

MOMENTA PHARMACEUTICALS INC  
Form S-3  
August 18, 2009

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As filed with the Securities and Exchange Commission on August 18, 2009

Registration No. 333-

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM S-3**

REGISTRATION STATEMENT  
UNDER THE SECURITIES ACT OF 1933

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**MOMENTA PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction of Incorporation or Organization)

**04-3561634**  
(I.R.S. Employer Identification Number)

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**675 West Kendall Street  
Cambridge, MA 02142  
(617) 491-9700**

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

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**Bruce A. Leicher  
Senior Vice President, General Counsel and Secretary  
Momenta Pharmaceuticals, Inc.**

**675 West Kendall Street  
Cambridge, MA 02142  
(617) 491-9700**

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

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*Copy to:*

Steven D. Singer, Esq.  
Wilmer Cutler Pickering Hale and Dorr LLP  
60 State Street

# Edgar Filing: MOMENTA PHARMACEUTICALS INC - Form S-3

Boston, Massachusetts 02109  
Telephone: (617) 526-6000  
Telecopy: (617) 526-5000

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

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

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 of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

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

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.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

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## CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be Registered	Proposed Maximum Offering Price Per Unit(1)	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee
Common Stock, \$0.0001 par value per share	91,576	\$9.61	\$880,046	\$49.11

(1) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(c) under the Securities Act, based on average of high and low price per share of the common stock as reported on the Nasdaq Global Market on August 17, 2009.

**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 which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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The information in this prospectus is not complete and may be changed. The selling stockholder named in this prospectus 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 the selling stockholder named in this prospectus are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion, dated August 18, 2009

PROSPECTUS

**MOMENTA PHARMACEUTICALS, INC.**

**91,576 SHARES OF COMMON STOCK**

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This prospectus relates to the resale from time to time of up to 91,576 shares of common stock of Momenta Pharmaceuticals, Inc. by the selling stockholder identified in this prospectus.

We will not receive any proceeds from the sale of the shares.

The selling stockholder identified in this prospectus, or its pledgees, donees, transferees or other successors-in-interest, may offer the shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices.

Our common stock is traded on the Nasdaq Global Market under the symbol "MNTA." On August 17, 2009, the closing sale price of the common stock on Nasdaq was \$9.61 per share. You are urged to obtain current market quotations for the common stock.

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**Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 2.**

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**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.**

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The date of this prospectus is \_\_\_\_\_, \_\_\_\_\_.

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Unless otherwise stated, all references to "us," "our," "Momenta," "we," the "Company" and similar designations refer to Momenta Pharmaceuticals, Inc. Our logo, trademarks and service marks are the property of Momenta. Other trademarks or service marks appearing in this prospectus are the property of their respective holders.

We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus. The selling stockholder is offering to sell, and seeking offers to buy, shares of our 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 common stock.

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**PROSPECTUS SUMMARY**

*This summary highlights important features of this offering and the information included or incorporated by reference in this prospectus. This summary does not contain all of the information that you should consider before investing in our common stock. You should read the entire prospectus carefully, especially the risks of investing in our common stock discussed under "Risk Factors."*

**Momenta Pharmaceuticals, Inc.**

Momenta is a biotechnology company with a product pipeline of both complex mixture generic and novel drugs. This pipeline is derived from our proprietary, innovative technology platform for the detailed structural analysis of complex mixtures. We use this platform to study the *structure* (thorough characterization of chemical components), *structure-process* (design and control of manufacturing process), and *structure-activity* (relating structure to biological and clinical activity) of complex mixture drugs. Our complex mixture generics and follow-on biologics effort is focused on building a thorough understanding of the *structure-process-activity* of complex mixture drugs to develop generic versions of marketed products. Our complex mixture novel drug research and development efforts leverage our analytical technology platform and *structure-process* knowledge to develop novel drugs by studying the *structure-activity* of complex mixtures.

We were incorporated in Delaware in May 2001 under the name Mimeon, Inc. In September 2002, we changed our name to Momenta Pharmaceuticals, Inc. Our principal executive offices are located at 675 West Kendall Street, Cambridge, MA 02142, and our telephone number is (617) 491-9700. Our website address is [www.momentapharma.com](http://www.momentapharma.com). The information on our website is not incorporated by reference into this prospectus and should not be considered to be a part of this prospectus. We have included our website address as an inactive technical reference only.

**THE OFFERING**

Common stock offered by selling stockholder	91,576 shares
Use of proceeds	We will not receive any proceeds from the sale of shares in this offering
Nasdaq Global Market symbol	MNTA

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**RISK FACTORS**

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below before purchasing our common stock. The risks and uncertainties described below are not the only ones facing our company. Additional risks and uncertainties may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could fall, and you may lose all or part of the money you paid to buy our common stock.*

**Risks Relating to our Business**

***We have a limited operating history and have incurred a cumulative loss since inception. If we do not generate significant revenues, we will not be profitable.***

We have incurred significant losses since our inception in May 2001. At June 30, 2009, our accumulated deficit was \$291.7 million. We have not generated revenues from the sale of any products to date. We expect that our annual operating losses will increase over the next several years as we expand our drug commercialization, development and discovery efforts. To become profitable, we must successfully develop and obtain regulatory approval for our existing drug candidates, and effectively manufacture, market and sell any drugs we successfully develop. Accordingly, we may never generate significant revenues and, even if we do generate significant revenues, we may never achieve profitability.

To become and remain profitable, we must succeed in developing and commercializing drugs with significant market potential. This will require us to be successful in a range of challenging activities: developing drugs; obtaining regulatory approval for them through either existing or new regulatory approval pathways; clearing allegedly infringing patent rights; and manufacturing, distributing, marketing and selling them. We may never succeed in these activities and may never generate revenues that are significant or large enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would cause the market price of our common stock to decrease and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

***If we fail to obtain approval for and commercialize our most advanced product candidate, M-Enoxaparin, we may have to curtail our product development programs and our business would be materially harmed.***

We have invested a significant portion of our time, financial resources and collaboration efforts in the development of our most advanced product candidate, M-Enoxaparin, a technology-enabled generic version of Lovenox. Our near-term ability to generate revenues and our future success, in large part, depend on the successful development and commercialization of M-Enoxaparin.

