystems, Inc. and decision to exploit technologies associated with on the development of therapies for stroke and other vascular disorders, using our proprietary microsphere technology together with ultrasound. Management determined that the rights sold did not constitute a reportable segment during the periods the Company owned the technology rights. Accordingly, management has not reported the revenues and costs of these technologies as discontinued operations. The accompanying financial statements have been prepared assuming that the Company 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 \$91.3 million at December 31, 2008. Management plans in regards to these matters are also described in Note 1. The financial statements do not include any adjustments for the recoverability and classification of assets, or the amounts and classification of liabilities that may result from the outcome of this uncertainty. /s/ McKennon, Wilson & Morgan LLP

Irvine, California March 6, 2009

See accompanying notes.

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#### **Report of Independent Registered Public Accounting Firm**

Board of Directors and Stockholders

ImaRx Therapeutics, Inc.

We have audited the accompanying balance sheets of ImaRx Therapeutics, Inc. as of December 31, 2007, and the related statements of operations, redeemable convertible preferred stock and stockholders equity (deficit), and cash flows for 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. 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 financial position of ImaRx Therapeutics, Inc. at December 31, 2007, and the results of its operations and its cash flows for the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the 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

See accompanying notes.



# ImaRx Therapeutics, Inc. (A Development Stage Company) Balance Sheets (in thousands, except share data)

	Decem 2007	ber 3	1, 2008
Assets			
Current assets:			
Cash and cash equivalents	\$ 12,861	\$	757
Restricted cash	388		
Accounts receivable	349		
Inventory	11,138		
Inventory subject to return	2,560		12
Assets held for sale			108
Prepaid expenses and other	589		144
Total current assets	27,885		1,021
Long-term assets:			
Property and equipment, net	1,170		51
Intangible assets, net	1,633		
Other	19		
Total assets	\$ 30,707	\$	1,072
Liabilities and stockholders equity			
Current liabilities:			
Accounts payable	\$ 1,277	\$	117
Accrued expenses	837		82
Accrued chargebacks and administrative fees	1,317		
Deferred revenue	5,373		226
Notes payable and accrued interest	11,698		
Other			154
Total current liabilities	20,502		579
Commitments and contingencies (Notes 1, 5, 8, and 14)	20,302		517
Stockholders equity:			
Common stock, \$.0001 par			
100,000,000 shares authorized, 10,046,683 issued and outstanding at			
December 31, 2007 and 10,165,733 issued and outstanding at December 31,			
2008	1		1
Additional paid-in capital	91,386		91,808
Accumulated deficit	(81,182)		(91,316)
	(01,102)		()1,010)
Total stockholders equity	10,205		493
Total liabilities and stockholders equity	\$ 30,707	\$	1,072

See accompanying notes.

# ImaRx Therapeutics, Inc. (A Development Stage Company) Statements of Operations (in thousands, except share data)

	Ye	ears Ended	Dece	mber 31,	September 23, 2008 (Inception) through December 31,	
		2007		2008		
Revenues:						
Product sales, net	\$	7,841	\$	6,511	\$ 960	
Research and development		519		223		
Total operating revenue		8,360		6,734	960	
Costs and expenses:						
Cost of product sales		3,518		3,051	575	
Research and development		7,424		3,040	87	
General and administrative		6,087		6,434	618	
Asset impairment				9,978		
Total cost and expenses		17,029		22,503	1,280	
Operating loss		(8,669)		(15,769)	(320)	
Other income (expense):						
Interest and other income		548		49	15	
Interest expense		(862)		(203)		
Gain on settlement of accounts payable				187	187	
Gain on extinguishment of debt		219		5,602		
Net loss		(8,764)		(10,134)	(118)	
Deemed dividend from beneficial conversion feature for						
Series F redeemable convertible preferred stock		(13,842)				
Accretion of dividends on preferred stock		(867)				
Reversal of accretion of dividends on preferred stock not						
paid		4,919				
Net loss attributed to common stockholders	\$	(18,554)	\$	(10,134)	\$ (118)	
Net loss attributed to common stockholders per share Basic and diluted	\$	(3.16)	\$	(1.00)		
		. ,				
Weighted-average shares outstanding Basic and diluted	-	5,868,131	1	0,116,808		

See accompanying notes.

