IMARX THERAPEUTICS INC
Form S-1/A
June 28, 2006

Table of Contents

As filed with the Securities and Exchange Commission on June 28, 2006
Registration No. 333-134311

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

AMENDMENT NO. 1
TO
FORM S-1
REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

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

Delaware	**2834**	**86-0974730**
(State or Other Jurisdiction of Incorporation or Organization)	*(Primary Standard Industrial Classification Code Number)*	*(I.R.S. Employer Identification Number)*

1635 East 18th Street
Tucson, AZ 85719
(520) 770-1259
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant s Principal Executive Offices)

Evan C. Unger
1635 East 18th Street
Tucson, AZ 85719
(520) 770-1259
(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

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Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o _____

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o _____

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o _____

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment that specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Table of Contents

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, Dated June , 2006

PROSPECTUS

Shares

Common Stock

$ per share

We are selling shares of our common stock. We have granted the underwriters an option for a period of 30 days to purchase up to additional shares of common stock to cover over-allotments.

This is the initial public offering of our common stock. We currently expect the initial public offering price to be between $ and $ per share. We will apply to have our common stock approved for quotation on The Nasdaq National Market under the symbol IMRX.

Investing in our common stock involves risks. See Risk Factors beginning on page 7.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public Offering Price	$	$
Underwriting Discounts	$	$
Proceeds to ImaRx Therapeutics, Inc. (before expenses)	$	$

The underwriters expect to deliver the shares to purchasers on or about , 2006.

CIBC World Markets

Jefferies & Company

First Albany Capital

The date of this prospectus is , 2006

Table of Contents

You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with information different from that contained in this prospectus. We are offering to sell, and are seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the common stock.

Table of Contents

Summary

You should read the entire prospectus carefully before deciding to invest in shares of our common stock.

ImaRx Therapeutics, Inc.

Overview

We are a biopharmaceutical company developing and commercializing innovative therapies for vascular disorders associated with blood clots. Our development efforts are primarily focused on therapies for treating ischemic stroke and massive pulmonary embolism by restoring the flow of blood and oxygen to the brain and vital tissues, and clearing occluded catheters. Between eight and 12 million patients in the U.S. are afflicted each year with these and other complications related to blood clots, yet available treatment options are subject to significant therapeutic limitations. For example, the most widely used treatment for ischemic stroke can be administered only during a narrow time window and poses a risk of bleeding, resulting in less than 6% of ischemic stroke patients receiving treatment. We believe our products and clinical development programs, including two product candidates with Phase 3 clinical trial data and one product approved for marketing, may address significant unmet needs in these markets.

We are pursuing two development programs as the foundation for our products. The first program is a group of clot-dissolving drugs, or thrombolytics, that are variants of urokinase, a natural human protein primarily produced in the kidneys that stimulates the body s natural clot-dissolving processes. The second program, SonoLysis therapy, centers on a novel treatment that breaks blood clots apart by applying ultrasound to our submicron-sized bubbles, which we call SonoLysis bubbles. We believe these therapeutic approaches can be used either alone or in combination to treat ischemic stroke and a broad variety of vascular disorders associated with blood clots, and may expand the number of patients for whom safe and effective clot-dissolving therapies are available.

Our Products

The following table summarizes our product candidates and their current development status:

Indication	Product Candidate	Product Elements	Development Status
Ischemic Stroke	PROLYSE™	Recombinant pro-urokinase	Completed one Phase 3 clinical trial
	SonoLysis ™ therapy	SonoLysis bubbles and ultrasound	Preclinical
	SonoLysis combination therapy	SonoLysis bubbles, ultrasound and a thrombolytic	Preclinical(1); ongoing Phase 2 proof of concept clinical trial using FDA-approved diagnostic bubbles and the thrombolytic tPA
Acute Massive Pulmonary Embolism	Abbokinase®	Tissue-culture urokinase	Approved for marketing
Catheter Clearance	Open-Cath-R®	Recombinant urokinase	Completed two Phase 3 clinical trials

(1) We have an approved investigational new drug application, or IND, for a Phase 1/2 dose escalation clinical trial using SonoLysis bubbles for which we intend to start enrolling patients in the second half of 2006.

Table of Contents

We have a broad portfolio of product candidates to treat ischemic stroke that is aimed at expanding the number of patients eligible for treatment. We believe our ischemic stroke product portfolio may have advantages related to safety, time to market, expanded window of administration, faster initiation of treatment, speed of restoration of blood flow and the ability to address multiple physician groups.

PROLYSE is a recombinant pro-urokinase, or a pro-drug form of urokinase that we believe, based on a number of published third-party scientific studies, does not become active until it reaches a blood clot, which may reduce the risk of bleeding. PROLYSE has been shown in a Phase 3 clinical trial of 180 patients conducted by Abbott Laboratories between 1996 and 1998 to be well tolerated and to demonstrate activity in dissolving cerebral blood clots when administered as long as six hours after the onset of stroke symptoms. This treatment window is twice as long as the three-hour restriction that the U.S. Food and Drug Administration, or FDA, has imposed on alteplase, or tPA, the only thrombolytic approved for use in ischemic stroke patients. We believe PROLYSE may become the first thrombolytic approved for intra-arterial therapy for treating ischemic stroke during a treatment window longer than three hours after onset of symptoms. As with other thrombolytics, the administration of PROLYSE involves a risk of bleeding complications. We are planning to initiate an additional Phase 3 clinical trial of the use of PROLYSE delivered intra-arterially directly to the site of a blood clot for ischemic stroke in 2007. We plan to request that the FDA allow us to use the preclinical testing and clinical trial data generated by Abbott Laboratories PROLYSE clinical trials in support of our eventual application to obtain regulatory approval for the use of PROLYSE for ischemic stroke, as well as the combination of PROLYSE and SonoLysis therapy to clear blood clots in patients with ischemic stroke. To use the clinical trial data generated by Abbott Laboratories in support of our application for regulatory approval, we will, at a minimum, be required to show the drug substance produced by our contract manufacturer is comparable to the drug substance produced previously by Abbott Laboratories.

SonoLysis therapy is the combination of SonoLysis bubbles and ultrasound that we believe breaks up blood clots via a mechanical mechanism of action. Because SonoLysis therapy does not include a thrombolytic and its associated risk of bleeding, we believe SonoLysis therapy may offer several advantages over other treatments for ischemic stroke, including an extended treatment window, rapid initiation of treatment via intravenous administration and availability for use in patients for whom thrombolytics are contraindicated due to risk of bleeding. We are planning to initiate a Phase 1/2 dose-escalation clinical trial to study the safety and efficacy of SonoLysis therapy as a treatment for ischemic stroke in the first half of 2007.

SonoLysis combination therapy is SonoLysis therapy in conjunction with a thrombolytic. We believe that SonoLysis combination therapy incorporates complementary mechanisms of action that will both reduce the time required to dissolve a blood clot and enable a lower dose of thrombolytic to be used. In addition, we believe a lower dose of thrombolytic will reduce the risk of bleeding and extend the current treatment window beyond that of a thrombolytic alone for ischemic stroke patients. We are currently conducting a Phase 2 proof of concept clinical trial using FDA-approved diagnostic bubbles, ultrasound and tPA to expand upon the prior work of academic investigators in this area. We are planning to initiate a Phase 1/2 dose-escalation clinical trial in the second half of 2006 using our SonoLysis therapy and tPA. If that clinical trial is successful, we intend to conduct future clinical trials utilizing our SonoLysis therapy and PROLYSE.

In addition to our product candidates for ischemic stroke, we recently acquired Abbokinase, a form of urokinase that is approved and marketed for the treatment of acute massive pulmonary embolism. We intend to begin selling Abbokinase in the second half of 2006. Abbokinase sales will provide us with near-term revenue, an opportunity to form sales relationships with vascular physicians and acute care institutions that regularly administer blood clot therapies and a commercialization infrastructure that we believe can grow to support our future products.

Open-Cath-R, another form of urokinase we acquired in 2005, has been shown in two Phase 3 multinational clinical trials conducted by Abbot Laboratories prior to 2003 to be well tolerated and active as a treatment for clearing blocked intravascular catheters. We are investigating the remaining regulatory and manufacturing requirements and the opportunity to license Open-Cath-R to a third party. We cannot be certain that the FDA will allow us to use the data generated by Abbott Laboratories clinical trials in support of our application to obtain regulatory approval of Open-Cath-R.

We acquired PROLYSE, Open-Cath-R and Abbokinase from Abbott Laboratories. In connection with these acquisitions, we issued a $15.0 million promissory note that matures in December 2006 and another $15.0 million promissory note that matures in December 2007. If we are unable to satisfy these debt obligations when due, Abbott Laboratories will have a right to reclaim the acquired assets and our rights relating to PROLYSE and Open-Cath-R, in the case of the December 2006 promissory note, and

Table of Contents

Abbokinase, including a portion of the cash from our sales of Abbokinase, in the case of the December 2007 promissory note.

Our Business Strategy

Our goal is to become the leading provider of innovative therapies for vascular disorders associated with blood clots. The key elements of our business strategy are to:

- expand the number of patients eligible for treatment by developing and commercializing our portfolio of ischemic stroke product candidates;
- capitalize on near-term revenue opportunities and develop an initial commercial infrastructure;
- leverage our product candidates to address additional vascular indications; and
- expand the use of our bubble technology to create a deep pipeline with broad therapeutic applications.

Risks Related to Our Business and Business Strategy

Our business is subject to numerous risks that could prevent us from successfully operating our business and implementing our business strategy. These risks are highlighted in the section entitled Risk Factors immediately following this prospectus summary, and they include the following:

- we have a history of operating losses, including an accumulated deficit of approximately $64.3 million and an overall stockholders deficit of approximately $32.6 million at March 31, 2006, and expect to continue to incur substantial losses for the foreseeable future;
- we will need substantial additional capital to fund our operations;
- we may never complete clinical development of our product candidates or have more than one product approved for marketing, and if approved our product candidates may never achieve market acceptance;
- failure to comply with various government regulations in connection with the development, manufacture and commercialization of our product candidates and post-approval manufacturing and marketing of our products could result in significant interruptions or delays in our development and commercialization activities;
- if we fail to satisfy our obligations to Abbott Laboratories that we assumed in connection with our acquisition of PROLYSE, Open-Cath-R, Abbokinase and related assets, Abbott Laboratories could reclaim the acquired technologies and other assets;
- if we are not able to use the clinical trial data acquired from Abbott Laboratories in support of our applications for regulatory approval, we will not be able to maintain our current development and commercialization timelines; and
- we compete against companies that have longer operating histories, more established products and greater resources than we do.

In addition, our independent registered public accounting firm has expressed doubt about our ability to continue as a going concern as of March 10, 2006.

Our Corporate Information

We were organized as an Arizona limited liability company on October 7, 1999, which was our date of inception for accounting purposes. We were subsequently converted to an Arizona corporation on January 12, 2000, and then reincorporated as a Delaware corporation on June 23, 2000. Our principal executive offices are located at 1635 E. 18th St., Tucson, Arizona 85719, and our telephone number at that location is (520) 770-1259. Our corporate website address is www.imarx.com. The information contained in or that can be accessed through our corporate website is not part of this prospectus. Unless the context indicates otherwise, as used in this prospectus, the terms ImaRx, we, us and our refer to ImaRx Therapeutics, Inc., a Delaware corporation.

Table of Contents

We have rights to use Abbokinase® and Open-Cath-R®, which are U.S. registered trademarks owned by Abbott Laboratories. We use PROLYSE™, Sonolysis™ and the ImaRx Therapeutics logo as trademarks in the U.S. and other countries. All other trademarks and trade names mentioned in this prospectus are the property of their respective owners.

Table of Contents

The Offering

Common stock offered	shares
Common stock to be outstanding after this offering	shares
Initial public offering price	$
Use of proceeds	To repay indebtedness, to continue the development of our product candidates, including clinical trials, to fund manufacturing of our product candidates and for working capital and other general corporate purposes. See Use of Proceeds.
Proposed Nasdaq National Market symbol	IMRX

The number of shares to be outstanding immediately after this offering as shown above is based on 21,197,795 shares outstanding as of May 15, 2006 and excludes:

- 2,777,024 shares of common stock issuable upon the exercise of options outstanding under our 2000 Stock Plan, having a weighted average exercise price of $3.01 per share;
- 1,761,749 shares of common stock issuable upon the exercise of warrants outstanding, having a weighted average exercise price of $3.16 per share;
- 1,658,376 shares of common stock reserved for future grants under our 2000 Stock Plan; and
- an aggregate of 1,800,000 shares of common stock reserved for future issuance under our 2006 Performance Incentive Plan, which has been approved by our board of directors and, subject to stockholder approval, will become effective immediately upon the signing of the underwriting agreement for this offering.

Except as otherwise indicated, all information in this prospectus assumes:

- the conversion of all our outstanding shares of preferred stock into 8,164,157 shares of common stock upon the closing of this offering, assuming a one-for-one conversion ratio of our Series F preferred stock. See Conversion of Series F Preferred Stock ;
- a -for- reverse stock split of our common stock that was effected on , 2006;
- the filing of our amended and restated certificate of incorporation upon completion of this offering; and
- no exercise of the underwriters over-allotment option.

Table of Contents

Summary Consolidated Financial Data

The following tables summarize certain of our consolidated financial data. We derived the consolidated statements of operations data for the years ended December 31, 2003, 2004 and 2005 from our consolidated audited financial statements included elsewhere in this prospectus. We derived the consolidated statements of operations data for the three months ended March 31, 2005 and 2006, as well as the balance sheet data at March 31, 2006, from our unaudited financial statements included elsewhere in this prospectus. You should read this data together with our financial statements and related notes included elsewhere in this prospectus and the information under Selected Consolidated Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations.

	Years Ended December 31,			Three Months Ended March 31,	
	2003	2004	2005	2005	2006
				(unaudited)	
	(in thousands, except share and per share data)				
Consolidated Statements of Operations Data:					
Grant and other revenue	$ 224	$ 575	$ 619	$ 173	$ 177
Costs and expenses:					
Research and development	1,878	2,490	3,579	764	1,724
General and administrative	1,654	3,183	4,142	661	1,618
Depreciation and amortization	209	186	194	47	60
Acquired in-process research and development			24,000		
Total operating expenses	3,741	5,859	31,915	1,472	3,402
Interest and other income	22	29	122	23	105
Interest expense	(325)	(469)	(587)	(53)	(225)
Gain on extinguishment of note			3,835	3,835	
Net (loss) income	(3,820)	(5,724)	(27,926)	2,506	(3,345)
Accretion of dividends on preferred stock	(1,287)	(301)	(601)	(150)	(150)
Net (loss) income available to common stockholders	$ (5,107)	$ (6,025)	$ (28,527)	$ 2,356	$ (3,495)
Net (loss) income available to common stockholders per share Basic	$ (1.74)	$ (1.07)	$ (3.01)	$ 0.30	$ (0.27)
Weighted average shares outstanding Basic	2,936,094	5,637,042	9,463,279	7,769,415	12,930,820
Net (loss) income available to common stockholders per share Diluted	$ (1.74)	$ (1.07)	$ (3.01)	$ 0.18	$ (0.27)
Weighted average shares outstanding Diluted	2,936,094	5,637,042	9,463,279	13,146,131	12,930,820

Table of Contents

The following table sets forth a summary of our consolidated balance sheet data at March 31, 2006:

- on an actual basis;
- on a pro forma basis to reflect:
  - the issuance of Series F preferred stock in April and May 2006 resulting in net proceeds of approximately $13.0 million;
  - a $5.0 million initial payment and the issuance of a $15.0 million promissory note in connection with an asset acquisition in April 2006; and
  - the conversion of all outstanding shares of preferred stock, valued at approximately $38.9 million, into 8,164,157 shares of common stock upon the closing of this offering; and
- On a pro forma as adjusted basis to reflect our receipt of the estimated net proceeds from our sale of shares of common stock in this offering at an assumed initial public offering price of $, the midpoint of the range on the front cover of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	At March 31, 2006		
	Actual	**Pro Forma**	**Pro Forma as Adjusted**
	(unaudited) (in thousands)		
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 6,349	$ 14,349	$
Working capital (deficit)	(11,388)	(3,388)	
Total assets	7,369	30,369	
Long-term notes payable, less current portion		15,000	
Total stockholders equity (deficit)	(32,618)	2,260	

Table of Contents

Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors and all other information contained in this prospectus before purchasing our common stock. If any of the following events were to occur, our business, financial condition or results of operations could be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose some or all of your investment.

Risks Relating to Our Business

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 are a development stage company with a history of net losses and negative cash flow from operations since inception. To date, we have not generated any product revenue and have funded our operations primarily from private sales of our securities. Net losses for the fiscal years ended December 31, 2003, December 31, 2004, and December 31, 2005 were approximately $5.1 million, $6.0 million, and $28.5 million, respectively. At March 31, 2006, we had an accumulated deficit of approximately $64.3 million. Except for Abbokinase, which is approved and marketed for the treatment of acute massive pulmonary embolism and which we acquired from Abbott Laboratories in April 2006, we do not have regulatory approval for any of our product candidates. Even if we receive regulatory approval for any product candidates, sales of such products may not generate sufficient revenue for us to achieve or maintain profitability.

Our ability to generate revenue depends on a number of factors, including our ability to:

- successfully market and sell our recently-acquired Abbokinase product or any of our product candidates following regulatory approval, if ever;
- obtain regulatory approval for PROLYSE, SonoLysis therapy, SonoLysis combination therapy and Open-Cath-R;
- obtain commercial quantities of our approved products at acceptable cost levels; and
- successfully enter into partnerships for some of our product candidates, including Open-Cath-R.

We anticipate that our expenses will increase substantially following this offering as a result of:

- research and development programs, including significant requirements for contract manufacturing, clinical trials, preclinical testing and potential regulatory submissions;
- developing additional infrastructure and hiring additional management and other employees to support the anticipated growth of our sales, development and regulatory activities;
- regulatory submissions and commercialization activities; and
- additional costs for intellectual property protection and enforcement and expenses as a result of being a public company.

Because of the numerous risks and uncertainties associated with developing and commercializing our potential products, we may experience larger than expected future losses and may never become profitable.

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 and net capital deficiency raise substantial doubt about our ability to continue as a going concern. We believe that the successful completion of this offering will eliminate this doubt and allow us to continue as a going concern at least in the near term. We estimate that the net proceeds from this offering together with our existing cash and cash

Table of Contents

equivalents will be sufficient to meet our anticipated cash requirements until December 2007. If we are unable to successfully complete this offering, we will need to obtain alternative financing and modify our operational plans to continue as a going concern.

We incurred significant indebtedness in connection with our acquisitions of assets from Abbott Laboratories. If we are unable to satisfy these obligations in 2006 and 2007 when due, Abbott Laboratories will have a right to reclaim the assets and our rights relating to PROLYSE, Open-Cath-R and Abbokinase, including a portion of the cash from our sales of Abbokinase.

In connection with our acquisition of PROLYSE, Open-Cath-R and related assets in September 2005, we issued a $15.0 million promissory note, which is secured by the acquired technologies and matures in December 2006. If we are unable to repay the promissory note, Abbott Laboratories has the right to reclaim the acquired technologies. Similarly, in connection with our April 2006 acquisition of the remaining inventory of and certain rights related to Abbokinase, we issued an additional $15.0 million promissory note that is secured by the inventory and rights acquired and matures in December 2007. Although we plan to commence selling Abbokinase to obtain near-term revenue that will help fund our cash needs while our other product candidates remain in development, the asset purchase agreement provides that after we have received initial net revenue of $5.0 million from the sale of Abbokinase, we are then required to deposit 50% of the additional net revenue we receive from sales of Abbokinase into an escrow account to secure the repayment of the promissory note. If the escrow amount is not adequate to repay the promissory note and we are otherwise unable to repay the promissory note by its maturity date, Abbott Laboratories has the right to reclaim the remaining inventory and rights related to Abbokinase.

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

Since our inception, we have financed our operations principally through the private placement of shares of our common and preferred stock and convertible notes and the receipt of government grants. We currently have working capital sufficient to meet our anticipated cash needs through December 2006. We expect our expenses to increase substantially following the offering, and we will require substantial additional financing at various times in the future as we expand our operations and as our debt obligations mature.

Our funding requirements will, however, depend on numerous factors, including:

- the timing, scope and results of our preclinical studies and clinical trials;
- the timing of initiation of manufacturing for our product candidates;
- the timing and amount of revenue;
- the timing of, and the costs involved in, obtaining regulatory approvals;
- our ability to establish and maintain collaborative relationships;
- personnel, facilities and equipment requirements; and
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs, if any, and the result of any such litigation.

We intend to seek additional funding from a variety of sources, which may include collaborations involving our technology, technology licensing, grants and public or private equity and debt financings. We cannot be certain that any additional funding will be available on terms acceptable to us, or at all. Accordingly, we may not be able to secure the substantial funding that is required to maintain and continue our commercialization and development programs at levels that may be required in the future. We may be forced to accept funds on

9

Table of Contents

terms or pricing that are highly dilutive or otherwise disadvantageous to our existing stockholders. We are restricted from granting a security interest in the assets we acquired in 2005 and 2006. Raising additional funds through debt financing, if available, may involve covenants that restrict our business activities. To the extent that we raise additional funds through collaborations and licensing arrangements, we may have to relinquish valuable rights and control over our technologies, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to secure adequate financing, we could be required to sell or license assets, delay, scale back or eliminate one or more of our development programs or enter into licenses or other arrangements with third parties to commercialize products or technologies that we would otherwise seek to develop and commercialize ourselves.