In November 2003, we entered into a collaboration and license agreement, or the 2003 Sandoz Collaboration, with Sandoz N.V. and Sandoz Inc. to jointly develop and commercialize M-Enoxaparin. Sandoz N.V. later assigned its rights in the 2003 Sandoz Collaboration to Sandoz AG. We refer to Sandoz AG and Sandoz Inc. together as Sandoz.

In accordance with our 2003 Sandoz Collaboration, Sandoz has submitted Abbreviated New Drug Applications, or ANDAs, to the U.S. Food and Drug Administration, or FDA, seeking approval to market M-Enoxaparin in the United States. In November 2007, Sandoz received a letter from the FDA stating that the syringe ANDA for M-Enoxaparin was not approvable because the ANDA did not adequately address the potential for immunogenicity of the drug product. In September 2008, Sandoz submitted an amendment to the M-Enoxaparin ANDA and the ANDA review process by FDA is ongoing. If any of the following occurs, we may never realize revenue from this product, we may have to

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curtail our other product development programs and, as a result, our business would be materially harmed:

if the response filed in September 2008 fails to answer the FDA's questions related to the potential for immunogenicity of the drug product;

if we fail to answer any subsequent questions from the FDA to its satisfaction as it proceeds with its review of the M-Enoxaparin ANDA;

if we are unable to satisfactorily demonstrate therapeutic equivalence of M-Enoxaparin to Lovenox;

if the FDA disagrees with our characterization approach or does not agree that M-Enoxaparin is equivalent to Lovenox;

if we otherwise fail to meet FDA requirements for the ANDA (including, but not limited to, manufacturing and bioequivalence requirements); or

if we fail to obtain FDA approval for, and successfully commercialize, M-Enoxaparin.

***If other generic versions of Lovenox are approved and successfully commercialized, our business would suffer.***

In March 2003, Amphastar Pharmaceuticals, Inc., or Amphastar, and Teva Pharmaceuticals USA, Inc., or Teva, each submitted ANDAs for generic versions of Lovenox with the FDA. In 2007, Hospira, Inc. filed ANDAs for generic versions of Lovenox with the FDA. In addition, other third parties, including, without limitation, Sanofi-Aventis, may seek approval to market generic versions of Lovenox in the United States. If a competitor obtains FDA approval or if Sanofi-Aventis decides to market its drug as a generic or license it to another company to be sold as a generic, both known as authorized generics, the financial returns to us from the marketing of M-Enoxaparin would be materially adversely affected. Under these circumstances, we may not gain any competitive advantage and the resulting market price for our M-Enoxaparin product may be lower, our commercial launch may be delayed or we may not be able to launch our product at all. Also, we may never achieve significant market share for M-Enoxaparin if one or more third parties markets generic versions of Lovenox.

The 2003 Sandoz Collaboration contains terms which specify the sharing of commercial returns of M-Enoxaparin between us and Sandoz. Under circumstances when one or more third parties successfully commercialize a generic version of Lovenox, significantly less favorable economic terms for us would be triggered. Consequently, if other generic versions of Lovenox are approved and commercialized, our revenues from M-Enoxaparin would be reduced and, as a result, our business, including our near-term financial results and our ability to fund future discovery and development programs, would suffer.

***Our patent litigation with Teva Pharmaceutical Industries Ltd., the manufacturer of Copaxone, may cause delays and additional expense in the commercialization of M356. If we are not successful in commercializing M356 or are significantly delayed in doing so, our business may be materially harmed.***

In July 2008, the FDA accepted for review the ANDA containing a paragraph IV certification for generic Copaxone submitted by Sandoz. Subsequently, in August 2008, Teva Pharmaceutical Industries Ltd. and related entities sued Sandoz, Novartis AG and us for patent infringement. This litigation could significantly delay, impair or prevent our ability to commercialize M356, our second major generic product candidate. Litigation involves many risks and uncertainties, and there is no assurance that Novartis AG, Sandoz or we will prevail in any lawsuit with Teva Pharmaceutical Industries. In addition, Teva Pharmaceutical Industries has significant resources and any litigation with Teva Pharmaceutical Industries could last a number of years, potentially delaying or prohibiting the commercialization of M356. If we are not successful in commercializing M356 or are significantly delayed in doing so, our business may be materially harmed.

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***If other generic versions of our product candidates are approved and successfully commercialized, our business would suffer.***

We expect that certain of our product candidates may face intense and increasing competition from other manufacturers of generic and/or branded products. As patents for branded products and related exclusivity periods expire, manufacturers of generic products may receive regulatory approval for generic equivalents and may be able to achieve significant market penetration. As this happens, or as branded manufacturers launch authorized generic versions of such products, market share, revenues and gross profit typically decline, in some cases, dramatically. If any of our generic product offerings, including M-Enoxaparin or M356, enter markets with a number of competitors, we may not achieve significant market share, revenues or gross profit. In addition, as other generic products are introduced to the markets in which we participate, the market share, revenues and gross profit of our generic products could decline.

***We utilize new technologies in the development of some of our products that have not been reviewed or accepted by regulatory authorities.***

The approvals of some of our products in current or future development, including M-Enoxaparin and M356, are based upon new technologies that may have not previously been accepted by the FDA or other regulatory authorities. The FDA's review and acceptance of our technologies may take time and resources, or require independent third-party analysis. Alternatively, our technologies may not be accepted by the FDA and other regulatory authorities. For some of our products, the regulatory approval path and requirements may not be clear, which could add significant delay and expense. Delays or failure to obtain regulatory approval of any of the products that we develop would adversely affect our business.