#### ImaRx Therapeutics, Inc. (A Development Stage Company) Statements of Redeemable Convertible Preferred Stock and Stockholders Equity (Deficit) (in thousands, except share data)

Redeemable Convertible Preferred Stock Series B Series C Series D Series F						Series Redeem Conver					
ing 1e	Shares	Carrying Value	Shares	Carrying Value	Shares	Carrying Value	Shares	Carrying Value	Preferred Shares	Shares Amount	Common Stocl Shares Amo
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

567

48

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

\$	\$	\$	\$	\$	10,046,683 \$
					119,050
\$	\$	\$	\$	\$	10,165,733 \$
Φ	J	э F-б	Φ	Φ	10,105,755 \$

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# ImaRx Therapeutics, Inc. (A Development Stage Company) Statements of Cash Flows (in thousands)

	Ye	ars Ended	September 23, 2008 (Inception) December 31,			
		2007 2008			2008	
Operating activities						
Net loss	\$	(8,764)	\$	(10,134)	\$	(118)
Adjustments to reconcile net loss to net cash (used in)						
provided by operating activities:						
Depreciation and amortization		1,174		563		18
Stock-based compensation		700		422		156
Gain on extinguishments of debt		(219)		(5,602)		
Asset impairment				9,978		
Loss on disposal of property and equipment		19		118		1
Changes in operating assets and liabilities:						
Inventory		4,922		937		
Inventory subject to return		(2,115)		2,548		574
Accounts receivable		227		349		
Prepaid expenses and other		(49)		445		64
Other assets		(19)		19		
Accounts payable		(136)		(1, 160)		(1,256)
Accrued expenses and other liabilities		1,781		(5,147)		(153)
Deferred revenue		4,417		(1,715)		(968)
		,				· · ·
Net cash provided by (used in) operating activities		1,938		(8,379)		(1,682)
Investing activities						
Purchase of property and equipment, net		(577)		(11)		
Proceeds from sale of property and equipment		. ,		197		
Proceeds from sale of urokinase asset				2,000		
				·		
Net cash used in investing activities		(577)		2,186		
Financing activities		. ,				
Change in restricted cash		(388)		388		
Payment on note payable		(4,780)		(6,299)		
Proceeds from sale of common stock		12,412		,		
Net cash provided by financing activities		7,244		(5,911)		
Net increase (decrease) in cash and cash equivalents		8,605		(12,104)		(1,682)
Cash and cash equivalents at the beginning of the year		4,256		12,861		2,439
Cash and cash equivalents at the end of the year	\$	12,861	\$	757	\$	757
Supplemental schedule of cash flow information						
••	¢	1 251	¢	220	¢	
Cash paid for interest	\$	1,351	\$	329	\$	

Supplemental Schedule of Noncash Investing and Financing Activities:					
Accretion of undeclared dividends on Series A/D/F					
redeemable convertible preferred stock	\$	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			
See accompanyin	ig not	æs.			

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# ImaRx Therapeutics, Inc. (A Development Stage Company) Notes to Financial Statements

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

We are a development stage biopharmaceutical company whose research and development efforts have focused on the development of therapies for stroke and other vascular disorders, using our proprietary microsphere technology together with ultrasound. Our lead program, SonoLysis, involves the administration of our proprietary MRX-801 microspheres and ultrasound to break up blood clots and restore blood flow to oxygen deprived tissues. We were previously engaged in the commercialization of one drug approved by the Food and Drug Administration or FDA, urokinase, but sold all rights to that product to Microbix Biosystems, Inc., or Microbix, on September 23, 2008. On June 11, 2008, in response to new risks and challenges facing the Company, we announced a restructuring that included a significant workforce reduction in which all of our employees other than Bradford Zakes, our president and chief executive officer, and one additional employee were terminated. We paid a retention bonus to each of the remaining employees and entered into agreements with each of them to reimburse us a portion of the retention bonus should they voluntarily leave the employ of the Company prior to certain agreed upon dates.

We are seeking strategic alternatives that would enable the continued development of our SonoLysis program and are preserving our cash resources in order to provide sufficient time to accomplish this objective. Historically, one of our primary sources of cash has been the sale of our urokinase product. Due to the sale of the urokinase asset to Microbix, we do not currently have any significant source of cash.