We recently expanded our business strategy to include development and sale of thrombolytics that expose us to additional risks, which we may not overcome successfully.

Until September 2005, our business strategy focused on the development of SonoLysis bubbles for the treatment of blood clots and various vascular disorders. In September 2005, we began to broaden our focus to also include the development of thrombolytics and therapies involving both SonoLysis bubbles and thrombolytics by acquiring the technology and development assets relating to two thrombolytic product candidates, PROLYSE and Open-Cath-R. In the second half of 2006 we plan to begin selling Abbokinase, a thrombolytic that we acquired in April 2006. Abbokinase is approved by the FDA for marketing in the U.S. for acute massive pulmonary embolism. We have no experience in marketing, selling, developing or manufacturing thrombolytics, and we may not be successful in one or more of these undertakings. Use of thrombolytics in general involves significant risks, such as bleeding. In addition, adding these product candidates and Abbokinase to our business will place additional burdens on our management and technical staff to undertake additional commercialization activities and may distract them from development activities.

The thrombolytic market is highly competitive and dominated by products from Genentech. We have limited sales and marketing capabilities and will depend on drug wholesalers to distribute our products.

The market for thrombolytics is currently dominated by thrombolytics offered by Genentech, Inc., in particular alteplase, or tPA. Any resistance to change among practitioners could delay or hinder market acceptance of our thrombolytic product candidates, which could have a material adverse effect on our business. In addition, a number of different competing thrombolytics are under development for treating blood clots, such as alfimeprase and desmoteplase. These competitive products are being developed or are marketed by companies with significantly greater resources and commercial capabilities than we currently possess. If we are unable to manage or overcome these competitive risks, our planned thrombolytics business, as well as our overall financial condition and prospects, could be severely damaged.

We cannot be certain that we will have sufficient resources to effectively market or sell Abbokinase and continue to develop and commercialize new thrombolytic product candidates. We have a limited sales and marketing staff and will depend on the efforts of third parties for the sale and distribution of Abbokinase and our other product candidates to hospitals and clinics. If we are unable to arrange for effective and successful third party distribution of our products on commercially reasonable terms, we may be unable to successfully market and sell Abbokinase. In particular, we will need to enter into agreements with a majority of the major drug wholesale companies that have historically sold Abbokinase to customers. Drug wholesale companies may be unwilling to continue selling Abbokinase, or we may be forced to accept lower prices or other unfavorable terms or to expend significant additional resources to sell our Abbokinase inventory. If any of these events occurs, we may be unable to recover the cash portion of the purchase price we have already invested in Abbokinase or to achieve or maintain meaningful revenue unless or until our other product candidates are approved for sale, any of which could harm our financial condition. Additionally, even if we are able to successfully market and sell Abbokinase, we do not expect sales of Abbokinase to generate enough revenue for us to achieve profitability.

Table of Contents

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 affect on our business, financial condition and results of operations.

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

We currently have only one product, urokinase, currently marketed as Abbokinase, that has received regulatory approval, and we have no experience commercializing Abbokinase. The process to develop, obtain regulatory approval for and commercialize potential drug candidates is long, complex and costly. Two of our product candidates, PROLYSE and Open-Cath-R, are in advanced stages of development. The related clinical data for these product candidates were acquired from Abbott Laboratories. We cannot be certain that the acquired clinical data will be sufficient for us to pursue additional clinical trials of PROLYSE or achieve approval for Open-Cath-R without further clinical trials, and we have not determined whether we will be able to commercialize either of these products. Our proprietary SonoLysis bubbles technology has not been used in clinical trials, and we are using diagnostic ultrasound contrast agent microbubbles in our proof of concept clinical trial. We do not expect to have the results of any clinical trials using our proprietary SonoLysis bubbles until at least 2008. As a result, our business in the near term is substantially dependent upon our ability to sell Abbokinase and to complete development, obtain regulatory approval for and successfully commercialize our other thrombolytic product candidates in a timely manner. If we are unable to further develop, commercialize or license PROLYSE or Open-Cath-R, we may not be able to earn sufficient revenue to continue our business.

We may be unable to sell our existing inventory of Abbokinase before product expiration, and even if we are able to sell the existing inventory, the product may be returned prior to use by hospitals and clinics. Additionally, if we are successful in extending the product expiration dates, we will need to re-brand the product.

In our acquisition of Abbokinase, we received 153,000 vials of Abbokinase manufactured between 2003 and 2005 that we believe represents approximately a four-year supply of inventory. Based on current stability data, approximately 75% of this inventory will expire by September 2007 with the remainder expiring at various times up to August 2009. We have not commenced sales of Abbokinase and do not intend to begin selling Abbokinase until the second half of 2006. We do not expect to sell the entire inventory we acquired before the product expires, and we are not permitted to sell this inventory after expiration. Moreover, even if we are

Table of Contents

able to sell the Abbokinase inventory to wholesalers prior to expiration, unless the product is administered prior to expiration, the product may be returned to us and our sales could be significantly reduced. As a result, we may be unable to recover our purchase price for this inventory.

We intend to continue an ongoing stability program to potentially extend the expiration dates for this inventory. However, our license to use the Abbokinase trademark does not cover any inventory with extended expiration dates. Accordingly, if we are successful in demonstrating extended stability and shelf life, we would need to re-brand the inventory to commercialize it. We cannot be certain that we will be successful in establishing an alternate brand name for Abbokinase and obtaining market acceptance.

If we want to sell urokinase beyond our existing inventory of Abbokinase, we would need to undertake manufacturing and secure regulatory approval for a new manufacturing process and facility.

As part of our acquisition of Abbokinase we acquired cell lines that could be used to manufacture urokinase. If we want to sell urokinase beyond our existing inventory of acquired Abbokinase, we would need to undertake manufacturing and to demonstrate that our manufactured material is comparable to the urokinase we purchased from Abbott Laboratories. To demonstrate this, we would need to have our manufacturing process validated by the FDA and may be required to conduct additional preclinical studies, and possibly additional clinical trials. In addition, the manufacturing process for Abbokinase involves a roller bottle production method that is used infrequently today and is available only from a limited number of manufacturers worldwide. We do not currently intend to undertake these efforts in the near term and we cannot be certain that we would be able to successfully manufacture and receive regulatory approval for additional sales of urokinase beyond our existing inventory.

If we are not able to use the data and drug substance acquired from Abbott Laboratories for further clinical development of our PROLYSE and Open-Cath-R product candidates and our Abbokinase product, we will not be able to maintain our current timelines for further development and commercialization of these potential products and Abbokinase. Any additional clinical trial requirements could significantly increase our expenses and reduce the commercial value of PROLYSE, Open-Cath-R and Abbokinase.

As a result of our acquisitions of our thrombolytic product and product candidates, we acquired Phase 3 clinical data and drug substance for PROLYSE and Open-Cath-R as well as data in support of additional indications for Abbokinase. We need FDA approval to market PROLYSE and Open-Cath-R and to market Abbokinase for indications other than acute massive pulmonary embolism. In seeking such approval, we intend to rely on the Phase 3 clinical trial data related to PROLYSE and Open-Cath-R and to conduct additional clinical trials using our existing clinical grade drug substance that we acquired. The FDA may not allow us to rely on the clinical data, or may determine that such clinical data are insufficient to support approval, either of which would result in a need to conduct additional clinical trials with drug product manufactured for us. We may not be able to use the drug substance if it does not have activity within its original specifications. If we are unable to use either the data or drug substance that we acquired as the basis for further development or commercialization of these product candidates and Abbokinase, our clinical development and commercialization timelines would be significantly delayed and the commercial viability of these potential products may be jeopardized. We cannot be certain that the FDA will permit us to proceed with further development consistent with our current clinical development plans, and even if permitted to proceed with those plans, that we would succeed with those efforts.

To receive FDA marketing approval for PROLYSE or Open-Cath-R, we must demonstrate that the material manufactured for commercial use is equivalent to the material previously manufactured.

To receive FDA approval to market PROLYSE or Open-Cath-R, we must demonstrate that the drug substance and drug product we manufacture are equivalent to the drug substance and drug product we acquired and that was used in clinical testing. As part of the FDA approval process, we expect the FDA will require us to

Table of Contents

manufacture PROLYSE and Open-Cath-R to equivalent specifications and within the same tolerances as the drug substance that we acquired. The production of each of PROLYSE and Open-Cath-R involves a multi-step recombinant manufacturing process using cell lines that we acquired. If we obtain regulatory approvals, we will have to produce commercial supplies of PROLYSE and Open-Cath-R in accordance with current Good Manufacturing Process, or cGMP, through contract manufacturers to be able to sell either product. We cannot be certain that the manufacturing process we utilize will produce PROLYSE and Open-Cath-R to cGMP standards within the same tolerances as the manufacturing process previously managed by Abbott Laboratories and used in its clinical trials. If we are unable to produce PROLYSE and Open-Cath-R that the FDA determines to be equivalent, we will not receive FDA approval to market and sell these products without additional clinical trials.

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

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

Establishing contract manufacturing is costly and time-consuming and we cannot be certain that we will be able to engage contract manufacturers who can meet our quantity and quality requirements in a timely manner and at competitive costs. The manufacturing processes for our product candidates have not yet been tested at commercial levels, and it may not be possible to manufacture such materials in a cost-effective manner. Further, there is no guarantee that the components of our proposed drug product candidates will be available to our manufacturers when needed on terms acceptable to us. If we are unable to obtain contract manufacturing on commercially reasonable terms, we may not be able to conduct or complete planned or necessary clinical trials or commercialize our product candidates.

If our clinical trials are not successful, or if we are unable to obtain regulatory approvals, we will not be able to commercialize our products and we will continue to incur significant operating losses.

Abbokinase is our only product approved for commercial sale. The sale of all of our product candidates in the U.S. requires approval from the FDA and from foreign regulatory agencies for sales outside the U.S. To gain regulatory approval for the commercial sale of our products, we must demonstrate the safety and efficacy of each product candidate in human clinical trials. This process is expensive and can take many years, and failure can occur at any stage of the testing process. There are many risks associated with our clinical trials. For example:

- we did not conduct any of the prior clinical trials related to PROLYSE and Open-Cath-R, and we may be unable to demonstrate the same level of safety and effectiveness in clinical trials we conduct with these product candidates;

- the only clinical trials related to our development of SonoLysis therapy or SonoLysis combination therapy that we have conducted or are conducting use neither our SonoLysis bubbles nor PROLYSE and may not be indicative of the safety and effectiveness of our product candidates;

- clinicians, physicians and regulators may not favorably interpret the results of our preclinical studies and clinical trials;

- some patients in our clinical trials may experience unforeseen adverse medical events related or unrelated to the use of our product candidates;

Table of Contents

- we may be unable to secure a sufficient number of clinical trial sites or patients to enroll in our clinical trials;
- we may experience delays in securing the services of, or difficulty scheduling, clinical investigators for our clinical trials;
- third parties who conduct our clinical trials may not fulfill their obligations;
- we may in the future experience, and have in the past experienced, deviations from the approved clinical trial protocol by our clinical trial investigators;
- the FDA or the local institutional review board, or IRB, at one or more of our clinical trial sites may interrupt, suspend or terminate a clinical trial or the participation of a particular site in a clinical trial; and
- the FDA or other regulatory bodies may change the policies and procedures we are required to follow in connection with our clinical trials.

Any of these or other unexpected events could cause us to delay or terminate our ongoing clinical trials, increase the costs associated with our clinical trials or affect the statistical analysis of the safety and efficacy of our product candidates. If we fail to adequately demonstrate the safety and efficacy of our product candidates, we will not obtain regulatory approval to commercialize our products. Significant delays in clinical development could materially increase our product development costs or impair our competitive position. In addition, any approvals we may obtain may not cover all of the clinical indications for which we seek approval, or an approval may contain significant limitations in the form of narrow labeling and warnings, precautions or contraindications with respect to limitations on use. Accordingly, we may not be able to obtain our desired product registration or marketing approval for any of our product candidates.

We rely on third parties to conduct our clinical trials who may not successfully carry out their contractual duties, with resulting negative impacts on our clinical trials.

We depend on contract research organizations, or CROs, for managing some of our preclinical testing and clinical trials. If we are not able to retain CROs in a timely manner and on commercially reasonable terms, we may not be able to conduct or complete clinical trials or commercialize our product candidates and we do not know whether we will be able to develop or attract partners with such capabilities. We have established relationships with multiple CROs for our existing clinical trials, although there is no guarantee that the CROs will be available for future clinical trials on terms acceptable to us. We may not be able to control the amount and timing of resources that CROs devote to our clinical trials. In the event that we are unable to maintain our relationship with any of our CROs or elect to terminate the participation of any of these CROs, we may lose the ability to obtain follow-up information for patients enrolled in ongoing clinical trials unless we are able to transfer the care of those patients to another qualified CRO.

Our product candidates may never achieve market acceptance.

We cannot be certain that our products will achieve any degree of market acceptance among physicians and other health care providers and payors, even if necessary regulatory approvals are obtained. We believe that recommendations by physicians and other health care providers and payors will be essential for market acceptance of our products, and we cannot be certain we will ever receive any positive recommendations or reimbursement. Physicians will not recommend our products unless they conclude, based upon clinical data and other factors, that our products are safe and effective. We are unable to predict whether any of our product candidates will ever achieve market acceptance, either in the U.S. or internationally. A number of factors may limit the market acceptance of our products, including:

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

Table of Contents

the rate of adoption of our products by hospitals, doctors and nurses and acceptance by the health care community;

the product labeling permitted or required by regulatory agencies for each of our products;

the competitive features of our products, including price, as compared to other similar 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 commercially successful, 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 future success will depend to a substantial extent on our ability to successfully identify new market trends and develop, introduce and support our candidate products on a timely basis. If we fail to successfully develop and commercialize our product candidates on a timely basis, we may be unable to compete effectively. For example, we are aware of other thrombolytics in development such as alfimeprase and desmoteplase, which are currently in Phase 3 clinical trials as treatments for acute peripheral arterial occlusion and catheter occlusions, and acute ischemic stroke, respectively. In addition, we are aware of mechanical device-based treatments for blood clots such as the Mechanical Embolus Removal in Cerebral Ischemia Retriever as well as mechanical thrombectomy devices that are also approved and marketed for removing blood clots associated with peripheral vascular and coronary indications and dialysis access grafts.

If we are unable to obtain acceptable prices or adequate reimbursement from third-party payors for any product candidates that we seek to commercialize, our revenue and prospects for profitability will suffer.

The commercial success of our product candidates is substantially dependent on whether third-party coverage and reimbursement is available from governmental payors such as Medicare and Medicaid, private health insurers, including managed care organizations and other third-party payors. The U.S. Centers for Medicare and Medicaid Services, health maintenance organizations and other third-party payors in the U.S. and in other jurisdictions are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new drugs and medical devices and, as a result, they may not cover or provide adequate payment for our products. Our products may not be considered cost-effective and reimbursement may not be available to consumers or may not be sufficient to allow our products to be marketed on a competitive basis. Large private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, are challenging the prices charged for medical products and services, and many third-party payors limit or delay reimbursement for newly approved medical products and indications. Cost-control initiatives could lower the price we may establish for our products which could result in product revenue lower than anticipated. If the prices for our product candidates decrease or if governmental and other third-party payors do not provide adequate coverage and reimbursement levels, our prospects for profitability could suffer.

Table of Contents

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 thrombolytics and SonoLysis bubbles;
- conducting clinical trials;
- preparing, submitting and maintaining regulatory records sufficient to meet the requirements of the FDA; and
- marketing and distribution of our products.

We do not currently have many of these relationships in place. Although we use a third party manufacturer to produce SonoLysis bubbles for our clinical trials on a purchase order basis, that third party does not have the capacity to produce the volume of SonoLysis bubbles necessary for large-scale clinical trials or commercial sales. We currently have an agreement with a contract research organization to manage our clinical trials, an agreement with a clinical auditing company to audit our closed clinical trials, and an agreement with a clinical writing organization to help us write protocols and study reports for our clinical trials. To the extent that we are unable to maintain these relationships or to enter into any one or more of the additional relationships necessary to our business on commercially reasonable terms, or at all, or to eliminate the need for any such relationship by establishing our own capabilities in a particular functional area in a timely manner, we could experience significant delays or cost increases that could have a material adverse effect on our ability to develop and commercialize our product candidates.

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

A number of our development programs, including, for example, our SonoLysis therapy development 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 successful 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 successfully.

As a highly specialized scientific business enterprise, our success is substantially dependent on certain key members of our scientific and management staff, the loss of any of whom could have a material adverse effect on our business.

A small number of key officers and members of our professional staff are responsible for certain critical areas of our business, such as product research and development, clinical trials, regulatory affairs, manufacturing, intellectual property protection and licensing. The services provided by our key personnel, including: Evan Unger, our founder and Chief Executive Officer, Lynne Weissberger, our Vice President, Regulatory Affairs, Quality Assurance and Regulatory Compliance; Walter Singleton, our Chief Medical Officer; Terry Matsunaga, our Vice President, Research; Rajan Ramaswami, our Vice President, Product Development; and Greg Cobb, our Chief Financial Officer, would be difficult to replace. All of our employees are employed at will. Our business and future operating results also depend significantly on our ability to attract and retain qualified management, manufacturing, technical, marketing, regulatory, sales and support personnel for our operations, and competition for such personnel is intense. We cannot

be certain that our key executive officers and scientific staff members will remain with us or that we will be successful in

Table of Contents

attracting or retaining such personnel. Our inability to retain and continue to attract qualified management and technical staff could significantly delay and may prevent the achievement of our research, development and business objectives.

We will need to increase the size of our organization, and we may experience difficulties in managing our growth.

As of May 15, 2006, we had 42 full-time employees. In the future, we will need to expand our managerial, operational, financial, clinical, regulatory and other personnel to manage and expand our operations, undertake clinical trials, manufacture our product candidates, continue our research and development and collaborative activities and commercialize our product candidates. Our management and scientific personnel, systems and facilities currently in place will not be adequate to support our planned future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- successfully utilize a small sales and marketing organization;
- identify and manage third party manufacturers for our products;
- manage our clinical trials effectively;
- manage our internal research and development efforts effectively while carrying out our contractual obligations to collaborators and other third parties;
- continue to improve our operational, financial and management controls, reporting systems and procedures under increasing regulatory requirements; and
- attract and retain sufficient numbers of talented employees.

We may be unable to successfully implement many of these tasks on a larger scale or in a timely manner and, accordingly, may not achieve our research, development and commercialization goals.

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 success will depend in large part on our ability to obtain and effectively use patents and licensed patent rights, preserve trade secrets and operate without infringing upon the proprietary rights of others. Our Abbokinase product does not have patent protection. We have method of production patents for our PROLYSE and Open-Cath-R products that expire in 2014 and 2015. Some of our intellectual property rights are based on licenses that we have entered into with owners of patents.

Although we have rights to 96 issued U.S. patents, plus some foreign equivalents and numerous pending patent applications, the patent position of pharmaceutical, medical device and biotechnology companies in general is highly uncertain and involves complex legal and factual questions. Effective intellectual property protection may also be unavailable or limited in some foreign countries. We have not pursued foreign patent protection in all jurisdictions or for all of our patentable intellectual property. As a result, our patent protection for our intellectual property will likely be less comprehensive if and when we commence international sales.

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. We have been notified that, 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. This claim, if granted, and other such conflicts 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

Table of Contents

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. Such 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;
- a potentially shorter patent term as a result of legislation which sets the patent termination date at 20 years from the earliest effective filing date of the patent application instead of 17 years from the date of the grant; and
- loss of rights that we have licensed due to our failure or decision not to fund further research or failure to achieve required development or commercialization milestones or otherwise comply with our obligations under the license and technology transfer agreements.

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

We do not have any patent protection for Abbokinase, and third parties could develop urokinase without a license from us, which could decrease the market opportunity for Abbokinase.

The patents held by Abbott Laboratories relating to Abbokinase have expired, and we did not acquire rights to any patents in connection with our acquisition. We do not own any proprietary rights to Abbokinase other than our license to use the Abbokinase trademark that expires when the current inventory of 153,000 vials is sold or expires and trade secrets relating to the manufacturing process for Abbokinase. A third party could acquire or develop a cell line capable of producing urokinase and could devise a manufacturing process that could yield a product consistent with our Abbokinase product in quality, safety and activity, in each case without a license from us, which could decrease the market opportunity for Abbokinase.

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 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

Table of Contents

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 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 certain of our product candidates are 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 these products.

Our SonoLysis therapy and SonoLysis combination therapy product candidates are based in part on patents and other intellectual property that we license or sublicense from third parties. Our rights to develop and commercialize these product candidates using such intellectual property may terminate, in whole or in part, if we fail to meet certain milestones contained in the applicable license or sublicense agreement. We may also lose our rights to develop and commercialize such product candidates if we fail to pay royalties to third party licensors, fail to comply with certain restrictions regarding our development activities, or if we fail to meet certain milestones. 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, which would have a material adverse effect on our business. In the event of any such termination, 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 dissolving blood clots with ultrasound and bubbles. Bristol-Myers Squibb has waived its rights under this agreement with respect to our current generation of SonoLysis bubbles that we are developing for dissolving blood clots, as well as a new generation of SonoLysis bubbles that we are developing for dissolving 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.