***If the raw materials, including unfractionated heparin, or UFH, used in our products become difficult to obtain, significantly increase in cost or become unavailable, we may be unable to produce our products and this would have a material adverse impact on our business.***

We and our collaborative partners and vendors obtain certain raw materials, including UFH, from suppliers who in turn source the materials from other countries, including China. In 2008, due to the occurrence of adverse events associated with the use of UFH, there were global recalls of UFH products, including in the United States. Based on investigation by the FDA into those adverse events, the FDA identified a heparin-like contaminant in the implicated UFH products and recommended that manufacturers and suppliers of UFH use additional tests to screen their UFH active pharmaceutical ingredient. The FDA has also placed restrictions on the import of some raw materials from China, and may in the future place additional restrictions and testing requirements on the use of raw materials, including UFH, in products intended for sale in the United States. As a result, the raw materials, including UFH, used in our products may become difficult to obtain, significantly increase in cost, or become unavailable to us. If any of these events occur, we and our collaborative partners may be unable to produce our products in sufficient quantities to meet the requirements for the commercial launch of the product or to meet future demand, which would have a material adverse impact on our business.

***If we or our collaborative partners and other third parties are unable to satisfy FDA quality standards, experience manufacturing difficulties or are unable to manufacture sufficient quantities of our product candidates, including M-Enoxaparin, M356 and M118, our development and commercialization efforts may be materially harmed.***

We have limited personnel with experience in, and we do not own facilities for, manufacturing any products. We depend upon our collaborative partners and other third parties to provide raw materials meeting FDA quality standards, manufacture the drug substance, produce the final drug product and provide certain analytical services with respect to our product candidates, including M-Enoxaparin. We,



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our collaborative partners or our third-party contractors may have difficulty meeting FDA manufacturing requirements, including, but not limited to, reproducibility, validation and scale-up, and continued compliance with current good manufacturing practices requirements. In addition, events such as the contamination of UFH may have an adverse impact on the supply of starting or raw materials for some of our product candidates, and we, our collaborative partners or our third-party contractors may have difficulty producing products in the quantities necessary to meet FDA requirements or meet anticipated market demand. If we, our collaborative partners or our third-party manufacturers or suppliers are unable to satisfy the FDA pre-approval manufacturing requirements for our product candidates, or are unable to produce our products in sufficient quantities to meet the requirements for the launch of the product or to meet future demand, our revenues and gross margins could be adversely affected.

***We will require substantial additional funds to execute our business plan and, if additional capital is not available, we may need to limit, scale back or cease our operations.***

As of June 30, 2009, we had cash, cash equivalents and marketable securities totaling \$72.1 million. For the six months ended June 30, 2009, we had a net loss of \$34.7 million and used cash in operating activities of \$34.6 million. We will continue to require substantial funds to conduct research and development, process development, manufacturing, preclinical testing and clinical trials of our drug candidates, as well as funds necessary to manufacture and market any products that are approved for commercial sale. Because successful development of our drug candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our products under development.

Our future capital requirements may vary depending on the following:

the advancement of our generic product candidates and other development programs, including the timing of regulatory approvals;

the timing of FDA approval of the products of our competitors;

the cost of litigation, including with Teva Pharmaceuticals Industries relating to Copaxone, that is not otherwise covered by our collaboration agreement, or potential patent litigation with others, as well as any damages, including possibly treble damages, that may be owed to third parties should we be unsuccessful in such litigation;

the time and costs involved in obtaining regulatory approvals;

the continued progress in our research and development programs, including completion of our preclinical studies and clinical trials;

the potential acquisition and in-licensing of other technologies, products or assets; and

the cost of manufacturing, marketing and sales activities, if any.

We may seek additional funding in the future and intend to do so through collaborative arrangements and public or private equity and debt financings. Any additional capital raised through the sale of equity may dilute your percentage ownership of our common stock. Capital raised through debt financing would require us to make periodic interest payments and may impose potentially restrictive covenants on the conduct of our business. Additional funds may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products which we would otherwise pursue on our own.



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***We will need to develop or acquire additional technologies as part of our efforts to analyze the chemical composition of complex mixture drugs.***

In order to adequately analyze other complex mixture drugs, such as glycoproteins, we will need to develop or acquire new technologies. Our inability to develop or acquire and apply these new technologies would impair our ability to develop improved, next-generation or follow-on versions of existing products. Our inability to develop or acquire additional technology for the characterization of complex mixtures could reduce the likelihood of our success developing additional products.

***Competition in the biotechnology and pharmaceutical industries is intense, and if we are unable to compete effectively, our financial results will suffer.***

The markets in which we intend to compete are undergoing, and are expected to continue to undergo, rapid and significant technological change. We expect competition to intensify as technological advances are made or new biotechnology products are introduced. New developments by competitors may render our current or future product candidates and/or technologies non-competitive, obsolete or not economical. Our competitors' products may be more efficacious or marketed and sold more effectively than any of our products.

Many of our competitors have:

significantly greater financial, technical and human resources than we have at every stage of the discovery, development, manufacturing and commercialization process;

more extensive experience in commercializing generic drugs, conducting preclinical studies, conducting clinical trials, obtaining regulatory approvals, challenging patents and manufacturing and marketing pharmaceutical products;

products that have been approved or are in late stages of development; and

collaborative arrangements in our target markets with leading companies and/or research institutions.

If we successfully develop and obtain approval for our drug candidates, we will face competition based on many different factors, including:

the safety and effectiveness of our products;

with regard to our generic product candidates, the differential availability of clinical data and experience between a brand manufacturer that conducts clinical trials and a generic manufacturer;

the timing and scope of regulatory approvals for these products;

the availability and cost of manufacturing, marketing, distribution and sales capabilities;

the effectiveness of our marketing, distribution and sales capabilities;

the price of our products;

the availability and amount of third-party reimbursement for our products; and

the strength of our patent position.

Our competitors may develop or commercialize products with significant advantages in regard to any of these factors. Our competitors may therefore be more successful in commercializing their products than we are, which could adversely affect our competitive position and business.

