NORDSTROM JOHN N
Form 4
November 24, 2004

FORM 4

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

OMB APPROVAL

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Check this box if no longer subject to Section 16. Form 4 or Form 5 obligations may continue. *See* Instruction 1(b).

STATEMENT OF CHANGES IN BENEFICIAL OWNERSHIP OF SECURITIES

Filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, Section 17(a) of the Public Utility Holding Company Act of 1935 or Section 30(h) of the Investment Company Act of 1940

(Print or Type Responses)

1. Name and Address of Reporting Person *
NORDSTROM JOHN N

(Last) (First) (Middle)

C/O NORDSTROM, INC., 1617 SIXTH AVENUE

(Street)

SEATTLE, WA 98101

(City) (State) (Zip)

2. Issuer Name **and** Ticker or Trading Symbol
NORDSTROM INC [JWN]

3. Date of Earliest Transaction (Month/Day/Year)
11/23/2004

4. If Amendment, Date Original Filed(Month/Day/Year)

5. Relationship of Reporting Person(s) to Issuer

(Check all applicable)

__X__ Director _____ 10% Owner
_____ Officer (give title below) _____ Other (specify below)

6. Individual or Joint/Group Filing(Check Applicable Line)
_X_ Form filed by One Reporting Person
___ Form filed by More than One Reporting Person

Table I - Non-Derivative Securities Acquired, Disposed of, or Beneficially Owned

1.Title of Security (Instr. 3)	2. Transaction Date (Month/Day/Year)	2A. Deemed Execution Date, if any (Month/Day/Year)	3. Transaction Code (Instr. 8)		4. Securities Acquired (A) or Disposed of (D) (Instr. 3, 4 and 5)			5. Amount of Securities Beneficially Owned Following Reported Transaction(s) (Instr. 3 and 4)	6. Ownership Form: Direct (D) or Indirect (I) (Instr. 4)	7. Nature of Indirect Beneficial Ownership (Instr. 4)
			Code	V	Amount	(A) or (D)	Price			
Common Stock								796,216	D	
Common Stock								162,294	I	See (1)
Common Stock								2,006	I	See (2)
Common Stock								2,006	I	See (3)
Common Stock	11/23/2004		S		2,000	D	$ 45.04	2,141,205	I	See (4)

Common Stock	11/16/2004	S	3,000	D	$ 45.06	2,138,205	I	See (4)
Common Stock	11/23/2004	S	5,000	D	$ 45.09	2,133,205	I	See (4)
Common Stock	11/24/2004	S	5,000	D	$ 45.15	2,128,205	I	See (4)
Common Stock	11/23/2004	S	5,000	D	$ 45.3	2,123,205	I	See (4)
Common Stock	11/23/2004	S	14,000	D	$ 45.35	2,109,205	I	See (4)
Common Stock	11/23/2004	S	7,000	D	$ 45.39	2,102,205	I	See (4)
Common Stock	11/23/2004	S	2,000	D	$ 45.4	2,100,205	I	See (4)
Common Stock	11/23/2004	S	6,200	D	$ 45.42	2,094,005	I	See (4)
Common Stock	11/23/2004	S	8,000	D	$ 45.44	2,086,005	I	See (4)
Common Stock	11/24/2004	S	2,400	D	$ 45.45	2,083,605	I	See (4)
Common Stock	11/23/2004	S	300	D	$ 45.46	2,083,305	I	See (4)
Common Stock	11/23/2004	S	12,600	D	$ 45.47	2,070,705	I	See (4)
Common Stock	11/23/2004	S	9,400	D	$ 45.48	2,061,305	I	See (4)
Common Stock	11/23/2004	S	1,100	D	$ 45.49	2,060,205	I	See (4)

Reminder: Report on a separate line for each class of securities beneficially owned directly or indirectly.

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SEC 1474 (9-02)

Table II - Derivative Securities Acquired, Disposed of, or Beneficially Owned
(*e.g.*, puts, calls, warrants, options, convertible securities)

1. Title of Derivative Security (Instr. 3)	2. Conversion or Exercise Price of Derivative Security	3. Transaction Date (Month/Day/Year)	3A. Deemed Execution Date, if any (Month/Day/Year)	4. Transaction Code (Instr. 8)	5. Number of Derivative Securities Acquired (A) or	6. Date Exercisable and Expiration Date (Month/Day/Year)	7. Title and Amount of Underlying Securities (Instr. 3 and 4)	8. Price of Derivative Security (Instr. 5)	9. Nu Deriv Secur Bene Owne Follo Repo

			Disposed of (D) (Instr. 3, 4, and 5)						Trans (Instr
Code	V	(A)	(D)	Date Exercisable	Expiration Date	Title	Amount or Number of Shares		

Reporting Owners

Reporting Owner Name / Address	Relationships			
	Director	10% Owner	Officer	Other
NORDSTROM JOHN N C/O NORDSTROM, INC. 1617 SIXTH AVENUE SEATTLE, WA 98101	X			

Signatures

Duane E. Adams, Attorney-in-Fact for John N. Nordstrom	11/24/2004
**Signature of Reporting Person	Date

Explanation of Responses:

***** If the form is filed by more than one reporting person, *see* Instruction 4(b)(v).

****** Intentional misstatements or omissions of facts constitute Federal Criminal Violations. *See* 18 U.S.C. 1001 and 15 U.S.C. 78ff(a).

(1) By wife.

(2) By Mr. Nordstrom as trustee for the benefit of Beck Thomas Nordstrom.

(3) By Mr. Nordstrom as trustee for the benefit of Haley K. Nordstrom.

(4) By the John N. Nordstrom Interests L.P. ("JNN LP"), a limited partnership of which Mr. Nordstrom is a general partner. Mr. Nordstrom disclaims beneficial ownership of shares held by the JNN LP except to the extent of his pecuniary interest.

Note: File three copies of this Form, one of which must be manually signed. If space is insufficient, *see* Instruction 6 for procedure.
Potential persons who are to respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB number. ate 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

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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

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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;

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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;

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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.

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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

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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

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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

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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.

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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.

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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.

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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;

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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

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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.

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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;

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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

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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.

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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.

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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.

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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		