Table of Contents

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. Thrombolytics are known to involve certain medical hazards, such as risks of bleeding or immune reactions. Our other 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. Moreover, Abbokinase is made from human neonatal kidney cells. Products made from human source material may contain infectious agents, such as viruses, that can cause disease. We believe the risk that Abbokinase will transmit an infectious agent has been reduced by changes to the tissue acquisition and related manufacturing process that included screening donors for prior exposure to certain viruses, testing donors for the presence of certain current virus infections, testing for certain viruses during manufacturing and inactivating and/or removing certain viruses. Despite these measures, Abbokinase may still present a risk of transmitting infectious agents, which could expose us to product liability lawsuits.

If we use hazardous or biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

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

Table of Contents

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 investigational new drug 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 3 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.

Table of Contents

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

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

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

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

Even if we receive regulatory approval to market a particular product candidate, the FDA or foreign regulatory authority could condition approval on conducting additional and costly post-approval clinical trials or could limit the scope of approved labeling. For example, to sell Abbokinase, we are required to continue an ongoing 200-patient immunogenicity clinical trial. As of May 15, 2006, approximately 65 patients had been enrolled in this trial. 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;

Table of Contents

- 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 payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer s products from reimbursement under government programs, criminal fines and imprisonment.

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

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

We may market our products outside the U.S., either with a commercial partner or alone. To market our products in foreign jurisdictions, we may 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

Table of Contents

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 file 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 this Offering

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively. After payment of our debt obligations, our management will have broad discretion in the application of the remaining net proceeds of this offering, including for any of the purposes described in Use of Proceeds. The failure of our management to apply these funds effectively could result in financial losses and materially harm our business, cause the price of our common stock to decline and delay product development.

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

Our executive officers, current directors and holders of five percent or more of our common stock, as of May 15, 2006, beneficially owned approximately 20.6% of our common stock. We expect that upon the closing of this offering, that same group will continue to hold approximately % of our outstanding common stock. Consequently, even after this offering, these stockholders will likely continue to have significant influence over our operations. The interests of these stockholders may be different than the interests of other stockholders. This concentration of ownership could also have the effect of delaying or preventing a change in control of our company or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could reduce the price of our common stock.

We will incur increased costs as a public company which may make it more difficult to achieve profitability.

Upon effectiveness of the registration statement for this offering, we will become subject to the reporting obligations set forth in the Securities Exchange Act of 1934, as amended. As a public company, we will incur significant legal, accounting, insurance, investor relations and other expenses that we did not incur as a private company. The disclosures that we will be required to make will generally involve a substantial expenditure of financial resources. In addition, the Sarbanes-Oxley Act of 2002, as well as new rules subsequently implemented by the Securities and Exchange Commission, or SEC, and The Nasdaq National Market have required changes in corporate governance practices of public companies. We expect that full compliance with these new rules and regulations will significantly increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, in connection with becoming a reporting company, we have created additional board committees and will be required to adopt and maintain policies regarding internal controls and disclosure controls and procedures. We have retained a consultant to assist us in developing our internal controls to comply with regulatory requirements and may have to retain additional consultants and employees to assist us with other aspects of complying with regulatory requirements applicable to public companies. Such additional reporting and compliance costs may negatively impact our financial results and may make it more difficult to achieve profitability. The rules and regulations imposed by the SEC and as implemented under the Sarbanes-Oxley Act may also make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. To the extent our earnings suffer as a result of the financial impact of our SEC reporting or compliance costs, our business could be harmed.

Table of Contents

If you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of your investment.

Purchasers of common stock in this offering will pay a price per share that substantially exceeds the per share book value of our tangible assets after subtracting our liabilities and the per share price paid by our existing stockholders and by persons who exercise currently outstanding options to acquire our common stock. In addition, purchasers of common stock in this offering will have contributed % of our total capital raised through the sale of our stock but will own only % of the outstanding common stock and voting rights.

There has been no prior public market for our common stock, and an active trading market for our common stock may not develop, potentially lessening the value of your shares and impairing your ability to sell.

Prior to this offering, there has been no public market for our common stock. Although we have applied to have our common stock quoted on The Nasdaq National Market, an active trading market for our shares may never develop or be sustained following this offering. Accordingly, you may not be able to sell your shares quickly or at the market price if trading in our stock is not active. We will negotiate and determine the initial public offering price with representatives of the underwriters and this price may not be indicative of prices that will prevail in the trading market after the offering. Investors may not be able to sell their common stock at or above the initial public offering price. In addition, there are continuing eligibility requirements for companies listed on The Nasdaq National Market. If we are not able to continue to satisfy the eligibility requirements of The Nasdaq National Market, then our stock may be delisted. This could result in a lower price of our common stock and may limit the ability of our stockholders to sell our stock, any of which could result in your losing some or all of your investment.

We expect the price of our common stock to be volatile, and if you purchase shares of our common stock you could incur substantial losses if you are unable to sell your shares at or above the offering price.

The price for the shares of our common stock sold in this offering will be determined by negotiation between the representatives of the underwriters and us, but this price may not reflect the market price for our common stock following the offering. In addition, our stock price is likely to be volatile. The stock markets in general and the market for small health care companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the initial public offering price. The price for our common stock may be influenced by many factors, including:

- announcements of technological innovations or new products by us or our competitors;
- announcements of the status of FDA review of our products;
- 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;
- 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;

changes in the reimbursement policies of third-party insurance companies or government agencies;

Table of Contents

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; and

the loss of any of our key scientific or management personnel.

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.

A significant portion of our outstanding common stock may be sold into the market in the near future. Substantial sales of common stock, or the perception that such sales are likely to occur, could cause the price of our common stock to 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. All of the shares offered under this prospectus will be freely tradable without restriction or further registration under the federal securities laws, unless purchased by our affiliates as that term is defined in Rule 144 under the Securities Act of 1933. An aggregate of 13,585,264 shares of our common stock may be sold pursuant to Rule 144, 144(k) and 701 upon the expiration of 180-day lock-up agreements.

In addition, as of May 15, 2006, holders of an aggregate of 16,779,831 shares of common stock and warrants to purchase an aggregate of 1,474,739 shares of common stock have rights with respect to the registration of their shares of common stock with the SEC. See Description of Capital Stock Registration Rights. If we register their shares of common stock following the expiration of the lock-up agreements, they can immediately sell those shares in the public market.

Promptly following this offering, we intend to file a registration statement covering up to a maximum of 6,235,400 shares of common stock that are authorized for issuance under our equity incentive plans. As of May 15, 2006, 2,777,024 shares were subject to outstanding options, of which 920,231 shares were vested. Once we register these shares, they can be freely sold in the public market upon issuance, subject to lock-up agreements and restrictions on our affiliates. For more information, see the discussion under the caption Shares Eligible for Future Sale.

If we fail to develop and maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud; as a result, current and potential stockholders could lose confidence in our financial reporting, which could harm our business and the trading price of our common stock, should a market for such securities ever develop.

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. We have not undertaken any efforts to develop a sophisticated financial reporting system. Section 404 of the Sarbanes-Oxley Act of 2002 will require us, beginning with our fiscal year 2007, to evaluate and report on our internal controls over financial reporting and will require our independent registered public accounting firm annually to attest to such evaluation, as well as issue their own opinion on our internal control over financial reporting. Because we have historically operated as a private company, we have limited experience attempting to comply with public company obligations, including Section 404 of the Sarbanes-Oxley Act. The process of strengthening our internal controls and complying with Section 404 is expensive and time consuming, and requires significant management attention, especially given that we have not previously undertaken any efforts to comply with the requirements of Section 404. We have recently retained a consultant to assist us in developing our internal controls to comply with regulatory requirements and may be required to retain additional consultants or employees to assist us with other

aspects of complying with regulatory requirements applicable to public companies in the future. The implementation of compliance efforts with Section 404 will be challenging in the face of our planned rapid growth to support our operations as well as the establishment of infrastructure to support our commercial operations. We cannot be certain that the measures we will undertake will ensure that we will maintain adequate controls over our financial

Table of Contents

processes and reporting in the future. Furthermore, if we are able to rapidly grow our business, the internal controls that we will need will become more complex, and significantly more resources will be required to ensure our internal controls remain effective. Failure to implement required controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations. If we or our auditors discover a material weakness, the disclosure of that fact, even if quickly remedied, could diminish investors confidence in our financial statements and harm our stock price. In addition, non-compliance with Section 404 could subject us to a variety of administrative sanctions, including ineligibility for listing on The Nasdaq National Market and the inability of registered broker-dealers to make a market in our common stock.

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

Provisions of our 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 a 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 you of the opportunity to sell your shares to potential acquirors at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

We may become involved in securities class action litigation that could divert management s attention and harm our business.

The stock market in general, and The Nasdaq National Market and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and health care industry factors may materially harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market price of a particular company s securities, securities class action litigation has often been brought against that company. We may become involved in this type of litigation in the future, regardless of the merits. Litigation often is expensive and diverts management s attention and resources, which could materially harm our financial condition and results of operations.

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 currently do not anticipate paying any cash dividends in the foreseeable future. Instruments governing any future indebtedness may also contain various covenants that would limit our ability to pay dividends. Accordingly, our stockholders will not realize a return on their investment unless the trading price of our common stock appreciates. Our common stock may not appreciate in value after the offering and may not even maintain the price at which investors purchased shares.

Table of Contents

Forward-looking Statements

This prospectus contains forward-looking statements that are based on our management s beliefs and assumptions and on information currently available to our management. The forward-looking statements are contained principally in the sections entitled Summary, Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations and Business. Forward-looking statements include, but are not limited to, statements about:

- our ability to market and sell Abbokinase;
- our ability to conduct and complete our clinical trials and our use of acquired data;
- our expectations with respect to regulatory submissions and approvals;
- our ability to engage and retain qualified third parties to manufacture our product candidates in a timely and cost-effective manner;
- our ability to commercialize our product candidates;
- our estimates regarding our capital requirements and our need for additional financing; and
- our expectations with respect to our intellectual property position.

In some cases, you can identify forward-looking statements by terms such as may, will, should, could, would, plans, intends, anticipates, believes, estimates, projects, predicts, potential and similar expressions inter forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly in the Risk Factors section, that could cause actual results or events to differ materially from the forward-looking statements that we make.

You should read this prospectus and the documents that we have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements.

Table of Contents

Use of Proceeds

We estimate that we will receive approximately $ million in net proceeds from this offering, or $ million if the underwriters over-allotment option is exercised in full, based upon an assumed initial public offering price of $ per share, the midpoint of the range on the front cover of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the midpoint of the range on the front cover of this prospectus, would increase (decrease) the net proceeds to us from this offering by $ million after deducting underwriting discounts and commissions and estimated offering expenses payable by us, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same.

Regardless of whether there is a decrease by $1.00 in the assumed initial public offering price, we anticipate that the net proceeds from this offering together with our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements until December 2007.

We estimate that we will use the net proceeds from this offering in the following manner:

- approximately $16 million for payment of a $15 million promissory note plus accrued interest, that we issued in connection with our 2005 acquisition of recombinant urokinase drug technologies, which matures on December 31, 2006 and accrues interest at 6% annually;
- approximately $12 million to fund a portion of our PROLYSE development activities, including a portion of a Phase 3 clinical trial (approximately $12 million in additional funds will likely be required to complete the Phase 3 clinical trial), and manufacturing and materials costs related to the trial;
- approximately $10 million to fund a portion of our SonoLysis therapy development activities, including a Phase 1/2 clinical trial, preclinical safety and mechanism of action studies, manufacturing and material costs related to the trial;
- approximately $11 million to fund a portion of our SonoLysis combination therapy development activities, including a Phase 1/2 clinical trial, preclinical safety studies, manufacturing and material costs related to the trial;
- approximately $5 million to fund research and development activities for Abbokinase, Open-Cath-R and our other preclinical and research-stage product candidates;
- approximately $4 million to fund Abbokinase sales and marketing costs and other business development activities; and
- for working capital and other general corporate purposes.

The amounts we actually expend in these areas may vary significantly from our expectations and will depend on a number of factors, including operating costs and capital expenditures. Accordingly, management will retain broad discretion in the allocation of the net proceeds of this offering. A portion of the net proceeds may also be used to acquire or invest in complementary businesses, technologies, services or products. We have no current plans, agreements or commitments with respect to any such material acquisition or investment, and we are not currently engaged in any negotiations with respect to any such transaction. Pending such uses, the net proceeds of this offering will be invested in short-term, interest-bearing, investment-grade securities.

Dividend Policy

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

Table of Contents

Capitalization

The following table sets forth our capitalization as of March 31, 2006:

On an actual basis;

On a pro forma basis after giving effect to:

the issuance of 2,835,000 shares of Series F preferred stock in April and May 2006 resulting in net proceeds of approximately $13.0 million;

a $5.0 million initial payment and the issuance of a $15.0 million promissory note in connection with an asset acquisition in April 2006, consisting of $16.7 million of inventory and $3.3 million of intangible assets; and

the conversion of all outstanding shares of preferred stock, valued at approximately $38.9 million, into 8,164,157 shares common stock upon the closing of this offering; and

On a pro forma as adjusted basis to reflect our receipt of the estimated net proceeds from our sale of shares of common stock in this offering at an assumed initial public offering price of $, the midpoint of the range on the front cover of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	At March 31, 2006		
	Actual	**Pro Forma**	**Pro Forma as Adjusted**
	(in thousands) **(unaudited)**		
Long-term notes payable, less current portion	$	$ 15,000	$ 15,000
Mandatorily redeemable convertible preferred stock, $0.0001 par value: 3,608,316 shares issued and outstanding, actual, no shares issued or outstanding, pro forma and pro forma as adjusted	21,878		
Stockholders (deficit) equity:			
Preferred stock, $0.0001 par value: 30,000,000 shares authorized, actual and pro forma, 5,000,000 shares authorized, pro forma as adjusted; 1,000,000 shares issued and outstanding, actual, no shares issued or outstanding, pro forma and pro forma as adjusted	4,000		
Common stock, $0.0001 par value: 70,000,000 shares authorized, actual and pro forma, 100,000,000 shares authorized, pro forma as adjusted; 12,931,638 shares issued and outstanding, actual, 21,197,795 shares issued and outstanding, pro forma, and shares issued and outstanding, pro forma as adjusted	1	2	
Additional paid-in capital	27,638	66,515	
Deficit accumulated during the development stage	(64,257)	(64,257)	( )
Total stockholders (deficit) equity	(32,618)	2,260	
Total capitalization	$ (10,740)	$ 17,260	$

Table of Contents

The pro forma number of shares to be outstanding immediately after this offering as shown above is based on 12,931,638 shares outstanding as of March 31, 2006 and excludes:

2,579,024 shares of common stock issuable upon the exercise of options outstanding having a weighted average exercise price of $2.66 per share;

1,761,749 shares of common stock issuable upon the exercise of warrants outstanding having a weighted average exercise price of $3.16 per share;

1,958,376 shares of common stock reserved for future grants under our 2000 Stock Plan; and

an aggregate of 1,800,000 shares of common stock reserved for future issuance under our 2006 Performance Incentive Plan, which has been approved by our board of directors and, subject to stockholder approval, will become effective immediately upon the signing of the underwriting agreement for this offering.

Table of Contents

Dilution

If you invest in our common stock in this offering, the amount you pay per share will be substantially more than the net tangible book value per share of the common stock you purchase.

Our actual net tangible book value as of March 31, 2006 was a deficit of approximately $32.6 million, or approximately $2.52 per share of common stock. Net tangible book value per share represents total tangible assets less total liabilities, divided by the number of shares of common stock outstanding as of March 31, 2006. Our pro forma net tangible book value as of March 31, 2006 was a deficit of approximately $1.0 million, or approximately $0.05 per share of common stock. Our pro forma net tangible book value gives effect to:

- the issuance of 2,835,000 shares of Series F preferred stock in April and May 2006 resulting in net proceeds of approximately $13.0 million;
- a $5.0 million initial payment and the issuance of a $15.0 million promissory note in connection with an asset acquisition in April 2006 consisting of $16.7 million of inventory and $3.3 million of intangible assets; and
- the conversion of all outstanding shares of preferred stock, valued at approximately $38.9 million, into 8,164,157 shares common stock upon the closing of this offering.

After giving effect, based on an assumed initial public offering price of $ per share, the midpoint of the range on the front cover of this prospectus, to (i) the automatic conversion of our outstanding preferred stock into 8,164,157 shares of common stock in connection with the closing of this offering and (ii) receipt of the net proceeds from the sale of shares of common stock in this offering, after deducting underwriting discounts and commissions and estimated offering expenses, our pro forma as adjusted net tangible book value as of March 31, 2006 would have been approximately $ million, or $ per share. See Conversion of Series F Preferred Stock. This represents an immediate increase in pro forma as adjusted net tangible book value per share of $ to existing stockholders and an immediate dilution of $ per share to new investors purchasing shares of common stock in this offering at the assumed initial offering price.

The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		$
Actual net tangible book value (deficit) per share as of March 31, 2006	$ (2.52)	
Increase per share due to pro forma adjustments	2.47	
Pro forma net tangible book value (deficit) per share as of March 31, 2006, before this offering	(0.05)	
Increase in pro forma net tangible book value per share attributable to this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution in pro forma net tangible book value per share to new investors in this offering		$

If the underwriters exercise their over-allotment option to purchase additional shares from us in this offering, our pro forma as adjusted net tangible book value per share will increase to $ per share, representing an immediate increase to existing stockholders, of $ per share and an immediate dilution of $ per share to new investors assuming conversion of all shares of our preferred stock. If any shares are issued in connection with outstanding options, you will experience further dilution.

Table of Contents

The following table summarizes, on the pro forma as adjusted basis described above, as of March 31, 2006, the number of shares of common stock purchased from us, the total consideration paid and the average price per share paid to us by existing stockholders and to be paid by new investors purchasing shares of common stock in this offering. The table assumes an initial public offering price of $ per share, the midpoint of the range on the front cover of this prospectus, before deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	Total Shares		Total Consideration		
	Number	%	Amount	%	Average Price Per Share
Existing stockholders	18,260,795		$ 46,736,000		$ 2.20
New investors					
Total		100.0%		100.0%	

The number of shares to be outstanding immediately after this offering as shown above is based on 18,260,795 shares outstanding as of March 31, 2006 and excludes:

- 2,579,024 shares of common stock issuable upon the exercise of options outstanding having a weighted average exercise price of $2.66 per share;
- 1,761,749 shares of common stock issuable upon the exercise of warrants outstanding having a weighted average exercise price of $3.16 per share;
- 1,958,376 shares of common stock reserved for future grants under our 2000 Stock Plan as of March 31, 2006; and
- an aggregate of 1,800,000 shares of common stock reserved for future issuance under our 2006 Performance Incentive Plan, which has been approved by our board of directors and, subject to stockholder approval, will become effective immediately upon the signing of the underwriting agreement for this offering.

If the underwriters over-allotment option is exercised in full, the following will occur:

- the percentage of shares of common stock held by existing stockholders will decrease to approximately % of the total number of shares of common stock outstanding after this offering; and
- the number of shares held by new investors will increase to , or approximately %, of the total number of shares of common stock outstanding after this offering.

Assuming the exercise in full of all of our options and warrants outstanding as of March 31, 2006, pro forma net tangible book value as of March 31, 2006 would be a deficit of approximately $0.47 per share and, after giving effect to the sale of shares of common stock in this offering, there would be an immediate dilution of $ per share to new investors purchasing shares in this offering. If all options and warrants outstanding as of March 31, 2006 are exercised in full, new investors would have contributed % of the total consideration paid but would own only % of our capital stock outstanding after the offering and exercise of all such outstanding options and warrants.

Table of Contents

Conversion of Series F Preferred Stock

In connection with the closing of this offering, all of our outstanding preferred stock will convert into common stock. The per share conversion rate of our Series F preferred stock is variable and will be determined by dividing $5.00 (as adjusted for any stock dividends, combinations, splits, recapitalizations and the like with respect to such shares) by the lesser of (a) $5.00 (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 this offering. Therefore, depending on the price of the shares sold in this offering, the holders of the Series F preferred stock may receive more than one share of common stock for each share of Series F preferred stock converted in connection with this offering. We will not know the conversion rate of our Series F preferred stock until the public offering price is determined.

In this prospectus, we have estimated the number of shares of common stock issuable upon conversion of the Series F preferred stock assuming an initial public offering price of greater than $5.88 per share (as adjusted for any stock dividends, combinations, splits, recapitalizations and the like with respect to such shares), meaning that we have assumed a one-to-one conversion ration of our Series F preferred stock.

Upon completion of this offering, our existing stockholders will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. Because only some of our stockholders own Series F preferred stock, changes in our valuation in connection with this offering will impact the conversion ratio of our Series F preferred stock and thus the relative ownership of our common stock upon completion of this offering among our existing stockholders.