# **Basis of Presentation**

On September 23, 2008, Microbix purchased our remaining urokinase inventory and related assets and assumed full responsibility for all ongoing commercial and regulatory activities associated with the product for an upfront payment of \$2.0 million and the assumption of up to \$0.5 million in chargeback and other liabilities for commercial product currently in the distribution channel. If the assumed chargeback and other liabilities paid by Microbix are less than the \$0.5 million assumed, Microbix will issue payment to us for the difference. Microbix also agreed to pay us an additional \$2.5 million upon the release of certain inventory of urokinase currently under review by the FDA. In light of this transaction we will receive no cash from future sales of urokinase. As a result, we may not have sufficient capital resources to support operations and continue as a going concern.

On September 23, 2008, upon the sale of the urokinase asset to Microbix, we returned to the development stage. We no longer have any commercialized products or licensed technologies that will provide significant revenue in the immediate future. The sale of urokinase assets did not result in discontinued operations reporting as this was not considered a reportable segment. We purchased this inventory as it was complimentary to our SonoLysis program efforts and assisted us in obtaining contacts that would be beneficial to our developmental products. At the time we purchased the urokinase inventory from Abbott Laboratories there were no FDA approved manufacturing facilities that could manufacture additional supplies of urokinase for commercialization. We purchase urokinase with the intention of selling the purchased inventory for cash. Due to the amount of time and resources that it would require to build new manufacturing facilities and obtain FDA approval of the facility, it was not our intention to reproduce additional commercial supplies of inventory once the existing supplies had been sold. Since discontinued operations reporting was not appropriate, the urokinase assets were written off and we will continue to record revenue until the product at our wholesale distributors is completely sold through to a third party.

Our ability to continue as a going concern depends on our ability to enter into a strategic transaction for our SonoLysis program that results in significant cash proceeds to the Company and whether Microbix is successful in securing the release of the urokinase inventory by the FDA thereby triggering the \$2.5 million payment. We have had recurring losses, which have resulted in an accumulated deficit of \$91.3 million at December 31, 2008. These conditions, among others, raise substantial doubt about our ability to continue as a going concern. The financial statements include adjustments to reduce the value of certain assets to fair value, but do not include any other 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 or execute the strategic alternatives being

considered.

#### **Estimates and Assumptions**

Preparing financial statements in accordance with generally accepted accounting principles 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.

# 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 fair value. Our cash equivalents have been comprised mainly of marketable bank obligations, commercial paper, and corporate notes and bonds. The restricted cash represented 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 consisted of amounts due from wholesale distributors 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 was comprised of finished goods and was 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<sup>®</sup> (urokinase), rebranded under the name Kinlytic<sup>®</sup>, was our only commercially available FDA approved product. Abbokinase is a thrombolytic or clot-dissolving agent approved for the treatment of acute massive pulmonary embolism, or blood clots in the lungs.

On September 23, 2008, we divested the urokinase assets and sold all of the remaining urokinase inventory to Microbix. As such, the inventory value at December 31, 2008 is zero.

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



#### **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 and Other Long-Lived Assets

Intangible assets included customer relationships, trade name, contracts and technology and were accounted for based on SFAS No. 142, *Goodwill and Other Intangible Assets*. Intangible assets with finite useful lives were 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 had an estimated life of one year.

We account for long-lived assets in accordance with the provisions of SFAS No. 144 (SFAS 144), *Accounting for the Impairment or Disposal of Long-Lived Assets*. SFAS 144 addresses financial accounting and reporting for the impairment or disposal of long-lived assets. This Statement requires that long-lived assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparing the carrying amount of an asset to the expected future net cash flows generated by the asset. If it is determined that the asset may not be recoverable and if the carrying amount of an asset exceeds its estimated fair value, an impairment charge is recognized to the extent of the difference. SFAS 144 requires companies to separately report discontinued operations, including components of an entity that either have been disposed of (by sale, abandonment or in a distribution to owners) or classified as held for sale. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

At June 30, 2008, we evaluated our intangible assets for impairment due to the receipt of the Approvable Letter from the FDA and determined that all of the intangible assets were impaired. As such, these intangibles were written off by recording a \$1.3 million impairment. We also initiated a plan to sell a portion of our laboratory equipment, which we valued at fair value and recorded a \$0.5 million impairment. The assets were classified as held for sale. We completed the sale of \$152,000 of assets held for sale for cash of \$115,000 and the termination of a lease agreement, which resulted in a reduction of future lease payments of \$16,000. We recorded an additional loss on the sale of equipment in this transaction in the amount of \$21,000.