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***If we are unable to establish and maintain key customer distribution arrangements, sales of our products, and therefore revenues, would decline.***

Generic pharmaceutical products are sold through various channels, including retail, mail order, and to hospitals through group purchasing organizations, or GPOs. As enoxaparin is primarily a hospital-based product, we expect to derive a large percentage of our future revenue for M-Enoxaparin through contracts with GPOs. Currently, a relatively small number of GPOs control a substantial portion of generic pharmaceutical sales to hospital customers. In order to establish and maintain contracts with these GPOs, we believe that we, in collaboration with Sandoz, will need to maintain adequate drug supplies, remain price competitive, comply with FDA regulations and provide high-quality products. The GPOs with whom we hope to establish contracts may also have relationships with our competitors and may decide to contract for or otherwise prefer products other than ours, limiting access of M-Enoxaparin to certain hospital segments. Our sales could also be negatively affected by any rebates, discounts or fees that are required by our customers, including the GPOs, wholesalers, distributors, retail chains or mail order services, to gain and retain market acceptance for our products. We anticipate that M356 will be primarily distributed through retail channels and mail order services. If we are unable to establish and maintain distribution arrangements with all of these customers, future sales of our products, including M-Enoxaparin and M356, our revenues and our profits would suffer.

***Even if we receive approval to market our drug candidates, the market may not be receptive to our drug candidates upon their commercial introduction, which could prevent us from being profitable.***

Even if our drug candidates are successfully developed, our success and growth will also depend upon the acceptance of these drug candidates by physicians and third-party payors. Acceptance of our product development candidates will be a function of our products being clinically useful, being cost effective and demonstrating superior therapeutic effect with an acceptable side effect profile as compared to existing or future treatments. In addition, even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time.

Factors that we believe will materially affect market acceptance of our drug candidates under development include:

the timing of our receipt of any marketing approvals, the terms of any approval and the countries in which approvals are obtained;

the safety, efficacy and ease of administration of our products;

the competitive pricing of our products;

the success and extent of our physician education and marketing programs;

the clinical, medical affairs, sales, distribution and marketing efforts of competitors; and

the availability and amount of government and third-party payor reimbursement.

If our products do not achieve market acceptance, we will not be able to generate sufficient revenues from product sales to maintain or grow our business.

***If we are not able to retain our current management team or attract and retain qualified scientific, technical and business personnel, our business will suffer.***

We are dependent on the members of our management team for our business success. Our employment arrangements with our executive officers are terminable by either party on short notice or no notice. We do not carry life insurance on the lives of any of our personnel. The loss of any of our executive officers would result in a significant loss in the knowledge and experience that we, as an organization, possess and could cause significant delays, or outright failure, in the development and



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approval of our product candidates. In addition, there is intense competition from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions, for human resources, including management, in the technical fields in which we operate, and we may not be able to attract and retain qualified personnel necessary for the successful development and commercialization of our product candidates.

***There is a substantial risk of product liability claims in our business. If our existing product liability insurance is insufficient, a product liability claim against us that exceeds the amount of our insurance coverage could adversely affect our business.***

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and marketing of human therapeutic products. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in a recall of our products or a change in the indications for which they may be used. While we currently maintain product liability insurance coverage that we believe is adequate for our current operations, we cannot be sure that such coverage will be adequate to cover any incident or all incidents. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. These liabilities could prevent or interfere with our product development and commercialization efforts.

***As we evolve from a company primarily involved in drug discovery and development into one that is also involved in the commercialization of drug products, we may have difficulty managing our growth and expanding our operations successfully.***

As we advance our drug candidates through the development process, we will need to expand our development, regulatory, manufacturing, quality, distribution, sales and marketing capabilities or contract with other organizations to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various collaborative partners, suppliers and other organizations. Our ability to manage our operations and growth requires us to continue to improve our operational, financial and management controls, reporting systems and procedures. For example, several jurisdictions such as the District of Columbia and the Commonwealth of Massachusetts have imposed new licensing requirements for sales representatives and new reporting requirements that would require public reporting of consulting and research fees to health care professionals. Because the reporting requirements vary in each jurisdiction, compliance will be complex and expensive. The need to build new systems as part of our growth could place a strain on our administrative and operational infrastructure. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls.

***We may acquire or make investments in companies or technologies that could have an adverse effect on our business, results of operations and financial condition or cash flows.***

We may acquire or invest in companies, products and technologies. Such transactions involve a number of risks, including:

we may find that the acquired company or assets does not further our business strategy, or that we overpaid for the company or assets, or that economic conditions change, all of which may generate a future impairment charge;

difficulty integrating the operations and personnel of the acquired business, and difficulty retaining the key personnel of the acquired business;

difficulty incorporating the acquired technologies;

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difficulties or failures with the performance of the acquired technologies or drug products;

we may face product liability risks associated with the sale of the acquired company's products;

disruption or diversion of management's attention by transition or integration issues and the complexity of managing diverse locations;

difficulty maintaining uniform standards, internal controls, procedures and policies;

the acquisition may result in litigation from terminated employees or third parties; and

we may experience significant problems or liabilities associated with product quality, technology and legal contingencies.

These factors could have a material adverse effect on our business, results of operations and financial condition or cash flows, particularly in the case of a larger acquisition or multiple acquisitions in a short period of time. From time to time, we may enter into negotiations for acquisitions that are not ultimately consummated. Such negotiations could result in significant diversion of management time, as well as out-of-pocket costs.

The consideration paid in connection with an acquisition also affects our financial results. If we were to proceed with one or more significant acquisitions in which the consideration included cash, we could be required to use a substantial portion of our available cash to consummate any acquisition. To the extent we issue shares of stock or other rights to purchase stock, including options or other rights, existing stockholders may be diluted and earnings per share may decrease. In addition, acquisitions may result in the incurrence of debt, large one-time write-offs and restructuring charges. They may also result in goodwill and other intangible assets that are subject to impairment tests, which could result in future impairment charges.