Table of Contents

Selected Consolidated Financial Data

You should read the following selected consolidated financial data in conjunction with our consolidated financial statements and the related notes appearing elsewhere in this prospectus and the Management s Discussion and Analysis of Financial Condition and Results of Operations. We have derived the consolidated statements of operations data for the years ended December 31, 2003, 2004 and 2005 and the consolidated balance sheet data at December 31, 2004 and 2005 from our consolidated audited financial statements, which are included elsewhere in this prospectus. We have derived the consolidated statements of operations data for the years ended December 31, 2001 and 2002 and the consolidated balance sheet data as of December 31, 2001, 2002 and 2003, from our audited financial statements, which are not included in this prospectus. The selected consolidated statements of operations data for the three months ended March 31, 2005 and 2006, and the selected consolidated balance sheet data at March 31, 2006, are derived from our unaudited consolidated financial statements, which are included elsewhere in this prospectus. Our historical results for any prior period are not necessarily indicative of results to be expected for any future period.

	Years Ended December 31,					Three Months Ended March 31,	
	2001	2002	2003	2004	2005	2005	2006
						(unaudited)	
	(in thousands, except share and per share data)						
Consolidated Statements of Operations Data:							
Grant and other revenue	$ 261	$ 71	$ 224	$ 575	$ 619	$ 173	$ 177
Costs and expenses:							
Research and development	1,812	1,399	1,878	2,490	3,579	764	1,724
General and administrative	2,943	1,840	1,654	3,183	4,142	661	1,618
Depreciation and amortization	210	245	209	186	194	47	60
Acquired in-process research and development(1)					24,000		
License fees to development partner(2)	10,000						
Total operating expenses	14,965	3,484	3,741	5,859	31,915	1,472	3,402
Minority interest in loss of consolidated	2,269	369					

subsidiary							
Interest and other income	162	14	22	29	122	23	105
Interest expense	(53)	(170)	(325)	(469)	(587)	(53)	(225)
Gain on extinguishment of note(3)					3,835	3,835	
Net (loss) income	(12,326)	(3,200)	(3,820)	(5,724)	(27,926)	2,506	(3,345)
Accretion of dividends on preferred stock	(537)	(1,640)	(1,287)	(301)	(601)	(150)	(150)
Net (loss) income available to common stockholders	$ (12,863)	$ (4,840)	$ (5,107)	$ (6,025)	$ (28,527)	$ 2,356	$ (3,495)
Net (loss) income available to common stockholders per share Basic	$ (4.39)	$ (1.65)	$ (1.74)	$ (1.07)	$ (3.01)	$ 0.30	$ (0.27)
Weighted average shares outstanding Basic	2,927,961	2,938,706	2,936,094	5,637,042	9,463,279	7,769,415	12,930,820
Net (loss) income available to common stockholders per share Diluted	$ (4.39)	$ (1.65)	$ (1.74)	$ (1.07)	$ (3.01)	$ 0.18	$ (0.27)
Weighted average shares outstanding Diluted	2,927,961	2,938,706	2,936,094	5,637,042	9,463,279	13,146,131	12,930,820

	At December 31,					At March 31,
	2001	2002	2003	2004	2005	2006
						(unaudited)
			(in thousands)			(in thousands)
Consolidated Balance Sheet Data:						
Cash and cash equivalents	$ 368	$ 2,104	$ 736	$ 1,538	$ 8,513	$ 6,349
Working capital (deficit)	(102)	1,568	(1,440)	739	(8,111)	(11,388)
Total assets	1,438	2,908	1,298	2,122	9,516	7,369
		3,740	4,002	4,282		

Long-term notes payable, less current portion						
Mandatorily redeemable convertible preferred stock	16,715	19,189	20,826	21,127	21,727	21,878
Total stockholders deficit	(16,113)	(20,971)	(26,003)	(24,529)	(29,327)	(32,618)

(1) Research and development expense for the year ended December 31, 2005 includes the purchase of in-process research and development operations valued at $24,000,000 in accordance with an Asset Purchase Agreement entered into with Abbott Laboratories in September 2005 related to our acquisition of PROLYSE and Open-Cath-R.

(2) License fees in the amount of $10,000,000 were incurred in conjunction with entering into a joint development agreement with a development partner in January 2001.

(3) Extinguishment of the note payable to the development partner in the joint development agreement entered into in 2001 resulted in a gain on extinguishment of debt of $3.8 million in March 2005.

Table of Contents

Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with Selected Consolidated Financial Information and our consolidated financial statements and related notes included elsewhere in this prospectus. This discussion and analysis and other parts of the prospectus contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under Risk Factors and elsewhere in this prospectus. You should carefully read the Risk Factors section of this prospectus to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled Special Note Regarding Forward-Looking Statements.

Overview

We are a biopharmaceutical company developing and commercializing innovative therapies for vascular disorders associated with blood clots. Our development efforts are primarily focused on therapies for treating ischemic stroke and massive pulmonary embolism by restoring the flow of blood and oxygen to the brain and vital tissues, and clearing occluded catheters.

We were organized as an Arizona limited liability company on October 7, 1999, which was our date of inception for accounting purposes. We were subsequently converted to an Arizona corporation on January 12, 2000, and then reincorporated as a Delaware corporation on June 23, 2000. We have not yet generated any significant revenue from operations and remain a development stage company. From our inception through March 31, 2006, we accumulated a deficit from operations of $64.3 million. We have funded our operations to date primarily through private placements of our preferred and common stock as well as the sale of convertible notes and the receipt of government grants. Through March 31, 2006, we had received net proceeds of approximately $33.7 million from the issuance of shares of our preferred and common stock and convertible notes. In April and May 2006, we received an additional $13.0 million in net proceeds from the sale of shares of our Series F preferred stock.

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

In September 2005, we acquired the technology and development assets of Abbott Laboratories relating to two thrombolytic product candidates, PROLYSE and Open-Cath-R, including data and rights under various agreements and related applications filed with the U.S. Food and Drug Administration, or FDA, drug substance, raw materials, cell banks, related intellectual property and manufacturing know-how. Although these product candidates may have significant future importance, we determined that, since they had not yet received FDA approval and presented no alternative future use, they did not meet established guidelines for technological feasibility sufficiently to be recorded as assets. As a result, the full purchase price consideration of $24.0 million was recorded as acquired in-process research and development expense for the year ended December 31, 2005.

In April 2006, we also acquired from Abbott Laboratories the assets related to Abbokinase, including the remaining inventory of finished product, all regulatory and clinical documentation, validated cell lines, and intellectual property rights, including trade secrets and know-how relating to the manufacture of urokinase using the tissue culture method. Since no employees, equipment, manufacturing facilities or arrangements or sales and marketing organization were included in this transaction, we accounted for it as an acquisition of assets rather than as an acquisition of a business, with a purchase price of $20.0 million. The purchase price will be allocated to the assets acquired based upon the fair value of the assets acquired. The initial valuation recorded in April 2006 may change as management conducts its analysis of the purchase price allocation.

Table of Contents

We expect our operating losses to increase for at least the next several years due to increasing expenses associated with proposed clinical trials, product development, selling, general and administrative costs and regulatory activities. We also have significant acquisition-related financial obligations, including a $15.0 million note that we issued in connection with our 2005 acquisition of PROLYSE, Open-Cath-R and related assets that matures on December 31, 2006, and an additional $15.0 million note that we issued in connection with our April 2006 acquisition of Abbokinase assets that matures on December 31, 2007.

Revenue

We have generated only a limited amount of revenue to date, primarily by providing research services for projects funded under various government grants. We anticipate that we will begin to generate additional revenue during the second half of 2006 from sales of Abbokinase. However, any such revenue is difficult to predict as to both timing and amount, may not be achieved in any consistent or predictable pattern, and in any case will not be sufficient to prevent us from incurring continued and increasing losses from our development and other activities.

Research and Development Expenses

We classify our research and development expenses into five categories of activity, namely, research, development, program management, clinical and regulatory. To date, our research and development efforts have been focused primarily on product candidates from our bubble technology program. Historically we have not tracked research and development expenses by product candidate. However, with our recently acquired portfolio of thrombolytic product candidates, in the future we intend to separately track expenses related to activities such as manufacturing and preclinical studies or clinical trials for each of our primary product candidates. Beginning in September 2005, we expanded our research and development focus to include urokinase-based thrombolytic product candidates for dissolving blood clots. We expect our research and development expenses to increase with the planned commencement of clinical trials for our ischemic stroke product candidates. Clinical development timelines, likelihood of success and associated costs are uncertain and therefore vary widely. We anticipate that we will make determinations as to which research and development projects to pursue and how much funding to direct toward each project on an ongoing basis in response to the scientific and clinical success of each product candidate. From inception through March 31, 2006, we have incurred approximately $14.5 million in research and development expenses. These were incurred primarily to develop our SonoLysis bubble technology program. We currently estimate we will complete the current or imminent stage of development for each primary product candidate as follows:

For PROLYSE, we intend to establish contract manufacturing and to commence a Phase 3 clinical trial for ischemic stroke in 2007 after, and if, we secure regulatory approvals. We estimate these activities will cost approximately $24 million to complete. However, we have not yet discussed this planned clinical trial with the FDA. The outcome of our discussions with the FDA could significantly alter the costs to complete this stage of development of PROLYSE. We expect to allocate approximately $12 million of the net proceeds from this offering toward PROLYSE development.

For SonoLysis therapy, we intend to establish commercial-scale contract manufacturing of our SonoLysis bubbles, and conduct a Phase 1/2 trial for ischemic stroke beginning in the first half of 2007 after, and if, we secure appropriate regulatory approvals. We estimate that these efforts will cost approximately $10 million. However, we have not yet discussed this planned clinical trial with the FDA. The outcome of our discussions with the FDA could significantly alter the costs to complete this stage of development of SonoLysis therapy. We expect to allocate approximately $10 million of the net proceeds from this offering toward development of our SonoLysis therapy.

For SonoLysis combination therapy, we intend to establish commercial-scale contract manufacturing of our SonoLysis bubbles, establish contract manufacturing of PROLYSE and conduct a Phase 1/2 clinical trial for ischemic stroke using t-PA beginning in the second half of 2006. We estimate that these efforts will cost approximately $11 million. We intend to allocate the costs of SonoLysis bubble manufacturing equally between our SonoLysis therapy and our SonoLysis combination therapy product candidates. We also intend to allocate the

costs of PROLYSE manufacturing equally between our PROLYSE and

Table of Contents

SonoLysis combination therapy product candidates. We expect to allocate approximately $11 million of the net proceeds from this offering toward development of our SonoLysis combination therapy.

We intend to maintain the regulatory status of Abbokinase as an FDA-approved product and to investigate the feasibility and challenges of reestablishing manufacturing of the product. We estimate that these efforts may cost approximately $3 million through 2007, some or all of which would be funded by anticipated Abbokinase product sales.

The next stage of development for Open-Cath-R is to establish contract manufacturing and to demonstrate comparability with the recombinant urokinase previously manufactured by Abbott Laboratories. We estimate this effort may cost approximately $12 million, some or all of which may be financed through a development partner.

In addition, we intend to further pursue research of our bubble technology and thrombolytic programs and estimate that this effort may cost approximately $2 million through 2007, some or all of which may be financed through government grants or research collaborations. Any new government grants or research collaborations could significantly alter our total research expense depending on the timing and amount of any such awards or agreements. We expect to allocate an aggregate of approximately $5 million of the net proceeds from this offering toward expenses related to Abbokinase, Open-Cath-R and research projects.

At this time, due to the risks inherent in the clinical trial process and the related regulatory process, our development completion dates and costs vary significantly for each product candidate and are very difficult to estimate. Furthermore, we only recently acquired our thrombolytic product candidates, and we are continuing to assess the related clinical and regulatory requirements necessary to develop the product candidates. The lengthy process of seeking regulatory approvals and the subsequent compliance with applicable regulations require the expenditure of substantial additional resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals for our product candidates could cause our research and development expenditures to increase and, in turn, have a material adverse effect on our results of operations. We cannot be certain when, if ever, any cash flows from our current product candidates will commence.

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 administrative support, business development, intellectual property protection, corporate compliance and preparing to become a public reporting company, as well as a portion of our overhead expenses. We anticipate that our selling expenses will increase as we expand our infrastructure to support planned increases in our development and commercialization efforts relating primarily to the initiation of our Abbokinase selling efforts. If we are successful in obtaining required regulatory approvals for any of our other product candidates, we will likely incur substantial additional sales and marketing expenses as we continue to build our U.S. sales force and marketing capabilities. We also anticipate incurring additional expenses of $1.5 million to $2.0 million per year as a public company following the completion of this offering as a result of additional legal, accounting and corporate governance expenses, including costs associated with tax return preparations, accounting support services, Sarbanes-Oxley compliance expenses, filing annual and quarterly reports with the SEC, directors fees, directors and officers insurance, listing and transfer agent fees, and investor relations expenses.

Critical Accounting Policies and Significant Judgments and Estimates

Our management s discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosed amounts of contingent assets and liabilities and our reported revenue and expenses. Significant management judgment is required to make estimates in relation to clinical trial costs and costs related to public reporting company preparation. We evaluate our estimates, and judgments related to these estimates, on an ongoing basis. We

Table of Contents

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 2 of our consolidated financial statements.

Clinical Trial Accrued Expenses

We record accruals for clinical trial costs associated with clinical research organizations, investigators and other vendors based upon the estimated amount of work completed on each clinical trial. All such costs are charged to research and development expenses based on these estimates. These estimates may or may not match the actual services performed by the organizations as determined by patient enrollment levels and related activities. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, correspondence and discussions with contract research organizations and review of contractual terms. However, if we have incomplete or inaccurate information, we may underestimate or overestimate activity levels associated with various clinical trials at a given point in time. In this event, we could record significant research and development expenses in future periods when the actual level of activities becomes known. To date, we have not experienced material changes in these estimates.

Deferred Tax Asset Valuation Allowance

Our estimate of the valuation allowance for deferred tax assets requires us to make significant estimates and judgments about our future operating results. Our ability to realize the deferred tax assets depends on our future taxable income as well as limitations on utilization. A deferred tax asset must be reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized prior to its expiration. The projections of our operating results on which the establishment of a valuation allowance is based involve significant estimates regarding future demand for our products, competitive conditions, product development efforts, approvals of regulatory agencies and product cost. We have recorded a full valuation allowance on our net deferred tax assets as of December 31, 2004 and 2005 due to uncertainties related to our ability to utilize our deferred tax assets in the foreseeable future. These deferred tax assets primarily consist of net operating loss carryforwards and research and development tax credits.

Stock-Based Compensation

In the first quarter of 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 vesting period. Prior to SFAS 123R, we disclosed the pro forma effects of SFAS 123R under the minimum value method. We adopted SFAS 123R effective January 1, 2006, prospectively for new equity awards issued subsequent to January 1, 2006. The adoption of SFAS 123R in the first quarter of 2006 resulted in the recognition of additional stock-based compensation expense and a reduction in net income of approximately $25,000 and no change in basic and diluted earnings per share. Under SFAS 123R we calculated the fair value of stock option grants using the Black-Scholes option-pricing model. The weighted average assumptions used in the Black-Scholes model were 7 years for the expected term, 75% for the expected volatility, 4.50% for the risk free rate and 0% for dividend yield for the three month period ended March 31, 2006. Future expense amounts for any particular quarterly or annual period could be affected by changes in our assumptions or changes in market conditions.

Table of Contents

The weighted average expected option term for 2006 reflects the application of the simplified method set out in SEC Staff Accounting Bulletin No., or SAB, 107 which was issued in March 2005. 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. Estimated volatility for fiscal 2006 also reflects the application of SAB 107 interpretive guidance and, accordingly, incorporates historical volatility of similar public entities.

Prior to January 1, 2006, we accounted for employee stock-based compensation in accordance with provisions of APB 25 and FASB Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation an Interpretation of APB No. 25*, and comply with the disclosure provisions of SFAS 123 and related SFAS 148, *Accounting for Stock-Based Compensation Transaction and Disclosure*. Under APB 25, compensation expense is based on the difference, if any, on the date of the grant, between the fair value of our stock and the exercise price of the option. We amortize deferred stock-based compensation using the straight-line method over the vesting period.

The accounting for and disclosure of employee equity instruments requires judgment by our management on a number of assumptions, including the fair value of the underlying instrument, estimated lives of the outstanding instruments, and the instrument s volatility. Changes in key assumptions will impact the valuation of such instruments. Because there has been no public market for our stock, our board of directors has determined the fair value of our common stock based on several factors, including, but not limited to, our operating and financial performance and internal valuation analyses considering key terms and rights of the related instruments.

Our board of directors estimated the fair value of common stock for options granted during the two-year period prior to the filing of this registration statement, with input from our management, using the market approach and sales to third parties of our common and preferred shares.

Results of Operations

Quarter Ended March 31, 2005 Compared to 2006

Grant and Other Revenue. Our revenue-producing activities during the first quarter of 2005 and 2006 consisted of providing services under research grants and contracts. Our revenue increased from approximately $173,000 in the first quarter of 2005 to approximately $177,000 in the first quarter of 2006, primarily due to the receipt of an additional grant.

Research and Development Expenses. Research and development expenses increased from approximately $764,000 in the first quarter of 2005 to approximately $1.7 million in the first quarter of 2006. This increase is principally a result of the Company s transition from a research organization to a clinical development organization, thus requiring the creation of both clinical and regulatory departments. The main components of cost incurred during this transition were additional compensation expenses, clinical trial costs and consulting expenses. Specifically, this increase was due to approximately $279,000 in increased compensation expense to support increased headcount, approximately $144,000 in increased expenses for the initiation of a clinical trial in stroke which began in March 2005 as well as other ongoing clinical trials, approximately $114,000 in increased preclinical study costs related to our Sonolysis bubble therapy and approximately $400,000 in increased third party service costs and other expenses.

General and Administrative Expenses. General and administrative expenses increased from approximately $661,000 in the first quarter of 2005 to approximately $1.6 million in the first quarter of 2006. This increase is principally a result of our transition from a research organization to a clinical development organization, thus requiring the addition of both clinical and regulatory departments. Specifically, this increase resulted from approximately $679,000 in increased third party service costs, principally legal and accounting expenses related to financing matters, asset acquisitions and matters associated with becoming a public company and

Table of Contents

approximately $260,000 in additional compensation expense to support increased headcount, stock-based compensation expense and public relations costs associated with company financings.

Interest and Other Income. Interest and other income increased from approximately $23,000 in the first quarter of 2005 to approximately $105,000 in the first quarter of 2006, as a result of a higher cash balance throughout the quarter and higher interest rates.

Interest Expense. Interest expense increased from approximately $53,000 in the first quarter of 2005 to approximately $225,000 in the first quarter of 2006, due to the interest on a note payable in September 2005 and the early extinguishment of a note payable to a former development partner in March 2005.

Gain on Extinguishment of Note. In March 2005, we repurchased a note from a former development partner at a discount. The outstanding principal and accrued interest, totaling approximately $4.3 million, was settled in cash for $500,000, resulting in a non-recurring gain of approximately $3.8 million.

Year Ended December 31, 2004 Compared to 2005

Grant and Other Revenue. Our revenue-producing activities during 2004 and 2005 consisted of providing services under research grants and contracts. Revenue increased from approximately $575,000 in 2004 to approximately $619,000 in 2005, primarily due to an additional grant received in July 2005.

Research and Development Expenses. Research and development expenses increased from approximately $2.5 million in 2004 to approximately $3.6 million in 2005. This increase is principally a result of the Company s transition from a research-focused organization to a clinical development organization, thus requiring the creation of both clinical and regulatory departments. The main components of cost incurred during this transition were clinical trial costs, consulting, compensation and cost of hiring and increased overhead. Of the total increase, approximately $560,000 was for the initiation of our current clinical trial in stroke which began in March 2005, approximately $230,000 resulted from increased third party service costs, approximately $200,000 resulted from increased compensation expense to support increased headcount, and approximately $450,000 resulted from increased overhead, laboratory chemicals and supplies, travel and other expenses. An offset of approximately $360,000 was due to timing of preclinical and manufacturing expenses.

General and Administrative Expenses. General and administrative expenses increased from approximately $3.2 million in 2004 to approximately $4.1 million in 2005. This increase resulted primarily from the expenditure of approximately $610,000 in increased compensation expense to support increased headcount, approximately $220,000 in increased third party service costs, principally legal and accounting expenses related to financing matters and asset acquisitions, and approximately $69,000 in increased business development and other expenses.

Interest and Other Income. Interest and other income increased from approximately $29,000 in 2004 to approximately $122,000 in 2005, as a result of higher cash balances and higher interest rates.

Interest Expense. Interest expense increased from approximately $469,000 in 2004 to approximately $587,000 in 2005, primarily due to the interest on the promissory note issued in September 2005 and the early extinguishment of the note payable to a former development partner in March 2005.

Gain on Extinguishment of Note. In April 2004, our development partner was experiencing financial difficulty and began auctioning portions of its investment portfolio. In March 2005, we repurchased a note from the development partner at a discount. The outstanding principal and accrued interest, totaling approximately $4.3 million, was settled in cash for $500,000, resulting in a non-recurring gain of approximately $3.8 million. No other consideration was paid in connection with the repurchase of the note.

Table of Contents

Year Ended December 31, 2003 Compared to 2004

Grant and Other Revenue. Our revenue producing activities during 2003 and 2004 consisted of providing services for research grants and contracts. Revenue increased from approximately $224,000 in 2003 to approximately $575,000 in 2004, as a result of the newly issued grants.