#### **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) collectability 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 consisted 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.

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AmerisourceBergen accounted for 19%, Cardinal accounted for 38% and McKesson Corporation accounted for 38% of our total 2008 product revenues. AmerisourceBergen and Cardinal each accounted for 34% of our 2007 revenues and McKesson Corporation accounted for 25% of our 2007 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.

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, 2007 and 2008 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.

# **Research and Development Expenses**

We classify our research and development expenses into four categories of activity, namely: research, development, clinical and regulatory. Our research and development efforts were focused primarily on product candidates from our SonoLysis program. As part of our restructuring effort announced in June 2008, we have ceased substantially all research related activities.

# 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.

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 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.

	Years Ended I	December 31,
	2007	2008
Stock options	1,534,269	732,079
Warrants	1,023,913	1,023,913

#### Concentration of Credit Risk

We maintain cash balances at financial institutions and such cash balances commonly exceed the \$250,000 insured amount by the Federal Deposit Insurance Corporation. We have not experienced any losses in such accounts and management believes that we are not exposed to any significant credit risk with respect to such cash and cash equivalents.

#### **Recently Issued Accounting Pronouncements**

In May 2008, the FASB issued SFAS No. 162 (SFAS 162), *The Hierarchy of Generally Accepted Accounting Principles.* SFAS 162 sets forth the level of authority to a given accounting pronouncement or document by category. Where there might be conflicting guidance between two categories, the more authoritative category will prevail. SFAS 162 becomes effective 60 days after the SEC approves the PCAOB s amendments to AU Section 411 of the AICPA Professional Standards. SFAS 162 will not have an impact on our financial statements.

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 have an impact on our financial statements.

#### Impact of Recently Issued Accounting Standards

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors requests for expanded information about the extent to which a company measures assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and was adopted by us in the first quarter of 2008. The adoption of SFAS 157 did not have a material impact on our results of operations and financial condition.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities-including an amendment of FASB Statement No. 115 (SFAS 159). SFAS 159 expands the use of fair value accounting but does not affect existing standards which require assets or liabilities to be carried at fair value. Under SFAS 159, a company may elect to use fair value to measure accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees and issued debt. Other eligible items include firm commitments for financial instruments that otherwise would not be recognized at inception and non-cash warranty obligations where a warrantor is permitted to pay a third party to provide the warranty goods or services. If the use of fair value is elected, any upfront costs and fees related to the item must be recognized in earnings and cannot be deferred, e.g., debt issue costs. The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. At the adoption date, unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings. Subsequent to the adoption of SFAS 159, changes in fair value are recognized in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007, and was adopted by us in the first quarter of 2008. The adoption of SFAS 159 did not have any impact on our results of operations and financial condition as the fair value option was not elected for any of our financial assets or financial liabilities.

In June 2007, the FASB ratified Emerging Issues Task Force (EITF) Issue No. 07-3 (EITF No. 07-3), *Accounting for Non-Refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, which requires nonrefundable advance payments for goods and services that will be used or rendered for future research and development activities to be deferred and capitalized. These amounts will be recognized as expense in the period that the related goods are delivered or the related services are performed. EITF No. 07-3 is effective for fiscal years beginning after December 15, 2007. We adopted the provisions of EITF No. 07-3 in the first quarter of 2008 and the adoption of EITF No. 07-3 did not have a material impact on our results of operations and financial condition.

#### 2. Balance Sheet Data

#### **Property and Equipment**

Property and equipment consist of the following:

	December 31,			
	2007			008
		(in thou	isands)	
Leasehold improvements	\$	652	\$	
Laboratory equipment		2,212		
Computer and communications equipment		279		99
Office furniture and equipment		157		
Construction in progress		43		
		3,343		99
Less accumulated depreciation		2,173		48
	\$	1,170	\$	51

For the years ended December 31, 2007 and 2008, we recorded depreciation expense of \$0.3 million and \$0.2 million, respectively.