### **Risks Relating to Development and Regulatory Approval**

*If we are not able to obtain regulatory approval for commercial sale of our generic product candidates, including M-Enoxaparin and M356, as therapeutic equivalents to their corresponding reference listed drugs, our future results of operations will be adversely affected.*

Our future results of operations depend to a significant degree on our ability to obtain regulatory approval for and commercialize generic versions of complex drugs, such as M-Enoxaparin and M356. We will be required to demonstrate to the satisfaction of the FDA, among other things, that our generic products:

contain the same active ingredients as the branded products upon which they are based,

are of the same dosage form, strength and route of administration as the branded products upon which they are based, and have the same labeling as the approved labeling for the branded products, with certain exceptions, and

meet compendial or other applicable standards for strength, quality, purity and identity, including potency.

In addition, approval of a generic product generally requires demonstrating that the generic drug is bioequivalent to the reference listed drug upon which it is based, meaning that there are no significant differences with respect to the rate and extent to which the active ingredients are absorbed and become available at the site of drug action. However, the FDA may or may not waive the requirements for certain bioequivalence data (including clinical data) for certain drug products, including injectable solutions that have been shown to contain the same active and inactive ingredients in the same concentration as the reference listed drug.





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Determination of therapeutic equivalence of our generic versions of complex drugs to the reference listed drugs will be based, in part, on our demonstration of the chemical equivalence of our versions to their respective reference listed drugs. The FDA may not agree that we have adequately characterized our products or that our products and their respective branded drugs are chemical equivalents. In that case, the FDA may require additional information, including preclinical or clinical test results, to determine therapeutic equivalence or to confirm that any inactive ingredients or impurities do not compromise the product's safety and efficacy. Provision of sufficient information for approval may be difficult, expensive and lengthy. We cannot predict whether any of our generic product candidates will receive FDA approval.

In the event that the FDA modifies its current standards for therapeutic equivalence with respect to generic versions of Lovenox, Copaxone or other complex drug products, does not establish standards for interchangeability for generic versions of complex drug products, or requires us to conduct clinical trials or complete other lengthy procedures, the commercialization of some of our development candidates could be delayed or prevented or become more expensive. Delays in any part of the process or our inability to obtain regulatory approval for our products could adversely affect our operating results by restricting or significantly delaying our introduction of new products.

***If the United States Congress does not take action to create an abbreviated regulatory pathway for follow-on biologics, or if the FDA is not able to establish specific guidelines regarding the scientific analyses required for characterizing follow-on versions of biologics and complex protein drugs, then the uncertainty about the potential value of our glycoprotein program will be increased.***

The regulatory climate in the United States for follow-on versions of biologics and complex protein products remains uncertain. Although there has been recent legislative activity, there is currently no established statutory or regulatory pathway for approval of follow-on versions of biologics and most protein drugs. The FDA has approved the majority of new protein products under the Public Health Service Act, or PHSA, through the use of Biologic License Applications, or BLAs. There is no provision in the PHSA for an abbreviated BLA approval pathway comparable to an ANDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, and the FDA has stated it does not believe it has the authority to rely on prior BLA approvals or on their underlying data to approve follow-on products. Moreover, even for proteins originally approved as NDAs under Section 505(b) of the FDCA, there is uncertainty as to what data the FDA may require to demonstrate the sameness required for approval of an ANDA. In addition, there has been opposition to the FDA's use of section 505(b)(2), which allows an applicant to rely on information from published scientific literature and/or a prior approval of a similar drug, to approve follow-on versions of protein and other complex drug products approved under section 505(b)(1) of the FDCA.

Although the FDA has previously stated its intention to draft guidance that is broadly applicable to follow-on protein products, the agency has not issued such guidance to date and may never do so. Protracted timelines and failure of the FDA to establish standards for approval of follow-on protein products or failure of the United States Congress to enact legislation establishing an abbreviated pathway for approval of follow-on biologics could reduce the value of, or render obsolete, our glycoprotein program. Moreover, even if the United States Congress enacts legislation establishing a pathway for approval of follow-on biologics, the nature of the pathway, the timing of the implementation, and the procedures enacted for utilizing the pathway could also reduce the value, or render non-competitive, our glycoprotein program.

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***If our preclinical studies and clinical trials for our development candidates, including M118 and M402, are not successful, we will not be able to obtain regulatory approval for commercial sale of our novel or improved drug candidates.***

To obtain regulatory approval for the commercial sale of our novel drug candidates, we are required to demonstrate through preclinical studies and clinical trials that our drug development candidates are safe and effective. Preclinical studies and clinical trials of new development candidates are lengthy and expensive and the historical failure rate for development candidates is high.

A failure of one or more of our preclinical studies or clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our novel product, including M118, our novel anticoagulant, M402, our novel drug candidate engineered to have potent anti-metastatic properties and low anticoagulant activity, or our other drug candidates, including:

regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;

our preclinical studies or clinical trials may produce negative or inconclusive results, and we may be required to conduct additional preclinical studies or clinical trials or we may abandon projects that we previously expected to be promising;

enrollment in our clinical trials may be slower than we anticipate, resulting in significant delays, and participants may drop out of our clinical trials at a higher rate than we anticipate;

we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;

regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;

the cost of our clinical trials may be greater than we anticipate; and

the effects of our drug candidates may not be the desired effects or may include undesirable side effects or our product candidates may have other unexpected characteristics.

The results from preclinical studies of a development candidate may not predict the results that will be obtained in human clinical trials. If we are required to conduct additional clinical trials or other testing of M118, M402 or our future product candidates, if we are unable to successfully complete our clinical trials or other tests, or if the results of these trials are not positive or are only modestly positive, we may be delayed in obtaining marketing approval for our drug candidates or we may not be able to obtain marketing approval at all. Our product development costs will also increase if we experience delays in testing or approvals. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products or potential products. If any of these events occur, our business will be materially harmed.

***Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products abroad.***

We intend in the future to market our products outside of the United States. In order to market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with the numerous and varying regulatory requirements of each jurisdiction. The approval procedure and requirements vary among countries, and can require, among other things, submitting or conducting additional testing in each jurisdiction. The time required to obtain approval abroad may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval, and we may not



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obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in any other foreign country or by the FDA. We and our collaborators may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market outside of the United States. The failure to obtain these approvals could materially adversely affect our business, financial condition and results of operations.

***Even if we obtain regulatory approvals, our marketed drugs will be subject to ongoing regulatory review. If we fail to comply with continuing United States and foreign regulations, we could lose our approvals to market drugs and our business would be seriously harmed.***

Even after approval, any drug products we develop will be subject to ongoing regulatory review, including the review of clinical results which are reported after our drug products are made commercially available. In addition, the manufacturer and manufacturing facilities we use to produce any of our drug candidates will be subject to periodic review and inspection by the FDA. We will be required to report any serious and unexpected adverse experiences and certain quality problems with our products and make other periodic reports to the FDA. The discovery of any new or previously unknown problems with the product, manufacturer or facility may result in restrictions on the drug or manufacturer or facility, including withdrawal of the drug from the market. Certain changes to an approved product, including in the way it is manufactured or promoted, often require prior FDA approval before the product as modified may be marketed. If we fail to comply with applicable continuing FDA regulatory requirements, we may be subject to warning letters, civil penalties, suspension or withdrawal of regulatory approvals, product recalls and seizures, injunctions, operating restrictions and/or criminal prosecutions and penalties.

Similarly, we will be subject to comprehensive compliance obligations under state and federal reimbursement, anti-kickback and government pricing regulations. If we make false price reports, fail to implement adequate compliance controls or our employees violate the laws and regulations governing relationships with health care providers, we could also be subject to substantial fines and penalties, criminal prosecution and debarment from participation in the Medicare, Medicaid or other government reimbursement programs.

***If third-party payors do not adequately reimburse customers for any of our approved products, they might not be purchased or used, and our revenues and profits will not develop or increase.***

Our revenues and profits will depend heavily upon the availability of adequate reimbursement for the use of our approved product candidates from governmental and other third-party payors, both in the United States and in foreign markets. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

a covered benefit under its health plan;

safe, effective and medically necessary;

appropriate for the specific patient;

cost-effective; and

neither experimental nor investigational.

Obtaining reimbursement approval for a product from each government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement. There is substantial uncertainty whether any particular payor will reimburse the use of any drug product incorporating new technology.

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Even when a payor determines that a product is eligible for reimbursement, the payor may impose coverage limitations that preclude payment for some uses that are approved by the FDA or comparable authority. Moreover, eligibility for coverage does not imply that any product will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or imperfections in Medicare, Medicaid or other data used to calculate these rates. Net prices for products may be reduced by mandatory discounts or rebates required by government health care programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

There have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect payments for our products. The Centers for Medicare and Medicaid Services, or CMS, frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and both CMS and other third-party payors may have sufficient market power to demand significant price reductions. Due in part to actions by third-party payors, the health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products.

Our inability to promptly obtain coverage and profitable reimbursement rates from government-funded and private payors for our products could have a material adverse effect on our operating results and our overall financial condition.

***If efforts by manufacturers of branded products to delay or limit the use of generics are successful, our sales of technology-enabled generic products may suffer.***

Many manufacturers of branded products have increasingly used legislative, regulatory and other means to delay competition from manufacturers of generic drugs. These efforts have included:

settling patent lawsuits with generic companies, resulting in such patents remaining an obstacle for generic approval by others;

settling paragraph IV patent litigation with generic companies to prevent the expiration of the 180-day generic marketing exclusivity period or to delay the triggering of such exclusivity period;

submitting Citizen Petitions to request the FDA Commissioner to take administrative action with respect to prospective and submitted generic drug applications;

seeking changes to the United States Pharmacopeia, an industry recognized compilation of drug standards;

pursuing new patents for existing products or processes which could extend patent protection for a number of years or otherwise delay the launch of generic drugs; and

attaching special patent extension amendments to unrelated federal legislation.

In February 2003, Sanofi-Aventis filed a Citizen Petition with the FDA requesting that the FDA withhold approval of any ANDA for a generic version of Lovenox until and unless the FDA determines that the manufacturing process used by the generic applicant is equivalent to the process used to make Lovenox, or until the generic applicant demonstrates through clinical trials that its product is equally safe and effective as Lovenox, and unless the generic product is shown to contain a specific molecular



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structure. Teva, Amphastar, and others have filed comments opposing the Sanofi-Aventis Citizen Petition, and Sanofi-Aventis has filed numerous supplements and reply comments in support of its Citizen Petition. The FDA has yet to rule on the Sanofi-Aventis Citizen Petition, and if the FDA ultimately grants the Sanofi-Aventis Citizen Petition, we and Sandoz may be unable to obtain approval of our ANDA for M-Enoxaparin, which would materially harm our business.

In September 2008, Teva Neuroscience, Inc. (on behalf of Teva Pharmaceutical Industries Ltd.) filed a Citizen Petition with the FDA requesting that the FDA neither approve nor accept for filing any ANDA for a generic version of Copaxone because the complexity of Copaxone makes it impossible to demonstrate that the active ingredient in the generic version is the same as Copaxone. The FDA dismissed the petition in March 2009 without ruling on the merits. The FDA's policy is to rule on Citizens Petitions within 180 days that seek to prevent approval of an ANDA if the petition was filed after the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA. If at the end of the 180 period, the ANDA is not ready for approval or rejection, then the FDA's policy is to dismiss the petition without acting on the petition. Teva Neuroscience, Inc. may seek to refile the petition, if it does, and if the FDA accepts the subsequent filing and ultimately grants the Citizen Petition, we and Sandoz may be unable to obtain approval of the ANDA for M356, which would materially harm our business.

Further, some manufacturers of branded products have engaged in state-by-state initiatives to enact legislation that restricts the substitution of some branded drugs with generic drugs. If these efforts to delay or block competition are successful, we may be unable to sell our generic products, which could have a material adverse effect on our sales and profitability.