Research and Development Expenses. Research and development expenses increased from approximately $1.9 million in 2003 to approximately $2.5 million in 2004. The increase was primarily due to the initiation of our first clinical trial using our SonoLysis therapy in dialysis grafts, which included approximately $285,000 in increased clinical trial costs, approximately $200,000 in increased compensation expense to support increased headcount and approximately $175,000 in increased contract manufacturing costs for our Sonolysis bubble therapy and offset by a decrease of $60,000 in general laboratory supplies and other expenses.

General and Administrative Expenses. General and administrative expenses increased from approximately $1.7 million in 2003 to approximately $3.2 million in 2004. The increase resulted primarily from approximately $790,000 in increased third party service costs for the engagement of financial advisors and investor relations consultants pursuant to long-term financial strategies, approximately $450,000 in increased warrant expense for terminated services, approximately $145,000 in increased compensation expense to support increased headcount and year-end bonuses and approximately $100,000 in increased travel and other expenses for development activities with potential business partners and other potential funding sources.

Interest and Other Income. Interest and other income increased from approximately $22,000 in 2003 to approximately $29,000 in 2004, as a result of increased cash balances.

Interest Expense. Interest expense increased from approximately $326,000 in 2003 to approximately $469,000 in 2004. The increase was due to the issuance of additional convertible notes in January 2004, including a discount for the value of warrants issued as consideration for the notes.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred losses since our inception. As of March 31, 2006 we had an accumulated deficit of $64.3 million. We have historically financed our operations principally through the private placement of shares of our common and preferred stock, convertible notes and government grants. During the years ended December 31, 2003, 2004 and 2005, the quarters ended March 31, 2005 and 2006, and the period from October 7, 1999 (inception) to March 31, 2006, we received net proceeds of approximately $1.8 million, $5.0 million, $17.9 million, $5.5 million, $4,100 and $33.7 million, respectively, from the issuance of shares of our common and preferred stock and convertible notes. These amounts do not include the $15.0 million secured promissory note and $4.0 million of Series E preferred stock that we issued as partial consideration for an asset acquisition in September 2005, the $15.0 million secured promissory note that we issued to acquire Abbokinase and related assets in April 2006 and the approximately $13.0 million, net of expenses, that we received from the sale of Series F preferred stock in April and May 2006. At March 31, 2006, we had $6.3 million in cash and cash equivalents. In April and May 2006, we received net proceeds of approximately $13.0 million from a private placement of our Series F preferred stock. A portion of the proceeds of that offering was used to enable us to close our acquisition of Abbokinase, which required a payment of $5.0 million in cash at closing. We intend to begin selling Abbokinase in the second half of 2006, although the exact timing of commencement of these efforts will depend on a number of external factors, such as our ability to establish new sales relationships with current wholesalers and customers for that product, inventory levels of the wholesalers that are currently stocking the product and other competitive and regulatory factors. Based on annualized Intercontinental Marketing Services, or IMS, sales data, we believe the inventory that we acquired represents approximately a four-year supply. Based on current stability data, approximately 75% of this inventory will expire by September 2007 with the remainder expiring at various times up to August 2009. We do not expect to sell the entire inventory we acquired before the product expires, and we are not permitted to sell this inventory after expiration. If the expiration dates of

Table of Contents

this inventory are extended we will need to re-brand the remaining inventory because our license to use the Abbokinase trademark does not extend beyond the current inventory expiration dates.
We allocated the $20 million purchase price for Abbokinase as follows:

Asset	Estimated Value
Inventory	$ 16.7 million
Identifiable Intangibles	$ 3.3 million

The estimated useful life of the identifiable intangibles is 4 years. While we intend to investigate the requirements for us to manufacture Abbokinase, we currently have no plans to manufacture Abbokinase in the near term. Not manufacturing Abbokinase reduces the period of benefit to the Company to four years, which is directly related to the years of inventory supply.

Cash Flows

Net Cash Used in Operating Activities. Net cash used in operating activities was approximately $3.0 million, $4.1 million and $11.2 million for the years ended December 31, 2003, 2004 and 2005, respectively, and approximately $743,000 and $2.0 million for the quarters ended March 31, 2005 and 2006, respectively. The net cash used in each of these periods primarily reflects the net loss for those periods, offset in part by depreciation, amortization of warrant expense and debt discount, stock-based compensation and changes in working capital.
Net Cash Used in Investing Activities. Net cash used in investing activities was approximately $16,000, $65,000 and $564,000 for the years ended December 31, 2003, 2004 and 2005, respectively, and approximately $301,000 and $198,000 for the quarters ended March 31, 2005 and 2006, respectively. Net cash used in investing activities primarily reflects purchases of property and equipment, including manufacturing, information technology, laboratory and office equipment.
Net Cash Provided by Financing Activities. Net cash provided by financing activities was approximately $1.6 million, $5.0 million and $18.7 million for the years ended December 31, 2003, 2004 and 2005, respectively, and approximately $5.5 million and $4,100 for the quarters ended March 31, 2005 and 2006, respectively. Net cash provided by financing activities was primarily attributable to the issuance of Series D preferred stock, totaling $350,000 net of issuance costs and the issuance of convertible notes totaling $1.4 million in 2003; the issuance of common stock totaling $4.4 million net of issuance costs and the issuance of convertible notes totaling $600,000 in 2004; the issuance of common stock totaling $17.9 million net of issuance costs and the issuance and repayment of secured promissory notes totaling $4.0 million in 2005.
Our cash flows for the remainder of 2006 and beyond will depend on a variety of factors, including the anticipated revenue and funding requirements discussed above, as well as the timing of completion of the offering contemplated by this prospectus and our use of offering proceeds as described under Use of Proceeds elsewhere in this prospectus. Despite our anticipated commencement of sales of our Abbokinase product during the second half of 2006, we expect our net cash outflows to continue increasing as we expand our research and development, manufacturing, regulatory and sales and marketing activities.

Funding Requirements

Based on our existing liquid assets, including the proceeds of our recently concluded offering of Series F preferred stock, we believe we have sufficient capital to fund anticipated levels of operations, and pay our debt obligations as they come due, until December 2006. We have received an audit report from our independent registered public accounting firm containing an explanatory paragraph stating that our historical recurring losses and net capital deficiency raise substantial doubt about our ability to continue as a going concern. We believe that the successful completion of this offering will enable us to continue as a going concern at least in the near term. If we are unable to successfully complete this offering, we will need to obtain alternative financing and modify our operational plan to continue as a going concern.

Table of Contents

Our funding requirements will, however, depend on numerous factors, including:

- the timing, scope and results of our preclinical studies and clinical trials;
- the timing of initiation of manufacturing for our product candidates;
- the timing and amount of revenue from sales of Abbokinase;
- the timing and amount of revenue;
- the timing of, and the costs involved in, obtaining regulatory approvals;
- our ability to establish and maintain collaborative relationships;
- personnel, facilities and equipment requirements; and
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs, if any, and the result of any such litigation.

Until we can generate significant cash from our operations, we expect to continue to fund our operations primarily from the proceeds of offerings of our equity securities, including this offering, from revenue or payments received under collaborations, grants, and possibly from debt financing. However, we may not be successful in obtaining additional collaboration agreements or grants, or in receiving milestone or royalty payments under any such agreements. If we do not generate sufficient revenue from collaborations and grants, we may require additional funding sooner than we currently anticipate. 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, financing will be obtained on terms favorable to us or our stockholders. Having insufficient funds may require us to delay, scale back or eliminate some or all of our research or development programs or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Failure to obtain adequate financing may also adversely affect our ability to operate as a going concern. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders will likely result. If we raise additional funds by incurring debt obligations, the terms of the debt will likely involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

Contractual Obligations

The following table summarizes our outstanding contractual obligations as of December 31, 2005:

		Payments Due By Period			
Total	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
Operating leases	$ 182,546	$ 64,428	$ 118,118		

Total	$ 182,546	$ 64,428	$ 118,118

The contractual summary above does not reflect a total of $30.0 million of debt represented by two $15.0 million secured promissory notes accruing interest at 6% annually and due on December 31, 2006 and 2007, respectively. We enter into agreements with clinical sites and contract research organizations, or CROs, that conduct our clinical trials. We make payments to these sites and CROs based upon the number of patients enrolled. For the years ended December 31, 2003, 2004 and 2005, we incurred clinical trial expenses of approximately $49,000, $334,000 and $892,000, and for the quarters ended March 31, 2005 and 2006, we incurred clinical trial expenses of approximately $319,000, and $463,000, respectively. Due to the variability associated with these agreements, we are unable to estimate with certainty the future patient enrollment costs we will incur and therefore have excluded these costs from the above table. We do, however, anticipate that these costs will increase significantly in future periods as a result of our initiation of multiple clinical trials for ischemic

Table of Contents

stroke. We also have contractual payment obligations that are contingent on future events. In addition, if we or our sublicensees sell products or processes that utilize the intellectual property we license from UNEMED Corporation, we will be obligated pay a royalty to UNEMED of 2% of such net sales. The UNEMED license also requires us to meet certain regulatory and product development milestones. If we or our sublicensees sell products or processes that utilize the intellectual property we license from the University of Arkansas, we will be obligated to pay, in addition to a one-time fee of $25,000, royalties to the University of Arkansas of (i) 4% of net sales up to $1 million; (ii) 3% of net sales between $1 million and $10 million; and (iii) 2% of net sales greater than $10 million, subject to minimal royalty thresholds and a maximum aggregate royalty of $20 million. If we or our sublicensees sell products or processes that utilize the intellectual property that we license from Dr. Schlief, we will be obligated to pay a royalty to Dr. Schlief of 2% of such net sales by us and 3% of any net sales by sublicensees.

Quantitative and Qualitative Disclosure About Market Risk

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

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

Off-Balance Sheet Transactions

At December 31, 2003, 2004 and 2005, and at March 31, 2006, 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 December 2004, the Financial Accounting Standards Board, or FASB, issued SFAS 153, *Exchanges of Nonmonetary Assets*, which is an amendment to APB 29, *Accounting for Nonmonetary Transactions*. SFAS 153 eliminates certain differences in the guidance in APB 29 as compared to the guidance contained in standards issued by the International Accounting Standards Board. The amendment to APB 29 eliminates the fair value exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. Such an exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS 153 is effective for nonmonetary asset exchanges occurring in periods beginning after June 15, 2005. Management does not expect adoption of SFAS 153 to have a material impact on our financial statements.

In May 2005, the FASB issued SFAS 154, *Accounting Changes and Error Corrections A Replacement of APB Opinion No. 20 and FASB Statement No. 3*. SFAS 154 requires the retrospective application to prior periods financial statements of changes in accounting principle, unless it is impractical to determine either the period-specific effects or cumulative effect of the accounting change. SFAS 154 also requires that a change in depreciation, amortization, or depletion method for long-lived non-financial assets be accounted for as a change in accounting estimate affected by a change in accounting principle. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005 and we will adopt this provision, as applicable, during 2006.

Table of Contents

In November 2005, the FASB issued FASB Staff Position, or FSP, Financial Accounting Standard, or FAS, 115-1 and FAS, 124-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*, which provides guidance on determining when investments in certain debt and equity securities are considered impaired, whether that impairment is other-than-temporary, and on measuring such impairment loss. FSP 115-1 also includes accounting considerations subsequent to the recognition of other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. We are required to apply FSP 115-1 to reporting periods beginning after December 15, 2005 and to adopt FSP 115-1 in the first quarter of fiscal 2006. We are currently evaluating the effect that the adoption of FSP 115-1 will have on our consolidated results of operations and financial condition but do not expect it to have a material impact.

Table of Contents

Our Business

Overview

We are a biopharmaceutical company developing and commercializing innovative therapies for vascular disorders associated with blood clots. Our development efforts are primarily focused on therapies for treating ischemic stroke and massive pulmonary embolism by restoring the flow of blood and oxygen to the brain and vital tissues, and clearing occluded catheters. Over eight million patients in the U.S. are afflicted each year with these and other complications related to blood clots, yet available treatment options are subject to significant therapeutic limitations. For example, the most widely used treatment for ischemic stroke can be administered only during a narrow time window and poses a risk of bleeding, resulting in less than 6% of ischemic stroke patients receiving treatment. We believe our products and clinical development programs, including two product candidates with Phase 3 clinical trial data and one product approved for marketing, may address significant unmet needs in these markets.

We are pursuing two development programs as the foundation for our products. The first program is a group of clot-dissolving drugs, or thrombolytics, that are variants of urokinase, a natural human protein primarily produced in the kidneys that stimulates the body s natural clot-dissolving processes. The second program, SonoLysis therapy, centers on a novel treatment that breaks blood clots apart by applying ultrasound to submicron-sized bubbles, which we call SonoLysis bubbles. We believe these therapeutic approaches can be used either alone or in combination to treat ischemic stroke and a broad variety of vascular disorders associated with blood clots, and may expand the number of patients for whom safe and effective clot-dissolving therapies are available.

We have a broad portfolio of product candidates to treat ischemic stroke that is aimed at expanding the number of patients eligible for treatment. We believe our ischemic stroke product portfolio may have advantages related to safety, time to market, expanded window of administration, faster initiation of treatment, speed of restoration of blood flow and the ability to address multiple physician groups. Our ischemic stroke product portfolio consists of:

PROLYSE, one of our proprietary thrombolytics;

SonoLysis therapy, our proprietary SonoLysis bubbles with ultrasound; and

SonoLysis combination therapy, our SonoLysis bubbles with ultrasound and a thrombolytic.

PROLYSE is a recombinant pro-urokinase, or a pro-drug form of urokinase that we believe, based on a number of published third-party scientific studies, does not become active until it reaches a blood clot, which may reduce the risk of bleeding. Like other thrombolytics, the administration of PROLYSE involves a risk of bleeding complications. PROLYSE has been shown in a Phase 3 clinical trial of 180 patients conducted by Abbott Laboratories between 1996 and 1998 to be well tolerated and to demonstrate activity in dissolving cerebral blood clots when administered as long as six hours after the onset of stroke symptoms. This treatment window is twice as long as the three-hour restriction that the U.S. Food and Drug Administration, or FDA, has imposed on alteplase, or tPA, the only thrombolytic approved for use in ischemic stroke patients. In addition, we believe there is an emerging trend to use device-based, or interventional, therapy delivered directly to the site of the blood clot in treating ischemic stroke. We believe PROLYSE may become the first thrombolytic approved for intra-arterial therapy for treating ischemic stroke. We are planning to initiate an additional Phase 3 clinical trial of the use of PROLYSE delivered intra-arterially directly to the site of a blood clot for ischemic stroke in 2007. We plan to request that the FDA allow us to use the preclinical study and clinical trial data generated by Abbott Laboratories PROLYSE preclinical studies and clinical trials in support of our eventual application to obtain regulatory approval for the use of PROLYSE for ischemic stroke, as well as for the combination of PROLYSE and SonoLysis therapy to clear blood clots in patients with ischemic stroke. We cannot be certain that the FDA will allow us to use that data in support of further clinical studies or our application for approval.

SonoLysis therapy is the combination of SonoLysis bubbles and ultrasound that we believe breaks up blood clots via a mechanical mechanism of action. Because SonoLysis therapy does not include a thrombolytic and

Table of Contents

its associated risk of bleeding, we believe SonoLysis therapy may offer several advantages over other treatments for ischemic stroke, including an extended treatment window, rapid initiation of treatment via intravenous administration and availability for use in patients for whom thrombolytics are contraindicated due to risk of bleeding. We are planning to initiate a Phase 1/2 dose-escalation clinical trial to study the safety and efficacy of SonoLysis therapy as a treatment for ischemic stroke in the first half of 2007.

SonoLysis combination therapy is SonoLysis therapy in conjunction with a thrombolytic. We believe that SonoLysis combination therapy incorporates complementary mechanisms of action that will both reduce the time required to dissolve a blood clot and enable a lower dose of thrombolytic to be used. In addition, we believe a lower dose of thrombolytic will reduce the risk of bleeding and extend the current treatment window beyond that of a thrombolytic alone for ischemic stroke patients. We are currently conducting a Phase 2 proof of concept clinical trial using FDA-approved diagnostic bubbles, ultrasound and tPA to expand upon the prior work of academic investigators in this area. We are planning to initiate a Phase 1/2 dose-escalation clinical trial in the second half of 2006 using our SonoLysis therapy and tPA. If that clinical trial is successful, we intend to conduct future clinical trials utilizing our SonoLysis therapy and PROLYSE.

In addition to our product candidates for ischemic stroke, we recently acquired Abbokinase, a form of urokinase that is marketed for the treatment of acute massive pulmonary embolism. We intend to begin selling Abbokinase in the second half of 2006. Abbokinase sales will provide us with near-term revenue, an opportunity to form sales relationships with vascular physicians and acute care institutions that regularly administer blood clot therapies and a commercialization infrastructure that we believe can grow to support our future products.

Open-Cath-R, another form of urokinase we acquired in 2005, has been shown in two Phase 3 multinational clinical trials conducted by Abbott Laboratories prior to 2003 to be well tolerated and active as a treatment for clearing blocked intravascular catheters. We are investigating the remaining regulatory and manufacturing requirements and the opportunity to license Open-Cath-R to a third party. We cannot be certain that the FDA will allow us to use the data generated by Abbott Laboratories clinical trials in support of our application to obtain regulatory approval of Open-Cath-R.

We acquired PROLYSE, Open-Cath-R and Abbokinase from Abbott Laboratories. In connection with these acquisitions, we issued a $15.0 million promissory note that matures in December 2006 and another $15.0 million promissory note that matures in December 2007. If we are unable to satisfy these debt obligations when due, Abbott Laboratories will have a right to reclaim the assets and our rights relating to PROLYSE, and Open-Cath-R in the case of the December 2006 promissory note, and Abbokinase, including a portion of the cash from our sales of Abbokinase in the case of the December 2007 promissory note.

The following table summarizes our product candidates and their current development status:

Indication	Product Candidate	Product Elements	Development Status
Ischemic Stroke	PROLYSE	Recombinant pro-urokinase	Completed one Phase 3 clinical trial
	SonoLysis therapy	SonoLysis bubbles and ultrasound	Preclinical
	SonoLysis combination therapy	SonoLysis bubbles, ultrasound and a thrombolytic	Preclinical[1]; ongoing Phase 2 proof of concept clinical trial using FDA-approved diagnostic bubbles and the thrombolytic tPA
Acute Massive Pulmonary Embolism	Abbokinase	Tissue-culture urokinase	Approved for marketing
	Open-Cath-R	Recombinant urokinase	Completed two Phase 3 clinical trials

Catheter
Clearance

(1) We have an approved investigational new drug application, or IND, for a Phase 1/2 dose escalation clinical trial using SonoLysis bubbles for which we intend to start enrolling patients in the second half of 2006.

Table of Contents

Business Strategy

Our goal is to become the leading provider of innovative therapies for vascular disorders associated with blood clots. The key elements of our business strategy are to:

Expand the number of patients eligible for treatment by developing and commercializing our portfolio of ischemic stroke product candidates. We are focused on further developing our ischemic stroke product portfolio that includes PROLYSE, SonoLysis therapy and SonoLysis combination therapy. We believe these product candidates may address significant unmet medical needs and expand the number of patients eligible for treatment. We believe our product candidates may lengthen the treatment window beyond three hours, treat patients contraindicated for thrombolytic therapy, shorten the time required to restore blood flow and provide both interventional and intravenous treatment options.

Capitalize on near-term revenue opportunities and develop an initial commercial infrastructure. In the second half of 2006, we intend to begin selling Abbokinase. We are also clarifying the regulatory and manufacturing requirements and investigating possible licensing opportunities related to Open-Cath-R. We believe that these late-stage product opportunities will provide us with a source of revenue that will help fund our development programs and allow us to broaden our domestic sales and marketing efforts. If we are successful in obtaining FDA approval to commercialize our portfolio of ischemic stroke product candidates, we plan to build on the sales relationships that we form with vascular physicians and acute care institutions through our Abbokinase sales and marketing program.

Leverage our product candidates to address additional vascular indications. We intend to explore using our core thrombolytic and SonoLysis bubble product candidates in other potential indications. We believe PROLYSE may be well suited for intravenous administration as a treatment for sub-massive pulmonary embolism. In addition, we plan to explore further developing Abbokinase or Open-Cath-R for the prevention of catheter occlusion. For example, Abbokinase demonstrated activity in a Phase 3 clinical trial in preventing catheter occlusions as compared to heparin. In addition, we believe that opportunities exist for the expansion of our SonoLysis combination therapy for the treatment of myocardial infarction, peripheral arterial occlusion and deep vein thrombosis.

Expand the use of our bubble technology to create a deep pipeline with broad therapeutic applications. We believe that our bubble technology could be adapted, by changing the composition and size of the bubbles, to a variety of applications that involve the delivery of gases such as oxygen or nitric oxide, drugs or genetic materials, either systemically or to targeted sites in the body. We have conducted preclinical studies relating to the delivery of oxygen using a proprietary bubble formulation that we call $NanO_2$. We intend to further investigate the potential use of our $NanO_2$ as an oxygen-delivery agent to help preserve tissues that are at risk due to blood clots in ischemic stroke, myocardial infarction and other ischemic indications. Separately, we are researching other classes of bubbles that could be used to deliver drugs to targeted cells and remove vulnerable plaque. Further, these various classes of bubbles may be applicable in neurovascular and oncology indications, as well as additional cardiovascular disorders.