#### Intangible Assets

Intangibles consisted of the following (in thousands):

	Weighted average			07 Accumulated	
	life		amount	amo	ortization
Customer lists	4 years	\$	2,700	\$	(1,125)
Trade name	1 year		500		(500)
Cell technology	4 years		100		(42)
		\$	3,300	\$	(1,667)

The intangible assets were written off in June 2008. See Note 1 for disclosure. *Accrued Expenses* 

Accrued expenses consist of the following:

	D	December 31,		
	2007		2008	
	(iı	n thousands	s)	
Accrued compensation	\$ 5	528 \$	43	
Accrued contract services	]	81		
Other accrued expenses	1	28	39	
	¢	) <b>)</b> 77 (†	02	
	\$ 8	\$37 \$	82	

#### 3. Restructuring

Our board of directors authorized a restructuring that was implemented on June 11, 2008, that included a workforce reduction in which the employment of all of our employees other than Bradford Zakes, our president and chief executive officer, and one additional employee were terminated. The costs associated with these actions for the year ended December 31, 2008 was \$0.8 million, of which \$0.5 million represented severance payments for the affected employees, all of which were paid prior to June 30, 2008. We also incurred a \$0.5 million asset impairment for long-lived assets. See Note 4 for disclosure. All expenses incurred due to the restructuring, other than assets impaired, have been included in the statement of operations under general and administrative. Certain of the Company s former key employees entered into consulting agreements with us in order to assist us in exploring strategic alternatives for our clinical-stage SonoLysis program and other assets.

The following table presents the activity and balances of the restructuring (in thousands):

	Emp	loyee			
	Separ	ations	Facility Closing	,	Fotal
Liability, July 1, 2008	\$	40	\$ 242	\$	282
Cash payments		(40)			(40)
Amortization			(72)		(72)
Adjustments to expense			(16)		(16)
Liability, December 31, 2008	\$		\$ 154	\$	154

# 4. Assets Held for Sale

In connection with the June 11, 2008 restructuring, we discontinued substantially all research and development activity. As such, we initiated a process to sell certain items of laboratory equipment that will not be required for a future strategic transaction associated with our SonoLysis program. We determined that the plan of sale criteria in SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, had been met. Accordingly, the carrying value of the laboratory equipment was adjusted to its fair value less costs to sell, amounting to \$0.3 million, which was determined based on quoted market prices of similar assets.

In the three months ended September 30, 2008, we completed the sale of \$152,000 of assets held for sale for cash of \$115,000 and the termination of a lease agreement, which resulted in a reduction of future lease payments of \$16,000. We recorded an additional loss on the sale of equipment in this transaction in the amount of \$21,000.

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#### 5. Income Taxes

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

	Years End 2007	led December 31, 2008
Current: Federal State	\$	\$
Total current provision Deferred: Federal State Valuation allowance	(3,24 (32 3,57	8) (243)
Total deferred provision		
Total tax provision	\$	\$

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

	Years Ended December 31,			
		2007		2008
Tax benefit at statutory rate	\$	(2,979)	\$	(3,413)
State taxes (net of federal benefit)		(328)		(243)
Net benefit from research and development credits		(547)		(86)
Stock compensation		96		23
Other, net		184		94
Valuation allowance		3,574		3,625
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:

	20	Decem 007 (in thou	20	008
Current deferred tax assets: Reserves and accrued liabilities Other	\$	47 5	\$	13 3
		52		16
Noncurrent deferred tax assets: Property and equipment		110		(8)

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Deferred revenue	2,004	84
Intangibles	2,301	1,854
Stock compensation	448	552
Research and development credits	2,188	2,197
Net operating loss carryforward	13,973	20,006
	21,024	24,685
	21,024	24,085
Total deferred tax assets	21,076	24,701
Valuation allowance	(21,076)	(24,701)
Net deferred tax assets	\$	\$

At December 31, 2008, we had net operating loss carryforwards of \$53.4 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, 2008 of \$37.9 million that expire within five years of being incurred and will begin to expire for state purposes in 2009. Additionally, we have research and development credit carryforwards of \$1.4 million for federal purposes and \$0.8 million for state purposes that begin to expire in 2020 and 2015 for federal and state purposes, respectively. Finally, we generated a capital loss carryforward of \$13.6 million in 2007, which will expire in 2012 for which no tax benefit was recorded.

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For financial reporting purposes, a valuation allowance of \$21.1 million and \$24.7 million has been established at December 31, 2007 and 2008, 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 \$3.6 million during both years ended December 31, 2007 and 2008.