***Federal legislation will increase the pressure to reduce prices of pharmaceutical products paid for by Medicare, which could adversely affect our revenues, if any.***

The MMA changed the way Medicare covers and reimburses for pharmaceutical products. The legislation introduced a new reimbursement methodology based on average sales prices for drugs that are used in hospital settings or under the direct supervision of a physician and, starting in 2006, expanded Medicare coverage for drug purchases by the elderly. In addition, the MMA requires the creation of formularies for self-administered drugs, and provides authority for limiting the number of drugs that will be covered in any therapeutic class and provides for plan sponsors to negotiate prices with manufacturers and suppliers of covered drugs. As a result of the MMA and the expansion of federal coverage of drug products, we expect continuing pressure to contain and reduce costs of pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for our products and could materially adversely affect our operating results and overall financial condition. While the MMA generally applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement policies, and any reduction in coverage or payment that results from the MMA may result in a similar reduction in coverage or payments from private payors.

Congress has from time to time considered other legislation, which if enacted, would permit more widespread re-importation of drugs from foreign countries into the United States and which may include re-importation from foreign countries where drugs are frequently sold at lower prices than in the United States; other proposed legislation would have removed restrictions on CMS' ability to negotiate discounts directly with prescription drug manufacturers provided through the Medicare program. Such legislation, or similar regulatory changes, could decrease the reimbursement we receive for any approved products which, in turn, could materially adversely affect our operating results and our overall financial condition.



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***Foreign governments tend to impose strict price or reimbursement controls, which may adversely affect our revenues, if any.***

In some foreign countries, particularly the countries of the European Union, the pricing and/or reimbursement of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

***If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.***

Our research and development involves, and may in the future involve, the use of hazardous materials and chemicals and certain radioactive materials and related equipment. For the years ended December 31, 2008, 2007 and 2006, we spent approximately \$65,000, \$64,000 and \$31,000, respectively, in order to comply with environmental and waste disposal regulations. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. Although we maintain workers' compensation insurance as prescribed by the Commonwealth of Massachusetts and, for claims not covered by workers' compensation insurance, employer's liability insurance, to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

#### **Risks Relating to Patents and Licenses**

***If we are not able to obtain and enforce patent protection for our discoveries, our ability to successfully commercialize our product candidates will be harmed and we may not be able to operate our business profitably.***

Our success depends, in part, on our ability to protect proprietary methods and technologies that we develop under the patent and other intellectual property laws of the United States and other countries, so that we can prevent others from using our inventions and proprietary information. However, we may not hold proprietary rights to some patents related to our current or future product candidates. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patent applications. As a result, we may be required to obtain licenses under third-party patents to market our proposed products. If licenses are not available to us on acceptable terms, or at all, we will not be able to market the affected products.

Our strategy depends on our ability to rapidly identify and seek patent protection for our discoveries. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. The issuance of a patent does not guarantee that it is

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valid or enforceable, so even if we obtain patents, they may not be valid or enforceable against third parties. In addition, the issuance of a patent does not guarantee that we have the right to practice the patented invention. Third parties may have blocking patents that could be used to prevent us from marketing our own patented product and practicing our own patented technology.

Our pending patent applications may not result in issued patents. The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards which the U.S. Patent and Trademark Office and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. The laws of some foreign countries do not protect proprietary information to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary information in these foreign countries. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims allowed in any patents issued to us or to others.

The allowance of broader claims may increase the incidence and cost of patent interference proceedings and/or opposition proceedings, and the risk of infringement litigation. On the other hand, the allowance of narrower claims may limit the value of our proprietary rights. Our issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products, or provide us with any competitive advantage. Moreover, once they have issued, our patents and any patent for which we have licensed or may license rights may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited, other companies will be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition.

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

***Third parties may allege that we are infringing their intellectual property rights, forcing us to expend substantial resources in resulting litigation, the outcome of which would be uncertain. Any unfavorable outcome of such litigation could have a material adverse effect on our business, financial position and results of operations.***

If any party asserts that we are infringing its intellectual property rights or that our creation or use of proprietary technology infringes upon its intellectual property rights, we might be forced to incur expenses to respond to and litigate the claims. Furthermore, we may be ordered to pay damages, potentially including treble damages, if we are found to have willfully infringed a party's patent rights. In addition, if we are unsuccessful in litigation, or pending the outcome of litigation, a court could issue a temporary injunction or a permanent injunction preventing us from marketing and selling the patented drug or other technology for the life of the patent that we have allegedly or been deemed to have infringed. Litigation concerning intellectual property and proprietary technologies is becoming more widespread and can be protracted and expensive, and can distract management and other key personnel from performing their duties for us.

Any legal action against us or our collaborators claiming damages and seeking to enjoin any activities, including commercial activities relating to the affected products, and processes could, in addition to subjecting us to potential liability for damages, require us or our collaborators to obtain a license in order to continue to manufacture or market the affected products and processes. Any license required under any patent may not be made available on commercially acceptable terms, if at all. In addition, some licenses may be non-exclusive, and therefore, our competitors may have access to the same technology licensed to us.

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If we fail to obtain a required license or are unable to design around a patent, we may be unable to effectively market some of our technology and products, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

***If we become involved in patent litigation or other proceedings to determine or enforce our intellectual property rights, we could incur substantial costs which could adversely affect our business.***

We may need to resort to litigation to enforce a patent issued to us or to determine the scope and validity of third-party patent or other proprietary rights in jurisdictions where we intend to market our products, including the United States, the European Union, and many other foreign jurisdictions. The cost to us of any litigation or other proceeding relating to determining the validity of intellectual property rights, even if resolved in our favor, could be substantial and could divert our management's efforts. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they may have substantially greater resources. Moreover, the failure to obtain a favorable outcome in any litigation in a jurisdiction where there is a claim of patent infringement could significantly delay the marketing of our products in that particular jurisdiction. The costs and uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

***We in-license a significant portion of our proprietary technologies and if we fail to comply with our obligations under any of the related agreements, we could lose license rights that are necessary to develop our product candidates.***

We are a party to and rely on a number of in-license agreements with third parties, such as those with the Massachusetts Institute of Technology, that give us rights to intellectual property that is necessary for our business. In addition, we expect to enter into additional licenses in the future. Our current in-license arrangements impose various diligence, development, royalty and other obligations on us. If we breach our obligations with regard to our exclusive in-licenses, they could be converted to non-exclusive licenses or the agreements could be terminated, which would result in our being unable to develop, manufacture and sell products that are covered by the licensed technology.