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. An embolism occurs if all or part of the thrombus breaks away and lodges in another part of the body. 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. 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, tissue damage, stroke or even death. 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.

We are initially targeting three segments of the thrombosis market in which safe and rapid removal of blood clots is essential for patient care, including ischemic stroke, pulmonary embolism and catheter occlusion.

Table of Contents

Ischemic Stroke

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 people each year in the U.S. have an ischemic stroke. Stroke is the third leading cause of death and the leading cause of serious long-term disability in the U.S., according to the American Stroke Association. Approximately 80% of U.S. ischemic stroke patients reach an emergency room within 24 hours after the onset of stroke symptoms, according to Datamonitor. In contrast, only approximately 23% 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, according to Datamonitor. However, due to the three-hour treatment window and other limitations, according to Datamonitor only 1.6% to 2.7% of patients with ischemic stroke treated in community hospitals and 4.1% to 6.3% treated in academic hospitals or specialized stroke centers currently are treated with a thrombolytic.

There are two emerging trends in ischemic stroke therapy: interventional therapy with a catheter and intravenous administration of a drug. Interventional therapy requires specialized facilities and trained personnel that enables localized treatment at the site of the clot. Intravenous administration can be initiated more quickly, such as in the emergency room, but it is not a therapeutic approach targeted directly to the site of the blood clot.

Pulmonary Embolism

Blood clots that lodge in the lungs are called pulmonary emboli and occur in approximately 600,000 people in the U.S. every year. A portion of these are classified as massive pulmonary emboli, meaning the obstruction of blood flow to a lobe or multiple segments which result in nearly 60,000 deaths in the U.S. annually. Massive pulmonary emboli must be treated quickly, as most of these deaths occur within 30 to 60 minutes after the onset of symptoms.

Catheter Occlusion

The formation of a blood clot within or around an indwelling vascular catheter can cause a condition known as catheter occlusion. Over five million intravascular catheters are placed in patients, and approximately 750,000 of those become occluded by blood clots, in the U.S. annually.

Existing Blood Clot Therapies and Their Limitations

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.

Thrombolytics

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

Table of Contents

Thrombolytics involve a variety of identified risks and potential side effects that can limit their usefulness:

Risk of Bleeding Thrombolytics 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 thrombolytics. 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 thrombolytics, due to the increased difficulty of controlling bleeding. As such, thrombolytics approved by the FDA are 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 23% of ischemic stroke patients in the U.S. recognize their symptoms and reach an emergency room within the three-hour window, however, due to this and other limitations, only between 10.4% to 18.8% of these patients ultimately receive treatment with a thrombolytic.

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

Mechanical Devices and Procedures

There are several mechanical means for removing or destroying blood clots. Thrombectomy, or surgical clot removal, is used to treat patients with occluded dialysis grafts or some clots in the peripheral vascular system. These procedures are invasive and entail delays, costs and risks that accompany any major surgery. Although these procedures are less suitable for removing blood clots from the brain, there are devices approved for these 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 therapy. While they do not cause the same bleeding risk as thrombolytics, 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.

Our Development Programs and Product Candidates

We are pursuing two development programs as our foundation for treatments of vascular disorders associated with blood clots: our urokinase-based thrombolytics and our proprietary bubble technology.

Urokinase-based Thrombolytic Programs

Our thrombolytic product and product candidates are based on urokinase, a natural human protein primarily produced in the kidneys that stimulates the body s natural clot-dissolving processes. Urokinase breaks up blood clots by converting plasminogen, the inactive precursor, into the enzyme plasmin, which in turn degrades fibrin protein strands that are essential to the structural integrity of a clot. We have acquired three different proprietary forms of urokinase-based drugs from Abbott Laboratories: recombinant pro-urokinase (PROLYSE), which is in development for the treatment of patients with ischemic stroke; tissue culture urokinase (Abbokinase), which is approved for the treatment of acute massive pulmonary embolism; and recombinant urokinase (Open-Cath-R), which is in development for the treatment of patients with catheter occlusions. A pro-drug is an inactive compound or molecule that is converted in the body to an active drug either by spontaneous chemical reactions or enzymatic processes. As a pro-drug, PROLYSE is an inactive form of urokinase that we believe converts to its active form only after it has reached a blood clot. Once

Table of Contents

activated by coming into contact with the fibrin in the blood clot, PROLYSE works in the same manner as other forms of urokinase to dissolve the clot. Recombinant urokinase is substantially equivalent in overall structure and function to tissue culture urokinase, but is manufactured using a recombinant technology, meaning that it is genetically engineered rather than derived from a human tissue culture process.

Bubble Technology Program

Our proprietary bubbles are biocompatible spheres of varying size and composition that we believe could be injected into the bloodstream to treat a variety of vascular disorders and other therapeutic applications. We believe our bubble technology could be adapted, by changing their composition and size, for a variety of applications that involve the delivery of gases such as oxygen or nitric oxide, drugs or genetic materials, either systemically or to selected sites in the body. Certain bubbles, such as those designed to break up clots or as a drug delivery technology, are designed to be energized by ultrasound. Conversely, other bubbles may not require an energy source and could be used to deliver oxygen or drugs. Our current focus is on the development of our proprietary SonoLysis bubbles to dissolve blood clots in combination with ultrasound.

Our scientific team previously developed Definity®, a microbubble product that has been administered safely as a diagnostic ultrasound contrast agent since it received regulatory approval in 2001. Our proprietary SonoLysis bubbles are similar in composition to Definity microbubbles, which we believe may improve the prospects for acceptance of our SonoLysis bubbles by physicians, regulators, health care providers and third-party payors. We have designed our SonoLysis bubbles with a proprietary formulation for use as a therapeutic agent. We believe the small size of our SonoLysis bubbles allows them to penetrate and disperse within a blood clot, so that their cavitation will break the clot into very small particles, which we believe reduces the risk that an embolism may occur downstream from the original blood clot. In addition, we have developed a proprietary SonoLysis bubble manufacturing process that we believe enables us to reliably and cost-effectively create sterile and stable sub-micron sized bubbles from a suspension of lipid nanoparticles. We believe our manufacturing know-how enables us to create bubble product candidates having unique and useful characteristics such as a defined size distribution, increased functionality and batch-to-batch consistency.

Our Product Candidates for Treatment of Ischemic Stroke

PROLYSE

PROLYSE is recombinant pro-urokinase that we are developing for the treatment of ischemic stroke. We acquired PROLYSE from Abbott Laboratories in September 2005.

Prior Clinical Trials

Following four Phase 1 clinical trials between 1990 and 1995 in which Abbott Laboratories studied the safety of PROLYSE, Abbott Laboratories evaluated PROLYSE delivered intra-arterially to treat ischemic stroke in two Phase 2 clinical trials between 1994 and 1998, involving a total of 220 patients, including a randomized 180-patient Phase 3 clinical trial. The first clinical trial, known as the PROACT trial, was a randomized, double-blind Phase 2 clinical trial in 40 patients that evaluated the safety and recanalization efficacy, or restored blood flow, of PROLYSE versus placebo administered within six hours of onset of stroke symptoms. This clinical trial evaluated patients with ischemic stroke caused by a middle cerebral artery occlusion, the most frequent site of arterial occlusion in patients with severe stroke presenting within six hours. The median time from onset of symptoms to treatment was 5.5 hours in this clinical trial. Of the 40 patients, 26 received PROLYSE plus heparin, a widely used anticoagulant, and the control group of 14 received heparin only. The primary efficacy endpoint was the percentage of patients who had partial or complete recanalization of the blocked artery two hours after receiving treatment. The trial showed that 57% of the patients who received PROLYSE plus heparin had partial or complete recanalization after two hours, compared to 14% of the patients who received heparin alone. This difference was statistically significant, with a p-value of 0.017. A p-value measures the likelihood that a difference between the investigational and control groups is due to random chance. A p-value of less than or equal to 0.05 means the chance that the difference is due to random chance is less than 5.0%, and is a commonly accepted threshold for denoting a meaningful difference between

investigational and control groups. The primary measure of safety was intracranial hemorrhage with clinical deterioration, which occurred in 15% of PROLYSE patients and 7% of placebo patients. Although the participating investigators concluded that symptomatic hemorrhage was a concern, there was not a statistically significant difference between patients treated with PROLYSE and placebo patients with a p-value of 0.64. Both recanalization and hemorrhage frequencies were influenced by heparin dose.

The second clinical trial, known as the PROACT II trial, was conducted by Abbott Laboratories between 1996 and 1998. The PROACT II trial was a randomized Phase 3 clinical trial in 180 patients that evaluated the clinical efficacy and safety of PROLYSE versus placebo administered within six hours of onset of stroke symptoms. This clinical trial evaluated patients with ischemic stroke caused by a middle cerebral artery occlusion. Of the 180 patients, 121 received PROLYSE plus heparin and the control group of 59 patients received heparin only, in each case administered intravenously. The median time from onset of symptoms to treatment was 5.3 hours in this clinical trial. The primary clinical efficacy endpoint was an assessment at 90 days of patients modified Rankin score, a clinically-accepted test for assessing neurological functioning in stroke patients, wherein a score of two or less signifies slight or no neurological disability. Of the patients who received PROLYSE plus heparin, 40% had a modified Rankin score of two or less at the 90-day follow up, compared to 25% of the patients in the control group. This difference was statistically significant, with a p-value of 0.04.

Secondary outcomes measured in the PROACT II trial included recanalization, the frequency of intracranial hemorrhage with neurological deterioration and mortality. Of the patients who received PROLYSE plus heparin, 66% had partial or complete recanalization after two hours, compared to 18% of the patients who received heparin alone. This difference was statistically significant, with a p-value of less than 0.001. Of the patients treated with PROLYSE in the PROACT II trial, 10% experienced intracranial hemorrhage with clinical deterioration within 24 hours following treatment, as compared to 2% of the control group. This difference was not statistically significant, with a p-value of 0.06. We believe the rate of hemorrhage seen with PROLYSE may be due to the severe nature of the strokes in the PROACT II trial patients, with a median baseline NIH Stroke Scale, or NIHSS. NIHSS is a scale used to determine the level of disability of a patient following a stroke, ranging from 0 to 22+, with a score of 2 or less indicating minimal neurological deficit, and a score of 20 or more indicating severe neurological deficit. Two other secondary outcomes measured in the PROACT II trial did not show statistically significant differences between the investigational and control groups. The first of these is the ability of patients to live at home without assistance at 90 days after treatment, or the Barthel index. The second of these measured patients degree of neurological damage based on the NIHSS. Mortality was 25% for the PROLYSE group and 27% for the control group. This difference was not statistically significant, with a p-value of 0.80. However, the PROACT II trial demonstrated that ischemic stroke patients treated with PROLYSE plus heparin within six hours of the onset of stroke symptoms had a statistically significantly higher probability of avoiding moderate or severe neurological disabilities after 90 days when compared with patients treated with only heparin. The participating investigators concluded that the PROACT II trial has demonstrated the therapeutic window for a significant number of patients with major ischemic stroke may extend to at least six hours. We intend to use the results of the PROACT II trial to conduct additional trials refining patient selection, with a goal of reducing the risk of hemorrhage, optimizing delivery techniques and combining treatment strategies to build on these results.

Table of Contents

The following table illustrates the results of the PROACT and PROACT II clinical trials:

Clinical Trial	Total Patients in Clinical Trial	Patients Receiving PROLYSE + Heparin	Patients Receiving Heparin (control)	Primary and Selected Secondary Endpoints	PROLYSE Therapy	Control	P-value
PROACT	40	26	14	Recanalization (%) at 2 hours[1]	57%	14%	0.017
				Intracranial Hemorrhage (%) at 24 hours [1]	15%	7%	0.64
PROACT II	180	121	59	Modified Rankin Score≤ 2 at 90 days [1]	40%	25%	0.04
				Recanalization (%) at 2 hours	66%	18%	0.001
				Intracranial Hemorrhage (%) at 24 hours	10%	2%	0.06
				Mortality at 90 days	25%	27%	0.80
				Barthel Index≥ 90 at 90 days	41%	32%	0.24
				NIHSS Score≤ 2 at 90 days	18%	12%	0.30

(1) Primary endpoints.

Including the PROACT and PROACT II trials, PROLYSE has been studied in eight clinical trials where 480 patients were treated with acute ischemic stoke, peripheral arterial occlusion, acute myocardial infarction or occluded dialysis access grafts. Safety data for thrombolytics are generally broken into two categories, bleeding complications and non-hemorrhagic adverse events. PROLYSE has been shown to have bleeding complications similar to other thrombolytics, including superficial or surface bleeding, observed mainly at invaded or disturbed sites, as well as internal bleeding, involving the gastrointestinal tract, genital/urinary tract, or intramuscular, retroperitoneal, or intracranial sites. A wide array of treatment-emergent non-hemorrhagic adverse events were noted in PROLYSE subjects, including back pain, injection site hemorrhage, fever, injection site pain, peripheral vascular disorder and anemia. Some of these treatment-related effects were also seen in control subjects and may not have been related to treatment with PROLYSE. At the request of Abbott Laboratories, in August 2003 the FDA placed the IND for PROLYSE in the FDA s inactive files, and all clinical investigations of PROLYSE ceased.

Competitive Advantages

We believe that PROLYSE may be less likely than other marketed thrombolytics to cause bleeding as it circulates through the bloodstream, because it is an inactive form of urokinase that we believe becomes active only after it comes into contact with a blood clot. Because of its pro-drug nature, we also believe that PROLYSE may be safely administered within a longer window of time after an ischemic stroke. The PROACT II clinical trial demonstrated that ischemic stroke patients treated with PROLYSE in conjunction with an anticoagulant within six hours of the onset of stroke symptoms had a statistically significant higher probability of avoiding moderate or severe neurological disabilities after 90 days when compared with patients treated with only the anticoagulant. This six-hour treatment window is twice as long as the three-hour label claim permitted for tPA, the only thrombolytic currently approved by the FDA for treatment of ischemic stroke. This three-hour window is considered to be one of the primary limiting factors in currently available treatments for acute ischemic stroke. According to Datamonitor, approximately 47% of U.S. ischemic stroke patients reach an emergency room within six hours after onset of symptoms. We believe there is a significant unmet need for safe and effective therapies that can be used in an extended window of administration. We believe PROLYSE may become the first thrombolytic approved for intra-arterial therapy for treating ischemic stroke during a treatment window longer than three hours after the onset of symptoms.

Planned Clinical Development

We believe that the FDA will require at least a second Phase 3 clinical trial be conducted to confirm the safety and efficacy of PROLYSE in improving clinical outcomes in ischemic stroke patients. We are planning to initiate an additional Phase 3 clinical trial using PROLYSE for ischemic stroke in 2007. The FDA has been

Table of Contents

notified of our acquisition of PROLYSE. We plan to request that the FDA allow us to use the preclinical testing and clinical trial data generated by Abbott Laboratories PROLYSE clinical trials in support of our eventual application to obtain regulatory approval for the use of PROLYSE for ischemic stroke, as well as for the combination of PROLYSE and SonoLysis therapy to clear blood clots in patients with ischemic stroke. The PROLYSE clinical trials were conducted with drug substance produced by Abbott Laboratories at its manufacturing facility using Abbott Laboratories original manufacturing process. We intend to manufacture PROLYSE at a different facility through a contract manufacturer. In addition, we intend to improve the manufacturing process for PROLYSE and update it to more current good manufacturing practices. To use the preclinical study and clinical trial data generated by Abbott Laboratories in support of our applications for regulatory approval, we will be required to show that the drug substance produced by our contract manufacturer using our improved manufacturing process is comparable to the drug substance produced previously by Abbott Laboratories. We cannot be certain that we will be able to show that the drug substance we produce is comparable to the drug substance used in prior tests and clinical trials, and, as a result, we cannot be certain that the FDA will allow us to use that preclinical testing and clinical trial data in support of further clinical studies or our application for approval.

SonoLysis Therapy

SonoLysis therapy is a process for breaking up blood clots, which we believe occurs by means of mechanical action resulting from the application of ultrasound to our proprietary SonoLysis bubbles. To administer this therapy, SonoLysis bubbles are injected intravenously into the bloodstream, disperse naturally throughout the body and are carried to the site of the blood clot. Our SonoLysis bubbles, predominantly submicron in size, are composed of a lipid shell and an inert biocompatible gas. We believe that the small size of our SonoLysis bubbles enables them to penetrate into the clot. Ultrasound is then administered to the site of the blood clot, and the energy from the ultrasound causes the SonoLysis bubbles to expand and contract vigorously, or cavitate, and then collapse, mechanically breaking up the blood clot. The gas released by the SonoLysis bubbles is then cleared from the body by exhaling, and the lipid shell is processed like other fats in the body. We believe that the ability of our proprietary SonoLysis bubbles to penetrate and break up blood clots, and their activity whether administered with or without a thrombolytic, will make them suitable for use in the treatment of ischemic stroke patients with limited treatment options.

Competitive Advantages

We believe SonoLysis therapy represents a new approach to the treatment of ischemic stroke. Recent studies have shown that nearly 25% of ischemic stroke victims still have at-risk but viable brain tissue as long as 24 hours after onset of stroke symptoms. We believe that SonoLysis therapy breaks-up blood clots via a mechanical mechanism of action. Because SonoLysis therapy does not include a thrombolytic and its associated risk of bleeding, we believe SonoLysis therapy may offer several advantages over other treatments for ischemic stroke, including an extended treatment window, rapid initiation of treatment via intravenous administration and availability for use in patients for whom thrombolytics are contraindicated due to risk of bleeding. This unique treatment approach could enable us to offer an effective therapy to stroke patients with fewer risks and restrictions, such as bleeding and narrow time window for application, than those associated with thrombolytic drugs, thus potentially affording a treatment option to many more patients than can be treated with thrombolytics today. Furthermore, since SonoLysis bubbles can be administered intravenously, the treatment does not require a catheter laboratory or personnel with highly specialized skills to administer the therapy. In addition to these therapeutic and administration advantages, we believe that the competitive position of SonoLysis therapy will be aided by our broad portfolio of issued patents, patent applications and exclusive licenses relating to the use of bubbles and ultrasound for treatment of blood clots in various parts of the body.

Planned Clinical Development

We have not yet conducted any clinical trials using our proprietary SonoLysis bubbles with ultrasound to treat blood clot indications. However, we conducted a 23-patient proof of concept clinical trial that applied ultrasound to Definity microbubbles as a means for breaking up blood clots in thrombosed dialysis grafts.

Table of Contents

This clinical trial demonstrated improved restoration of blood flow based on imaging, and there was one adverse event reported, involving moderate bleeding and oozing at an unspecified site, that may have been related to the treatment. All other adverse events were determined to be unrelated to the treatment. Based on our research to date, we intend to develop SonoLysis therapy as a stand-alone therapy for ischemic stroke patients, including those for whom treatment with thrombolytics may be contraindicated. SonoLysis therapy has been designated as a combination product for review as both a drug and a device by the FDA, and has been assigned to the Center for Devices and Radiological Health as the lead center for review. Based on our discussions with the FDA, we plan to submit an investigational device exemption, or IDE, in the second half of 2006 in order to conduct a Phase 1/2 clinical trial to study the tolerability and activity of our proprietary SonoLysis bubbles in combination with ultrasound to treat ischemic stroke. Such a trial would be designed as a dose-ranging clinical trial, with the primary purpose of demonstrating the tolerability of SonoLysis bubbles with ultrasound in the treatment of ischemic stroke.

SonoLysis Combination Therapy

We plan to combine product candidates from both of our development programs, SonoLysis therapy and our thrombolytics, for the treatment of ischemic stroke. We believe that, due to their complementary mechanisms of action, a combination treatment using our SonoLysis therapy and a thrombolytic may shorten the time required to dissolve a blood clot, enable a lower dose of thrombolytic to be used, reduce the risk of bleeding and extend the treatment window for ischemic stroke patients.

Prior Clinical Trials

An independent academic investigator has conducted a clinical trial to evaluate the effects of administering diagnostic microbubbles (not our SonoLysis bubbles) on the speed and degree of cerebral artery recanalization in combination with a thrombolytic and ultrasound. That clinical trial involved 111 patients with acute ischemic stroke who presented within three hours after onset of symptoms. Of the patients in the clinical trial, 38 patients were treated with ultrasound and microbubbles administered at two, 20 and 40 minutes after administration of tPA. The results of the clinical trial indicated that the rate of complete recanalization after two hours in the patients who received tPA, ultrasound and microbubbles was significantly higher, at 54.5%, than the 40.8% rate in patients who received tPA and ultrasound only, or the 23.9% rate in patients who received tPA alone. These differences were statistically significant, with a p-value of 0.038.

In addition, we are currently conducting a Phase 2 proof of concept clinical trial to assess the safety and activity of a combination therapy for the treatment of ischemic stroke. This proof of concept clinical trial combines Definity microbubbles, ultrasound and tPA. When combined with data from other investigators, we believe this clinical trial will provide proof of concept data to support initiation of a Phase 1/2 clinical trial using SonoLysis bubbles and ultrasound in combination with tPA that we plan to initiate in the second half of 2006.