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 2005 through 2007 are subject to tax examination by the U.S. Internal Revenue Service. We do not currently have any ongoing tax examinations. However, we had an examination of our 2006 U.S. Federal tax return by the U.S. Internal Revenue Service during the fiscal year ended December 31, 2008. The examination resulted in no changes. We believe that our income tax filing positions and deductions will continue to 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. 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 2008, 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.

#### 6. 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.

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.

# 7. Related Party Transactions

We leased 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 was terminated on August 1, 2008, amounted to \$0.1 million in 2007 and approximately \$57,000 in 2008.

#### 8. Notes Payable

#### 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 accrued 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.

In April 2008, we entered into a satisfaction, waiver and release agreement with Abbott Laboratories under which we paid Abbott Laboratories \$5.2 million in cash and upon payment of the funds, the debt obligation was deemed to be indefeasibly paid in full by us and the note was cancelled and returned to us. This transaction resulted in a gain on extinguishment of debt of \$5.6 million in our statement of operations for the year ended December 31, 2008.

# 9. Equity Transactions

# **Reverse Stock Splits**

The Company s Board of Directors and stockholders 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.

#### **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 which is included in the statement of operations under general and administrative expense.

On May 30, 2008, non-employee directors were issued a total of 119,050 shares of restricted stock at a grant date fair value of \$0.63 per share for services rendered on the Company s board of directors. The expense was recorded in the statement of operations under general and administrative expense.

# **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 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

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

# Warrants to Purchase Common Stock

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.

The following table summarizes the warrants that were outstanding as of December 31, 2008: *Warrants Issued* 

	Weighted-Average				
	Warrants	<b>Remaining Life</b>	Warrants		
Exercise Price	Outstanding	in Years	Exercisable		
\$5.75	671,589	8.58	671,589		
10.00 - 13.75	91,050	0.61	91,050		
15.00 - 16.50	150,664	0.55	150,664		
20.00 - 21.25	109,996	4.41	109,996		
35.00	614	2.18	614		
	1,023,913	6.24	1,023,913		

A summary of activity of warrants is as follows:

		Weighted-Average
	Warrants	<b>Exercise Price</b>
Balance at January 1, 2007	352,324	15.79
Granted	671,589	5.75
Exercised		
Canceled		
Balance at December 31, 2007	1,023,913	\$ 9.21
Granted		
Exercised		
Canceled		
Balance at December 31, 2008	1,023,913	\$ 9.21

#### **10. 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. There were a total of 850,000 shares available for grant under the 2007 Plan upon its effective date. Any shares forfeited under the 2000 Plan would be added to the shares available for grant under the 2007 Plan. As of December 31, 2008, a cumulative total of 885,600 shares of common stock authorized for issuance. As of December 31, 2008, the total compensation cost related to non-vested options not yet recognized is \$0.3 million, which will be charged to expense over the next 2 years.

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.

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

	Years Endeo	Years Ended December 31,		
	2007	2008		
Expected dividend yield	0.00%	0.00%		
	75.0 -	84.42 - 85.01%		
Expected stock price volatility	82.17%			
Risk free interest rate	3.78 - 4.93%	3.46 - 3.67%		
Expected life of option	7 years	7 years		
The following table shows the amounts recognized in the f	inancial statements for share-based cor	nnensation (in		

The following table shows the amounts recognized in the financial statements for share-based compensation (in thousands):

	Years Ended December 31,			
	2	007	2	008
Research and development General and administrative	\$	341 359	\$	157 265
Total cost of share-based compensation in net loss	\$	700	\$	422

Impact on net loss per share	basic and diluted		\$ (0.12)	\$ (0.04)
		F-19		

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

		Exercise	*** * *	
	Options	Price Per Share	0	nted-Average ercise Price
Balance at January 1, 2007	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
Granted	21,665	0.63-1.54		0.84
Exercised				
Canceled	(823,855)	1.54-30.00		6.53
Balance at December 31, 2008	732,079	\$ 0.63-27.50	\$	6.93

There was no aggregate intrinsic value on the options outstanding at December 31, 2008 since the exercise price of all outstanding options was greater than the closing stock price on December 31, 2008. The following table summarizes information relating to currently outstanding and vested options at December 31,

The following table summarizes information relating to currently outstanding and vested options at December 31, 2008:

	Options Outstanding Weighted-Average		<b>Options Exercisable</b>			
		Remaining				
	Options	Life	Options	Options	Weight	ed-Average
<b>Range of Exercise Prices</b>	Outstanding	(Years)	Vested	Exercisable	Exer	cise Price
\$0.63-2.10	362,914	8.99	183,289	183,289	\$	1.97
2.11-4.00	32,500	3.72	32,500	32,500		2.80
4.01-15.00	289,415	7.43	221,500	289,415		10.98
15.01-30.00	47,250	7.29	43,750	47,250		24.07
Total	732,079	8.03	481,039	552,454	\$	8.18

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.