Competitive Advantages

We believe that the synergistic combination of the mechanical action of SonoLysis therapy, together with the enzymatic activity of thrombolytics such as PROLYSE will both reduce the time required to dissolve a blood clot and restore blood flow more quickly as well as enable a lower dose of thrombolytic to be used than would be needed for administration of a thrombolytic alone. In addition, we believe a lower dose of thrombolytic will reduce the risk of bleeding and extend the treatment window beyond that of thrombolytic therapy alone for ischemic stroke patients. We believe that our combination therapy may have an improved safety profile that may support a window for treatment of ischemic stroke patients beyond even the six hours for which PROLYSE alone was shown to be generally well tolerated in the PROACT II clinical trial. In addition, because of the pro-drug characteristics of PROLYSE, and our intended intravenous administration of our SonoLysis bubbles, we believe our combination therapy may be suitable for intravenous administration of both elements. As with our stand-alone SonoLysis therapy, we believe our combination therapy could potentially make treatment available to many ischemic stroke patients for whom thrombolytic therapy would not otherwise be available.

Table of Contents

Planned Clinical Development

We plan to initiate a Phase 1/2 dose-escalation clinical trial that will employ our proprietary SonoLysis bubbles, ultrasound and tPA in the second half of 2006. If we initiate such a clinical trial, we intend to discontinue further enrollment in our ongoing Phase 2 clinical trial using Definity microbubbles and redirect our efforts on a new Phase 1/2 clinical trial that utilizes our proprietary SonoLysis bubbles. Following this Phase 1/2 clinical trial, we would plan to conduct additional clinical trials using our proprietary SonoLysis bubbles, ultrasound and PROLYSE.

Our Product for Treatment of Massive Pulmonary Embolism

Abbokinase

Abbokinase is the tissue culture form of urokinase that is currently approved by the FDA for treating acute massive pulmonary embolism. Abbokinase has been used in more than four million patients in a variety of peripheral vascular disorders, which has established its reputation as a safe and effective thrombolytic therapy. Abbokinase is currently on formulary and approved for dispensing at approximately 400 U.S. hospital pharmacies.

Prior to 1998, Abbokinase was approved by the FDA for catheter occlusion clearance, acute massive pulmonary embolism and acute myocardial infarction. The product was withdrawn from the market in 1998 due to concerns over the manufacturing process, including failure to screen donors and test materials for infectious disease, and inadequate storage and handling of materials to prevent contamination with infectious agents. After revising its manufacturing processes to the FDA s satisfaction, in 2002 Abbott Laboratories obtained FDA approval to resume commercial sales of Abbokinase for use in treating acute massive pulmonary embolism, but then halted its sales and marketing effort in 2004 when it decided to divest its thrombolytic assets. Based upon generally recognized industry sales measures, known as IMS data, sales of Abbokinase to end user customers since the product s relaunch were approximately $4 million, $27 million, $33 million and $19 million in 2002, 2003, 2004 and 2005, respectively. IMS reports show Abbokinase sales of approximately $1 million per month for each of the nine months ending March 2006. In our acquisition of Abbokinase in April 2006, we purchased substantially the entire inventory of Abbokinase in existence (except for that previously sold to and held by wholesalers and end user customers), and we will be the only company selling the product into the distribution network when we initiate our commercial efforts in the second half of 2006.

Commercialization

We acquired Abbokinase and related assets from Abbott Laboratories, 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. There are no patent rights associated with Abbokinase, and our right to use the Abbokinase trademark does not extend to additional product that we could manufacture in the future. We believe the Abbokinase inventory of 153,000 vials we acquired represents approximately a four-year supply estimated based on annualized IMS data, although the expiration dates for the inventory based on available stability data range from July 2007 to August 2009. Based on current stability data, approximately 75% of these vials will expire by September 2007 and the remainder will expire by August 2009. We do not expect that we will be able to sell all of this inventory prior to the relevant expiration dates. However, we intend to continue the current stability program to seek to extend the expiration dates of this inventory. If the expiration dates of this inventory are extended, we will need to re-brand the remaining inventory because our license to use the Abbokinase trademark does not extend beyond the current inventory expiration dates. We intend to begin selling Abbokinase in the second half of 2006. We believe that Abbokinase sales will provide us with a source of near-term revenue, an opportunity to form sales relationships with vascular physicians and acute care institutions that regularly administer blood clot therapies and a commercialization infrastructure for our future products.

Table of Contents

To sell Abbokinase for the treatment of acute massive pulmonary embolism, we are required to continue an ongoing 200-patient immunogenicity clinical trial that commenced in 2003. The purpose of this trial is to evaluate the rate and severity of immune response in patients who are treated with Abbokinase. Since the original approval of Abbokinase, the FDA has changed its requirements for approval of biologic agents and now requires the sponsor to demonstrate in clinical trials that the biologic product does not induce an immune, or allergic, response in the patients treated. This is now one of the routine safety evaluations for all biologic agents. Abbokinase is a biologic agent and, although its original approval pre-dated this requirement, the FDA required this study to be done as a condition of re-approval. We can market and sell the product while this trial progresses. As of May 15, 2006, approximately 65 of a targeted 200 patients had been enrolled in the clinical trial.

Our Product Candidate for Treatment of Catheter Occlusions

Open-Cath-R

In 2005, we acquired the rights to a recombinant form of urokinase known as Open-Cath-R, which Abbott Laboratories tested as a therapy for dissolving central venous catheter occlusions.

Prior Clinical Trials

Between 1990 and 2002, Abbott Laboratories evaluated Open-Cath-R in 11 clinical trials involving 1,941 patients. These trials evaluated Open-Cath-R for treatment of acute myocardial infarction, peripheral arterial occlusion, deep vein thrombosis and catheter occlusions. Five of these clinical trials primarily evaluated the ability of Open-Cath-R to clear blood clots from central venous catheters, which is our intended use of Open-Cath-R, including two Phase 3 clinical trials for catheter clearance.

The first of these Phase 3 clinical trials was a randomized, double-blind, placebo-controlled clinical trial involving 180 patients, 119 of whom were treated with Open-Cath-R and 61 of whom were treated with placebo. The primary endpoint in this clinical trial was for the restoration of function to central venous catheters. Of the 119 patients treated with Open-Cath-R, one patient was excluded from the statistical analysis due to inclusion criteria. This clinical trial demonstrated that 54% of the catheters in the 118 evaluated patients treated with one or two doses of Open-Cath-R were cleared within 60 minutes of Open-Cath-R administration compared to only 30% in the control group. This difference was considered statistically significant, with a p-value of 0.002.

The primary safety endpoint was the occurrence of hemorrhagic or non-hemorrhagic adverse events within 72 hours after instillations. No statistically significant differences were observed between the randomized treatment groups in the rates of hemorrhagic or non-hemorrhagic adverse events. The overall incidence of hemorrhagic and non-hemorrhagic adverse events was 5% and 19.6% respectively for all patients receiving Open-Cath-R. The adverse events included vomiting, thrombosis, nosebleed, blood in urine and infection. Three subjects experienced major hemorrhagic events, none of which was considered related to study drug.

The second Phase 3, involving 878 patients, clinical trial was an open-label, single-arm, clinical trial to evaluate the safety of Open-Cath-R to restore patency to occluded central venous access devices. Safety was measured by adverse events within 72 hours after the first infusion of Open-Cath-R. A clinical efficacy measure was the percentage of patients whose catheters were cleared after a single dose of Open-Cath-R and after two doses of Open-Cath-R. In the clinical trial, 60% of the patients had catheter function restored after one dose, and 75% of the patients had catheter function restored after two doses. The adverse events included injection site bleeding, fever, abdominal pain, nosebleed and blood in urine.

Planned Clinical Development

We plan to meet with the FDA in mid-2006 to discuss the regulatory approval process for Open-Cath-R. The FDA has been notified of our acquisition of Open-Cath-R, and we intend to ask the FDA to be able to use the clinical trial data from the six Open-Cath-R catheter occlusion clearance clinical trials conducted by Abbott Laboratories. There can be no assurance, however, that the FDA will allow us to use this clinical trial

Table of Contents

data in support of an application to commercialize Open-Cath-R. To use the clinical trial data generated by Abbott Laboratories in support of our application for regulatory approval, we will be required to show that the material produced by our contract manufacturer is comparable to the material produced previously by Abbott Laboratories. In addition, we believe we will be required to conduct an immunogenicity clinical trial of approximately 200 catheter occlusion patients.

We are in the process of identifying a contract manufacturer capable of producing Open-Cath-R based on the proprietary manufacturing methods that we acquired. We may outlicense Open-Cath-R to a third party if we determine that a partnering relationship would be the most cost-effective way to commercialize Open-Cath-R.

Future Research and Development

We have identified and plan to explore a number of potential future product development opportunities that are based on our core thrombolytic program, such as:

- intravenous application of PROLYSE as a treatment for sub-massive pulmonary embolism;
- a catheter occlusion prophylaxis indication for Abbokinase or Open-Cath-R. Abbokinase has been shown in a Phase 3 clinical trial to be generally well tolerated and has demonstrated activity in preventing catheter occlusions when compared to heparin; and
- SonoLysis and thrombolytic combination therapy for myocardial infarction, peripheral arterial occlusion and deep vein thrombosis.

Combination Treatment of Vascular Disorders. We believe that the ability of our proprietary SonoLysis bubbles to penetrate and break up blood clots from within the clot and their flexibility in being administered with or without a thrombolytic or a catheter will make them suitable for use in treating a broad variety of vascular disorders beyond ischemic stroke. We also believe SonoLysis combination therapy could potentially enable the more rapid treatment of recently formed acute clots, such as those in myocardial infarction. We are conducting preclinical studies to treat myocardial infarction with SonoLysis PROLYSE combination therapy. In addition, we believe this combination therapy could be applied to treat more established sub-acute and chronic clots, such as those in peripheral vascular indications, that cannot be effectively treated with thrombolytic therapy alone. We have treated several patients in clinical proof of concept clinical trials using microbubbles with and without a thrombolytic to treat occluded dialysis grafts, peripheral artery occlusive disease and deep vein thrombosis. Our combination therapy clinical strategy is in an early stage of development.

Bubbles for Oxygen and Targeted Drug Delivery. We believe our proprietary bubble technology could be adapted, by changing the composition and size of the bubbles, for a variety of applications that involve delivery of gases such as oxygen or nitric oxide, drugs or genetic materials, either systemically or to selected sites in the body. We have conducted preclinical studies relating to the delivery of oxygen using a proprietary bubble formulation that we call $NanO_2$. We intend to further investigate the potential use of our $NanO_2$ bubbles as oxygen-delivery agents to help preserve tissues that are at risk due to blood clots in ischemic stroke, myocardial infarction and other ischemic indications. Separately, we are researching other classes of targeted bubbles to deliver drugs to specific cells, or that are targeted to vulnerable plaque. We have been awarded an aggregate of $3.6 million in grants to fund various applications of our bubble technology.

Manufacturing

We currently do not have, and do not intend to establish, our own manufacturing facilities. Instead, we plan to engage third parties to manufacture our products, which we believe will allow us to focus on our core research and product development programs. We also believe that the use of experienced manufacturers will provide facilities and processes qualified for current Good Manufacturing Practices, or cGMP, greater manufacturing specialization and expertise, higher levels of flexibility and responsiveness and faster delivery of products than we might achieve through in-house manufacturing. Specialized manufacturers are often used in the biopharmaceutical industry because they relieve product developers from the infrastructure required to

support applicable cGMP required by the FDA, and other rules and regulations required by foreign regulatory authorities.

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. However, we do not have control over and cannot ensure third-party manufacturers compliance with these regulations and standards. If one of our manufacturers fails to maintain compliance, the production of our products or product candidates could be interrupted, which could result in substantial delays, additional costs and lost sales.

We have contracted with a third party to produce small quantities of our SonoLysis bubbles for research purposes. We plan to enter into a services agreement with another third party to test and revalidate our inventory of clinical grade PROLYSE for use in anticipated clinical trials. We acquired the remaining inventory of Abbokinase in April 2006. No manufacturing facilities, equipment or personnel currently exist to produce additional inventory of Abbokinase. We may, however, investigate alternatives for third-party manufacturing of Abbokinase, including availability of a cell source that meets FDA safety requirements, at a later date. The manufacturing process for Abbokinase involves a roller bottle production method that is used infrequently today and is available from a very limited number of manufacturers worldwide.

Sales and Marketing

We intend to begin selling Abbokinase in the U.S. in the second half of 2006. We plan to develop an internal sales and marketing staff of initially not more than eight people to manage our relationships with third-party distribution partners and institutional Abbokinase customers, and to oversee our related direct and indirect advertising and promotional activities. We intend to limit our initial sales and marketing activities to servicing the existing demand for Abbokinase through existing sales channels, and we believe that our planned staffing will be sufficient to meet these needs.

For the marketing and sale of potential future products in the U.S, we intend to build on our Abbokinase commercialization experience to gradually expand our U.S. sales force and broaden our domestic sales and marketing efforts to the community of vascular physicians and acute care institutions that we believe will be most critical to acceptance and widespread adoption of our innovative therapies. Outside of the U.S., we intend to rely primarily on distribution partners. We may also enter into strategic relationships with pharmaceutical and other companies for the marketing and distribution of some of our products, and may rely on third parties for advertising and promotion of our products, particularly for markets outside the U.S. We intend to have our distribution partners manage any third-party logistics.

Competition

The market for therapies to treat vascular disorders associated with blood clots is highly competitive. Numerous companies either offer or are developing competing treatments for ischemic stroke, massive pulmonary embolism and catheter occlusion, the three indications we are currently targeting. Many of these competitors have significantly greater financial resources and expertise in development and regulatory matters than we do, as well as more established products, distribution and reimbursement. We expect that our competitors will also continue to develop new or improved treatments for the vascular disorders we are targeting.

To become accepted as treatments for ischemic stroke, massive pulmonary embolism or catheter occlusions, we believe competing therapies must offer a combination of efficacy, safety, rapid effect, ease of administration, approved window of administration and cost-effectiveness. While we believe that our product candidates will offer advantages over many of the currently available competing therapies, our business could be negatively impacted if our competitors present or future offerings are more effective, safer or less expensive than ours, or more readily accepted by regulators, health care providers or third-party payors.

Table of Contents

There are two principal groups of competitors offering treatments to break up or remove blood clots, thrombolytic companies and vendors of mechanical thrombectomy or similar devices.

Thrombolytic Competitors

The U.S. market for thrombolytics is dominated by Genentech, Inc., which manufactures tPA, the most widely used thrombolytic. We are not a significant competitor in the sale of thrombolytics, since we recently acquired our only approved product, Abbokinase, which is approved by the FDA for treatment of massive pulmonary embolism. Genentech s tPA in various formulations is currently the only thrombolytic that has been approved by the FDA for treatment of ischemic stroke and catheter occlusion clearance, and is also approved for myocardial infarction and pulmonary embolism indications. We are aware that other thrombolytics are also under development, such as alfimeprase and desmoteplase. Alfimeprase is a recombinant form of a derivative of copperhead snake venom being developed by Nuvelo, Inc. and is in clinical trials for use in catheter occlusion clearance and peripheral arterial occlusions, with clinical trials planned for ischemic stroke and deep vein thrombosis indications. Desmoteplase is a recombinant form of a derivative of vampire bat saliva being developed by PAION AG that is currently in a Phase 3 clinical trial for treatment of ischemic stroke. Other companies also offer or are developing thrombolytics for treatment of blood clots associated with myocardial infarction and peripheral vascular occlusions. We do not consider those product offerings or programs to be competitive with our current business strategy.

Device Competitors

We believe that the primary device-based treatment for ischemic stroke clots on the market is the MERCI (Mechanical Embolus Removal in Cerebral Ischemia) Retriever, 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. Mechanical thrombectomy devices are also approved and marketed for removing blood clots associated with peripheral vascular and coronary indications and dialysis access grafts, such as AngioJet by Possis Medical, Inc., Micro-Infusion Catheter by EKOS Corp., and Resolution Endovascular System by OmniSonics Medical Technologies, Inc. A variety of companies also offer catheter-delivery systems for thrombolytics or other drugs used in the treatment of blood clots. We do not consider these devices to be directly competitive with our current business strategy.

We do not know whether any other companies are developing bubble technologies for therapeutic use in vascular disorders.

Material Contracts

Following is a summary of our material contracts, other than contracts entered into in the ordinary course of business, to which we are a party:

September 2005 Agreements with Abbott Laboratories (Open-Cath-R and PROLYSE)

On September 30, 2005, we entered into an asset purchase agreement pursuant to which we acquired certain assets and rights used in the manufacture of Open-Cath-R and PROLYSE from Abbott Laboratories. The consideration for these assets included one million shares of our Series E preferred stock, valued at an aggregate of $4.0 million and including conversion, voting, antidilution and redemption rights, $5.0 million in cash, a $15.0 million promissory note that bears a 6% interest rate and matures on December 31, 2006 and is secured by the acquired assets, and our assumption of a 0.33% royalty obligation on net sales of Open-Cath-R and PROLYSE in Canada. The Series E preferred stock will automatically convert into common stock upon the closing of this offering and all special voting, antidilution and redemption rights will cease upon such conversion. We will be required to indemnify Abbott Laboratories, within limits, for any loss that arises out of our breach of the purchase agreement, liabilities that we expressly assumed under the purchase agreement or the manufacture, sale or use of any products we acquired from Abbott Laboratories.

In connection with the asset purchase agreement, we also entered into a services agreement to provide for transfer to us of the Open-Cath-R and PROLYSE manufacturing technologies that we acquired. Under this

agreement, Abbott Laboratories agreed to provide interim transitional services to assist us with the use of the acquired technologies through, at the latest, December 31, 2006. We are billed quarterly for Abbott Laboratories services based on scheduled hourly rates. We have not engaged and do not plan to engage these services. If the contractual services are engaged and completed on or prior to December 31, 2006, we will be obligated to make a final payment to Abbott Laboratories in an amount equal to the difference between $5.0 million and all amounts that we previously paid under the contract. However, since we do not plan to engage such services we do not anticipate having to make any payments in the future under this arrangement.

We have reviewed the documentation relating to manufacturing Open-Cath-R and PROLYSE that we acquired from Abbott Laboratories, including the master production batch records, operating procedures, product and raw material specifications and analytical method, equipment, and process justification and validation criteria. Based on our review of these records, we believe we are capable, with assistance from contract manufacturing organizations, contract research organizations and consultants, of transitioning the manufacturing technologies that we acquired without the assistance of Abbott Laboratories personnel. We believe that our decision not to engage Abbott Laboratories services pursuant to the services agreement will have no impact on our current development plans.

In connection with the asset purchase agreement, we also entered into a license agreement whereby Abbott Laboratories granted us an exclusive, transferable, royalty-free, worldwide license to its patents related to incorporating certain sequences of genetic material into cells. Under the license, we are entitled to make, distribute and sell thrombolytics that incorporate the licensed method. Abbott Laboratories retains all right, title and interest in and to the patents and may practice the patents in fields other than the development of thrombolytics. The license will terminate upon expiration of the last patent to which it relates on April 21, 2015. We may terminate the license agreement at any time, for any reason, upon written notice to Abbott Laboratories. Either party may terminate the agreement upon 30 days written notice for certain contractual breaches.

Abbott Laboratories rights in the licensed assets derive from a settlement agreement that it entered into on August 10, 1990 with Genentech, Inc. to settle a lawsuit relating to a patent dispute covering urokinase composition of matter and manufacturing technology. Pursuant to the terms of this settlement agreement, Genentech granted Abbott Laboratories a royalty-free license in limited territories, with a right to sublicense, to certain intellectual property and patents for the purposes of making, using and selling urokinase/pro-urokinase as a single entity product unaccompanied by any other plasminogen activator. In addition, Genentech granted to Abbott Laboratories a royalty-free, non-exclusive license, with no right to sublicense, to certain patented intellectual property to the extent that such license is employed for the manufacture of urokinase/pro-urokinase for use and sale. Finally, Genentech also granted Abbott Laboratories a royalty-free license to grant sublicenses under Genentech s patents to a single third party in each country in the designated territory (other than the U.S.) to sell urokinase/pro-urokinase in the event that Abbott Laboratories chose not to market in such country itself. This settlement agreement was assigned to us on September 30, 2005 in connection with our acquisition of the Open-Cath-R and PROLYSE assets from Abbott.

April 2006 Agreements with Abbott Laboratories (Abbokinase)

On April 10, 2006, we entered into an asset purchase agreement with Abbott Laboratories to acquire its entire remaining finished-product inventory of Abbokinase, for consideration consisting of $5.0 million in cash and a 6% non-recourse promissory note for $15.0 million that matures on December 31, 2007. The note is secured by the acquired inventories and related assets and an escrow of 50% of proceeds from our sales of such inventories in excess of $5.0 million, up to a maximum escrow of $15.0 million, and is subject to certain offsets in the event of a failure to transfer certain related distribution contracts to us.

As part of this arrangement we entered into a trademark license agreement with Abbott Laboratories in which it granted to us an exclusive, non-transferable license, without any sublicense rights, to use the Abbokinase trademark. We must adhere to certain quality control standards when marketing and selling the Abbokinase inventory under the trademark. This trademark license automatically terminates on the earlier to occur of the completion of our sale of the acquired Abbokinase inventory or the expiration date for all such Abbokinase inventory as of the date it was transferred to us. Abbott Laboratories is also entitled to terminate the license if we are in material breach of the agreement and fail to cure such breach within 15 days notice. Abbott

62

Table of Contents

Laboratories may also terminate the license if we commit a non-material breach of the agreement and fail to correct such breach within 30 days.

License Agreement with Bristol-Myers Squibb Medical Imaging, Inc.

We are party to an exclusive, worldwide, royalty-free license agreement with Bristol-Myers Squibb Medical Imaging, Inc. (as successor to DuPont Contrast Imaging, Inc.) dated October 7, 1999 for the use of intellectual property related to targeted and tissue-specific diagnostic ultrasound products, outside the field of contrast enhancement of diagnostic ultrasound imaging. Under the agreement, to the extent we develop any products or technology in the area of thrombus imaging or sonothrombolysis, which is the use of ultrasound to break up blood clots, we must first offer Bristol-Myers the right to negotiate an exclusive license for such product or technology for development and commercialization for a period of 90 days before offering it to any third party for license. This license is indefinite in duration and contains no express termination provisions. On September 1, 2005, Bristol-Myers executed a letter agreement confirming that it has no interest in our current SonoLysis bubbles, and that we have satisfied all of our obligations under the license agreement with respect to our SonoLysis bubbles, as they existed on that date. This acknowledgement encompasses our proprietary SonoLysis bubbles together with ultrasound, with or without a thrombolytic, currently under development.

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 microbubbles together with ultrasound for the treatment of thrombosis. To maintain this license we must meet certain product development milestones. We are obligated to pay UNEMED a royalty of 2% 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 in amounts from $3,000 to $7,000 annually for the life of the agreement. These fees are creditable against any royalty payments owed by us to UNEMED in the applicable calendar year. The license agreement will terminate contemporaneously with the expiration of the licensed patents, or on October 17, 2015. We may terminate the agreement, in our sole discretion, upon 90 days written notice for any reason. UNEMED may terminate the agreement for cause upon either 45 days or 90 days written notice, depending on the cause for termination, or at any time if we fail to meet certain milestones. Upon termination of the license, we would likely be required to change our SonoLysis therapy product development plans.

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 sublicense, to intellectual property and patents relating to methods of destroying cells by applying ultrasound to them in the presence of microbubbles. As consideration for this license, we reimbursed Dr. Schlief for certain past out-of-pocket costs, such as maintenance fees and patent transfer fees, and also granted Dr. Schlief a five-year warrant to purchase up to 20,000 shares of our common stock at an exercise price of $3.00 per share. 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, or on January 10, 2012. We may terminate the license, with or without cause, upon 60 days written notice and Dr. Schlief may terminate the agreement, with cause, 60 days after notice of the default is provided if the default has not been cured. Upon termination or expiration of the license, our plans for developing our SonoLysis bubbles would likely not change.

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

Table of Contents

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, subject to minimum annual royalties of $5,000 per year commencing February 10, 2007, increasing to $7,000 per year on February 10, 2009, and each year thereafter. The maximum aggregate royalty payable under this license is $20.0 million. 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 agreement will terminate contemporaneously with the expiration of the licensed patents, or on September 8, 2023. In addition, we may terminate this license at any time upon 90 days written notice to the University of Arkansas and the University may terminate the agreement for cause upon 90 days written notice. Upon termination or expiration of the license, our plans for developing our SonoLysis bubbles would likely not change.

Patents and Proprietary Rights

Our success depends in part on our ability to develop a competitive advantage over potential competitors for the use of bubbles 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 SonoLysis bubbles 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. As of May 15, 2006 we owned 49 issued U.S. patents, 39 U.S. pending patent applications, 37 foreign patents and 68 international or foreign patent applications. In addition, as of May 15, 2006 we have licensed patents from third parties that grant us exclusive rights to 47 U.S. patents, at least one U.S. patent application, and their respective international and foreign patent and patent application counterparts.

The U.S. patents that we own cover certain applications related to bubble compositions and methods of making and using such bubbles with ultrasound for the treatment of blood clots. Patents that cover our core technology expire between 2009 and 2021.

We have several pending patent claims, including allowed claims that have not yet issued, that cover additional elements of our bubble technology. For example, we have pending claims directed to the following aspects of bubble technology:

- methods of preparing gas filled bubbles;
- methods of using gas filled bubbles in combination with ultrasound for eliminating or reducing thrombi or for delivering drug compounds;
- methods of preparing gas filled bubbles that are targeted to specific cells in the body or that are activated at a specified temperature; and
- apparatus for preparing gas filled bubbles described above.

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 and are related to bubble 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.

We have been notified that, 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. In addition, in July 2003 we

Table of Contents

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

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

Government Regulation

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

Categories of Regulation

In the U.S., our product candidates may be subject to regulation as drugs, biologics, which are drugs derived from a living source, or medical devices. In some cases, our product candidates may fall into multiple categories and require regulatory approval in more than one category. For example, our thrombolytic product candidates are biologics, but they are subject to regulation as drugs. Our SonoLysis therapy and our SonoLysis combination therapy involve a combination of drug and device, which would require approval in each category before we could market either of these therapies. Our proprietary SonoLysis bubbles, which are injected into the bloodstream, may also be subject to regulation as drugs, although we plan to request the FDA to consider regulation of our SonoLysis therapy as a medical device rather than as a drug, since we believe its mechanism of action is principally mechanical in nature. Outside the U.S., our product candidates are also subject to regulation as drugs, biologics or medical devices, and must meet similar regulatory hurdles as in the U.S. to gain approval and reach the market.

Drug and Biologics Regulation

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

preclinical laboratory and animal tests;

submission and approval of an investigational new drug application, or IND;

adequate and well-controlled human clinical trials to establish the safety and efficacy of proposed drugs for their intended use and safety, purity and potency of biologic products for their intended use;

preapproval inspection of manufacturing facilities, company regulatory files and selected clinical investigators;

for drugs, FDA approval of a new drug application, or NDA, or FDA approval of an NDA supplement in the case of a new indication if the product is already approved for another indication; and

for biologics, FDA approval of a biologics license application, or BLA, or FDA approval of a BLA supplement in the case of a new indication if the product is already approved for another indication.

Prior to commencing the first human clinical trial, we must submit an IND to the FDA. The IND 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 sponsor and the FDA must resolve any outstanding concerns before the clinical trial may begin. A separate IND submission must be made for each successive clinical trial conducted during product development, and 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 investigation in human subjects within each medical center in which an investigator wishes to participate in the clinical trial must review and approve the preclinical drug testing and nonclinical safety evaluation and efficacy in animals or prior human clinical trials as well as the design and goals of the

proposed clinical trial before the clinical trial commences at that center. Regulatory authorities, an IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

For purposes of NDA or BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap. Moreover, the objectives of each phase may be split or combined, leading to Phase 1/2 and other similar trials that may be used to satisfy the requirements of otherwise separate clinical trials as follows:

Phase 1: Phase 1 clinical trials are conducted in a limited patient population to evaluate the product candidate for safety, dosage tolerance, absorption, metabolism, distribution and excretion in healthy humans or patients.

Phase 2: Phase 2 clinical trials are conducted in a limited patient population to further identify and measure possible adverse effects or other safety risks, to determine the efficacy of the product candidate for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning Phase 3 clinical trials.

Phase 3: When Phase 2 clinical trials demonstrate that a dosage range of the product candidate appears to be effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken in larger patient populations to further evaluate dosage, to confirm clinical efficacy and to evaluate safety in yet larger and more diverse patient populations at multiple clinical trial sites.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 clinical studies may be made a condition to be satisfied after a drug receives approval. The results of Phase 4 clinical studies may confirm the effectiveness of a product and may provide important safety information to augment the FDA s voluntary adverse drug reaction reporting system.

The results of product development, preclinical testing and clinical trials are submitted to the FDA as part of an NDA or BLA. The FDA may deny approval of an NDA or BLA if the applicable regulatory criteria are not satisfied or for any other reason, or it may require additional clinical data or an additional Phase 3 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 drug. The FDA also closely regulates the marketing and promotion of drugs. 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. generally involves the following:

product design, development and manufacture;

product safety, testing, labeling and storage;

preclinical testing in animals and in the laboratory;

clinical investigations in humans;

pre-marketing clearance or approval;

record keeping and document retention procedures;

advertising and promotion;

Table of Contents

product marketing, sales and distribution; and

post-marketing surveillance and medical device reporting, including reporting of deaths, serious injuries, device malfunctions or other adverse events.

Unless an exemption applies, each medical device distributed commercially in the U.S. will require 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. We believe all of our product candidates that are classified as devices will be deemed to be Class III devices subject to pre-market approval.

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

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

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

Table of Contents

Regulatory Enforcement

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

warning letters, fines, injunctions, consent decrees and civil penalties;

product recalls or market withdrawals;

customer notifications, repair, replacement, refunds, recall or seizure of our products;

operating restrictions, partial suspension or total shutdown of production;

refusal to grant new regulatory approvals;

withdrawing NDAs, BLAs, 510(k) clearance or PMA that have already been granted; and

criminal prosecution.

Employees

We had 42 full-time employees as of May 15, 2006. Fourteen of our employees are engaged in executive, administrative, business development and intellectual property functions, and 28 are engaged in research, development and clinical or regulatory activities. We anticipate that we will need to recruit additional personnel to manage our expanded research and development programs, manage our planned clinical trials and regulatory applications and commence sales and marketing functions, in accordance with our business strategy. We believe relations with our employees are generally good. None of our employees is covered by a collective bargaining agreement.

Facilities

Our current facilities are located in two leased buildings in Tucson, Arizona. One facility serves as office and storage space and laboratory facility, is approximately 3,500 square feet, and is subject to a one-year lease at approximately $28,886 per year that terminates December 31, 2006. We plan to extend this lease for at least another year. The other facility serves as our corporate headquarters and principal laboratory facility, is approximately 6,200 square feet, and is subject to a six-year lease at approximately $64,428 per year that terminates on October 31, 2008. This lease may be extended at our option for up to four additional six-year periods. Our headquarters facility is owned by a partnership whose beneficial owners include a director, several of our executive officers and stockholders, including our President and Chief Executive Officer, Dr. Evan Unger.

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.

Table of Contents

Management

Our executive officers and directors and their respective ages and positions as of May 15, 2006 are as follows:

Name	Age	Position
Evan C. Unger, M.D.	52	President, Chief Executive Officer and Director
Greg Cobb	36	Chief Financial Officer, Secretary and Treasurer
Terry Matsunaga, Ph.D.	53	Vice President, Research
Rajan Ramaswami, Ph.D.	53	Vice President, Product Development
Walter Singleton	64	Chief Medical Officer
Lynne E. Weissberger, Ph.D.	58	Vice President, Regulatory Affairs, Quality Assurance and Regulatory Compliance
Brad Zakes	40	Vice President, Business Development
Reena Zutshi, Ph.D.	38	Vice President, Program Management
Richard Otto(1)(3)	56	Chairman of the Board and Director
Richard Love(2)(3)	62	Director
Thomas W. Pew(2)(3)	67	Director
Philip Ranker(1)(3)	46	Director
James M. Strickland(1)(2)	63	Director

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and corporate governance committee.

Evan C. Unger, M.D. has served as our President and Chief Executive Officer and as a director since our inception in October 1999. Dr. Unger also served as the Chairman of our board from our inception until March 2004. Dr. Unger is a board-certified radiologist and a Fellow of the American College of Radiology. Since September 2004 he has been on a leave of absence from his position as Professor of Radiology and Bioengineering at the University of Arizona, Radiology Department to devote his efforts full time to our business. From January 1994 to January 1999, Dr. Unger served as Director of Cross-Sectional Imaging at the University of Arizona Health Sciences Center. Dr. Unger holds a B.A. in Economics from the University of California, Berkeley and an M.D. from the University of California, San Francisco.

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

Terry Matsunaga, Ph.D. has served as our Vice President, Research since March 2004. From October 1999 to March 2004, he served as our Senior Director, New Product Development. Dr. Matsunaga holds an AB from the University of California, Berkeley, and a Ph.D. in Pharmaceutical Chemistry and a Pharm.D. degree in Clinical Pharmacy from the University of California, San Francisco.

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

Walter Singleton has served as our Chief Medical Officer since May 2006. From August 2005 to April 2006, Dr. Singleton served as a consultant to us and other pharmaceutical and biotechnology companies through New Drug Development Services, a company that he founded in 1996 to advise companies in all areas of drug development and

medical affairs. From October 2004 to July 2005, Dr. Singleton served as Vice President, Regulatory Affairs for Inovio, Inc., a biotechnology company. From October 2000 to December 2003, Dr. Singleton was Senior Vice President of New Drug Development at Chugai Pharma U.S.A.

Table of Contents

(formerly Chugai Biopharmaceuticals, Inc.) a Japanese biotechnology company. Dr. Singleton holds a Masters Degree, B.M. and a B.Ch. degree (equivalent to M.D. in the U.S.) and a Masters Degree in Animal Physiology from Oxford University Medical School.

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

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

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

Richard E. Otto has served as a director since July 2004 and as Chairman of the Board of Directors since February 2006. Since February 2003 Mr. Otto has 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.

Richard L. Love has served as a director since March 2006. From January 2005 to January 2006 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, from January 2002 to January 2003 Mr. Love served as a director of Parexel International, a pharmaceutical services company, and ILEX Oncology, Inc., a biotechnology company evaluating cancer therapeutics, and from June 1993 to January 2002 Mr. Love served as Chief Executive Officer and a director of ILEX Oncology, Inc. Mr. Love also serves as a director for Parexel International, Systems Medicine Inc., Medical Consultant Services, Xilas Medical and Molecular Profiling Institute. Mr. Love holds B.S. and M.S. degrees in Chemical Engineering from the Virginia Polytechnic Institute.

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

Philip Ranker has served as a director since February 2006. Since August 2004, Mr. Ranker has 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. From July 1998 to December 2000, Mr. Ranker served as Assistant Controller of Scholastic Corporation. Mr. Ranker holds a B.A. in Accounting from the University of Kansas.

James M. 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 serves on the board of directors of MetaLink Corporation. 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).

Table of Contents

Board Composition

Our board of directors is currently composed of six members, including five non-employee members and our President and Chief Executive Officer, Evan C. Unger. Upon completion of this offering, our bylaws will be amended and restated to provide that the authorized number of directors may be changed only by resolution of the board of directors.

We believe that the composition of our board of directors meets the requirements for independence under the current requirements of The Nasdaq National Market. As required by The Nasdaq National Market, we anticipate that our independent directors will meet in regularly scheduled executive sessions at which only independent directors are present. We intend to comply with any governance requirements that are or become applicable to us.

Committees of the Board of Directors

Our board of directors has an audit committee, a compensation committee and a nominating and corporate governance committee, each of which has the composition and responsibilities described below.

Audit Committee

Our audit committee is comprised of Richard Otto, James Strickland and Philip Ranker, each of whom is a non-employee member of our board of directors. Mr. Otto is the chairperson of the audit committee. Our board of directors has determined that each of Messrs. Otto, Strickland and Ranker is an audit committee financial expert as defined under SEC rules and regulations. We believe that the composition of our audit committee meets the requirements for independence and financial sophistication under the current requirements of The Nasdaq National Market and SEC rules and regulations. In addition, our audit committee has the specific responsibilities and authority necessary to comply with the current requirements of The Nasdaq National Market and SEC rules and regulations. Our audit committee is responsible for, among other things, overseeing the independent auditors, reviewing the financial reporting, policies and processes, overseeing risk management, related party transactions and legal compliance and ethics and preparing the audit committee reports required by SEC rules.

Compensation Committee

Our compensation committee is comprised of James Strickland, Thomas Pew and Richard Love, each of whom is a non-employee member of our board of directors. James Strickland is the chairperson of the compensation committee. We believe that the composition of our compensation committee meets the requirements for independence under the current requirements of The Nasdaq National Market and SEC rules and regulations.

Our compensation committee is responsible for, among other things, reviewing and recommending compensation and annual performance objectives and goals for our Chief Executive Officer, reviewing and making recommendations to the board of directors regarding incentive-based or equity-based compensation plans, employment agreements, severance arrangements, change in control agreements and other benefits, compensations, compensation policies or arrangement for other executive officers and preparing the compensation committee reports required by SEC rules.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee is comprised of Richard Otto, Richard Love, Thomas Pew and Philip Ranker. Mr. Otto is the chairperson of the nominating and corporate governance committee. We believe that the composition of our nominating and corporate governance committee meets the requirements for independence under the current requirements of The Nasdaq National Market.

Our nominating and corporate governance committee is responsible for, among other things, identifying, evaluating and recommending individuals qualified to become directors, reviewing and making recommenda-

Table of Contents

tions to the board of directors regarding board of director and committee compensation, committee composition and reviewing compliance with corporate governance principles applicable to our company.

Compensation Committee Interlocks and Insider Participation

None of our executive officers currently serves, or served during 2005, on the compensation committee or board of directors of any other entity that has one or more executive officers serving as a member of our board of directors or compensation committee. Prior to establishing the compensation committee, our full board of directors made decisions relating to compensation of our executive officers. No member of our compensation committee has ever been an officer or employee of the company.

Director Compensation

The non-employee members of our board of directors receive the following compensation:

- $1,500 for each board and committee meeting attended in person;
- $250 for each board and committee meeting attended via teleconference;
- $1,500 annual retainer for each non-employee director that participates on a committee, plus an additional $1,000 for each non-employee director that participates on the audit committee, plus an additional $1,000 annual retainer for each non-employee director that is the chairman of a committee;
- one-time grant upon joining the board of directors of an option to purchase 55,000 shares of common stock with a four-year annual vesting schedule and 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.

Upon completion of this offering, and annually thereafter, each non-employee director will receive a $25,000 retainer in lieu of the $1,500 retainer described above, and the other compensation described above will remain unchanged. The following directors have each received the following option grants in connection with their services to us as directors:

Name	Number of Shares	Exercise Price	Grant Date	Termination Date
Richard Otto	55,000	$ 3.00	July 19, 2004	July 19, 2014
James M. Strickland	55,000	$ 3.00	August 2, 2004	August 2, 2014
Thomas W. Pew	55,000	$ 3.00	August 2, 2004	August 2, 2014
Richard Love	55,000	$ 5.00	May 6, 2006	May 6, 2016
Philip Ranker	55,000	$ 5.00	May 6, 2006	May 6, 2016

Each of these options vests in four equal annual installments measured from the grant date, although each may be exercised prior to vesting. To the extent exercised prior to vesting, we retain a right to repurchase at cost the unvested shares if the optionholder ceases to be a director of ours. As of May 15, 2006, none of these options has been exercised.

Table of Contents

Executive Compensation

The following table sets forth all compensation paid or accrued during the fiscal year ended December 31, 2005 to our Chief Executive Officer and to each of our four other most highly compensated executive officers whose salary and bonus exceeded $100,000 for the year ended December 31, 2005. We refer to these officers collectively as our named executive officers. The compensation described in this table does not include medical, group life insurance or other benefits which are available generally to all of our salaried employees.

Summary Compensation Table

	Annual Compensation		Long-Term Compensation	
Name and Principal Position	**Salary**	**Bonus**	**Securities Underlying Options**	**All Other Compensation**
Evan Unger, M.D. President and Chief Executive Officer	$ 229,617	$ 58,334	665,000	$
John Moore[1] Chairman and Executive Vice President	125,000	18,750		
Randall Miller, Ph.D.[2] Chief Operating Officer	132,809	12,000	195,000	22,212[3]
Greg Cobb[4] Chief Financial Officer, Secretary and Treasurer	100,963	24,000	195,000	10,434[3]
Terry Matsunaga, Ph.D Vice President, Research	120,770	19,750	32,000	

(1) Mr. Moore joined us in February 2004. Mr. Moore s employment with us terminated in February 2006, and he resigned as a director on March 31, 2006.

(2) Dr. Miller joined us in April 2005. Dr. Miller voluntarily terminated his employment with us in February 2006.

(3) Amount represents relocation expense reimbursement.

(4) Mr. Cobb provided consulting services to us from April 11, 2005 to April 26, 2005, and began full-time employment as our chief financial officer on April 27, 2005. The amounts reflected in the table include all compensation paid to Mr. Cobb in 2005.

Table of Contents

Stock Option Grants in 2005

The following table provides information concerning stock options granted to each of our named executive officers during the fiscal year ended December 31, 2005.

	Individual Grants				Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term	
Name	Number of Securities Underlying Options Granted(1)	% of Total Options Granted to Employees in 2005(2)	Exercise Price Per Share	Expiration Date	5%	10%
Evan Unger	30,303	2.0%	$ 3.30	08/08/10		
	149,697(3)	9.9%	3.00	08/08/15		
	100,000(4)	6.6%	3.00	08/08/15		
	100,000(4)	6.6%	3.00	08/08/15		
	100,000(5)	6.6%	3.00	08/08/15		
	120,000(6)	8.0%	3.00	08/08/15		
	65,000	4.3%	4.00	12/14/15		
John Moore						
Randall Miller	175,000(4)	11.6%	3.00	04/18/15		
	20,000(4)	1.3%&				