On May 31, 2008, in connection with a termination of employment, stock options granted to an executive officer were modified to accelerate the vesting for certain non-vested options by 12 months from the date of termination and the option exercise period was extended for 12 months. Options to purchase 118,000 shares of common stock were subject to this acceleration, which resulted in 29,500 shares vesting and a reduction in compensation expense of \$3,000 in the year ending December 31, 2008 using the assumptions on the date of modification per SFAS No. 123 (revised 2004), *Share-Based Payment*.

On June 11, 2008, in connection with termination of employment, the stock options granted to two executive officers were modified to accelerate the vesting for certain non-vested options by 12 months from the date of termination and the option exercise period was extended for 12 months. Options to purchase 399,666 shares of common stock were subject to this acceleration, which resulted in 132,082 shares vesting and a reduction in compensation expense of \$0.1 million in the year ending December31, 2008 using the assumptions on the date of modification per SFAS No. 123(r).

11. Benefit Plan

We have 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. In August 2008, we elected to discontinue the company match portion of the 401(k) Plan. Our contributions to the 401(k) Plan vest equally over five years. Our contributions to the 401(k) Plan were \$45,421 and \$43,947, for the years ended December 31, 2007 and 2008, respectively.

## 12. Asset Acquisition and Sale

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 for a total purchase price of \$20.0 million. The total purchase price was comprised of \$5.0 million in cash and a \$15.0 million secured promissory note. In April 2008, we entered into a satisfaction, waiver and release agreement with Abbott Laboratories under which we paid Abbott Laboratories \$5.2 million in cash and upon payment of the funds, the debt obligation was deemed to be indefeasibly paid in full by us and the note was cancelled and returned to us.

On September 23, 2008 we divested our urokinase business to Microbix. Under the terms of the agreement, Microbix purchased all remaining urokinase inventory and related assets and assumed full responsibility for ongoing commercial and regulatory activities associated with the product for an upfront payment of \$2.0 million in cash and the assumption of up to \$0.5 million of chargeback and other liabilities for commercial product in the distribution channel. If the assumed chargeback and other liabilities paid by Microbix are less than the \$0.5 million assumed, Microbix will issue payment to us for the difference. An additional payment of \$2.5 million will be made upon release by the FDA of the three lots of urokinase that are currently subject to a May 2008 Approvable Letter. Microbix is presently working with the FDA to secure the release of the three lots of urokinase. There can be no assurances that Microbix will be successful in securing such release in a timely manner or at all. If Microbix is unable to secure the release of the three lots we will not entitled to the additional \$2.5 million payment.

As a result of this transaction inventory and accrued chargebacks and administrative fees were written down to zero and offset with the \$2.0 million in cash and \$0.5 million in assumed liabilities. The sale of urokinase assets did not result in discontinued operations reporting as this was not considered a reportable segment. We purchased this inventory as it was complimentary to our SonoLysis program efforts and assisted us in obtaining contacts that would be beneficial to our developmental products. At the time we purchased the urokinase inventory from Abbott there were no FDA approved manufacturing facilities that could manufacture additional supplies of urokinase for commercialization. We purchase urokinase with the intention of selling the purchased inventory for cash. Due to the amount of time and resources that it would require to build new manufacturing facilities and obtain FDA approval of the facility, it was not our intention to reproduce additional commercial supplies of inventory once the existing supplies had been sold.

# 13. 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.

# 14. Commitments and Contingencies

# Lease Commitments

As of December 31, 2008, we had noncancelable operating leases for office and laboratory space that expire through 2012. Total rent expense was \$0.1 million in 2007 and \$0.4 million in 2008.

On January 8, 2009, we entered into a Lease Surrender and Termination Agreement with Cambric Partners pursuant to which we agreed to terminate our lease dated December 10, 2007, as amended on January 25, 2008, for the premises located at 1730 E. River Road, Suite 200, Tucson, Arizona.

Future minimum lease commitments for operating leases at December 31, 2008 is \$33,890 in 2009.

# **Contingencies**

We periodically evaluate all pending or threatened contingencies and any commitments, if any, that are reasonably likely to have a material adverse effect on our operations or financial position. We assess the probability of an adverse outcome and determine if it is remote, reasonably possible or probable as defined in accordance with the provisions of SFAS No. 5 (SFAS 5), *Accounting for Contingencies*. If information available prior to the issuance of our financial statements indicates that it is probable that an asset had been impaired or a liability had been incurred at the date of our financial statements, and the amount of the loss, or the range of probable loss can be reasonably estimated, then such loss is accrued and charged to operations. If no accrual is made for a loss contingency because one or both of the conditions pursuant to SFAS 5 are not met, but the probability of an adverse outcome is at least reasonably possible,

the Company will disclose the nature of the contingency and provide an estimate of the possible loss or range of loss, or state that such an estimate cannot be made.

At December 31, 2008, there was urokinase product at the wholesale distributors that had not been sold through to an end user. We do not currently have a returns reserve recorded in our financial statements for any potential product returns for expired product. There are lots of inventory that were sold to the wholesale distributors with expiry dates of November 2008 and December 2008. When the product was sold to Microbix on September 23, 2008, they assumed all liabilities up to \$0.5 million. There is a possibility that Microbix will incur liabilities in excess of the \$0.5 million. At this time, it is not possible to estimate any potential liability that we may be required to pay Microbix or other third parties.

# **15. 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 microspheres 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 Schlief

On January 4, 2005, Dr. med. Reinhard Schlief 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 microspheres. We are obligated to pay Dr. Schlief 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 in 2005 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.

#### 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.

#### **16. Subsequent Events**

On January 8, 2009, we entered into a Lease Surrender and Termination Agreement with Cambric Partners pursuant to which we agreed to terminate our lease dated December 10, 2007, as amended on January 25, 2008, for the premises located at 1730 E. River Road, Suite 200, Tucson, Arizona. As consideration of Cambric s acceptance of the early termination of the lease, we agreed to pay a termination fee of \$75,000 and to forfeit the security deposit in the amount of \$19,433.47 and to surrender the lease and the premises. The Termination Agreement is effective as of December 31, 2008 and contains other customary release provisions, representations, warranties and covenants. The \$75,000 termination fee was paid on January 9, 2009, which will result in a gain on settlement of \$79,384 in the first quarter of 2009.

# EXHIBIT INDEX

Exhibit		Filed	iled Exhibit			
No	Exhibit Title	Herewith	Form	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*			S-1	10.3	333-142646	5/4/2007

2000 Stock Plan and related agreements

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 Schlief	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

Exhibit		Filed		Incorporate Exhibit	d by Reference	
No	Exhibit Title	Herewith	Form	No.	File No.	Filing Date
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*	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

Exhibit		Incorporated by Referenc Filed Exhibit			d by Reference	ıce		
No	Exhibit Title	Herewith	Form	No.	File No.	Filing Date		
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		8-K	10.1	001-33043	2/7/2008		

	Agreement dated as of January 1, 2008 by and between the Company and Bradford A. Zakes				
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	Separation and Release of Claims Agreement with Greg Cobb	8-K	10.2	001-33043	6/10/2008
10.33	Separation and Release of Claims Agreement with Kevin Ontiveros	8-К	10.4	001-33043	6/10/2008
		<i>5</i> 1			

Exhibit		Filed	Incorporated by Reference Exhibit			
No	Exhibit Title	Herewith	Form	No.	File No.	Filing Date
10.33	Consulting Agreement with Greg Cobb		8-K	10.3	001-33043	6/10/2008
10.34	Amended Executive Employment Agreement with Brad Zakes		8-K	10.1	001-33043	6/27/2008
10.35	Commercial Lease dated December 10, 2007, between the registrant and Cambric Partners		10-К	10.32	001-33043	8/31/2008
10.36	Sublease Agreement dated December 29, 2008 between the Registrant and Koronis Pharmaceuticals, Inc	Х				
23.1	Consent of Independent Registered Public Accounting Firm McKennon, Wilson & Morgan, LLP	Х				
23.2	Consent of Independent Registered Public Accounting Firm Ernst & Young, LLP	Х				
24.1	Power of Attorney (included in the signature page hereto)	Х				
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	Х				
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and	Х				

Х

15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

32 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