### **Risks Relating to Our Dependence on Third Parties**

***Our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration are important to our business. If Sandoz fails to adequately perform under either collaboration, or if we or Sandoz terminate all or a portion of either collaboration, the development and commercialization of some of our drug candidates, including injectable enoxaparin, would be delayed or terminated and our business would be adversely affected.***

#### *2003 Sandoz Collaboration*

Either we or Sandoz may terminate the 2003 Sandoz Collaboration for material uncured breaches or certain events of bankruptcy or insolvency by the other party. Sandoz may also terminate the 2003 Sandoz Collaboration if the injectable enoxaparin product or the market lacks commercial viability, if new laws or regulations are passed or court decisions rendered that substantially diminish our legal avenues for commercialization of M-Enoxaparin, or, in multiple cases, if certain costs exceed mutually agreed upon limits. If the 2003 Sandoz Collaboration is terminated other than due to our uncured breach or bankruptcy, we will be granted an exclusive license under certain intellectual property of Sandoz to develop and commercialize injectable enoxaparin in the United States. In that event, we would need to expand our internal capabilities or enter into another collaboration, which could cause significant delays that could prevent us from completing the development and commercialization of injectable enoxaparin. If Sandoz terminates the 2003 Sandoz Collaboration due to our uncured breach or bankruptcy, Sandoz would retain the exclusive right to develop and commercialize injectable enoxaparin in the United States. In that event, we would no longer have any influence over the development or commercialization strategy of injectable M-Enoxaparin in the United States. In

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addition, Sandoz would retain its rights of first negotiation with respect to certain of our other products in certain circumstances and its rights of first refusal outside of the United States and the European Union. Accordingly, if Sandoz terminates the 2003 Sandoz Collaboration, our introduction of M-Enoxaparin may be significantly delayed, we may decide to discontinue the M-Enoxaparin project, or our revenues may be reduced, any one of which could have a material adverse effect on our business.

*2006 Sandoz Collaboration*

Either we or Sandoz may terminate the collaboration and license agreement, or Definitive Agreement, we executed with Sandoz in June 2007, as amended in April 2008, for material uncured breaches or certain events of bankruptcy or insolvency by the other party. In addition, the following termination rights apply to some of the products, on a product-by-product basis: if clinical trials are required; if the parties agree, or the relevant regulatory authority states in writing, that our intellectual property does not contribute to product approval; if Sandoz decides to permanently cease development and commercialization of a product; by either party with respect to certain products if, following a change of control of the other party, the other party fails to perform its material obligations with respect to such product. For some of the products, for any termination of the Definitive Agreement other than a termination by Sandoz due to our uncured breach or bankruptcy, or a termination by us alone due to the need for clinical trials, we will be granted an exclusive license under certain intellectual property of Sandoz to develop and commercialize the particular product. In that event, we would need to expand our internal capabilities or enter into another collaboration, which could cause significant delays that could prevent us from completing the development and commercialization of such product. For some products, if Sandoz terminates the Definitive Agreement due to our uncured breach or bankruptcy, or if there is a termination by us alone due to the need for clinical trials, Sandoz would retain the exclusive right to develop and commercialize the applicable product. In that event, we would no longer have any influence over the development or commercialization strategy of such product. In addition, for other products, if Sandoz terminates due to our uncured breach or bankruptcy, Sandoz retains a right to license certain of our intellectual property without the obligation to make any additional payments for such licenses. For certain products, if the Definitive Agreement is terminated other than due to our uncured breach or bankruptcy, neither party will have a license to the other party's intellectual property. In that event, we would need to expand our internal capabilities or enter into another collaboration, which could cause significant delays that could prevent us from completing the development and commercialization of such product. Accordingly, if the Definitive Agreement is terminated, our introduction of certain products may be significantly delayed, or our revenues may be significantly reduced either of which could have a material adverse effect on our business.

***We may need or elect to enter into alliances or collaborations with other companies to supplement and enhance our own capabilities or fund our development efforts. If we are unsuccessful in forming or maintaining these alliances on favorable terms, or if any collaborative partner terminates or fails to perform its obligations, our business could be adversely affected.***

Because we have limited or no capabilities for manufacturing, sales, marketing and distribution, we may need to enter into alliances or collaborations with other companies that can assist with the development and commercialization of our drug candidates. In those situations, we would expect our alliance or collaborative partners to provide substantial capabilities in manufacturing, sales, marketing and distribution. We may not be successful in entering into any such alliances. Even if we do succeed in securing such alliances, we may not be able to maintain them.

Factors that may affect the success of our collaborations include the following:

disputes may arise in the future with respect to the ownership of rights to technology developed with collaborators;

our collaborators may pursue alternative technologies or develop alternative products, either on their own or in collaboration with others, that may be competitive with the products on which

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they are collaborating with us or which could affect our collaborators' commitment to our collaborations;

our collaborators may terminate their collaborations with us, which could make it difficult for us to attract new collaborators or adversely affect how we are perceived in the business and financial communities;

our collaborators may pursue higher-priority programs or change the focus of their development programs, which could affect the collaborators' commitment to us; and

our collaborators with marketing rights may choose to devote fewer resources to the marketing of our product candidates, if any are approved for marketing, than to products from their own development programs.

In addition to relying on a third party for its capabilities, we may depend on our alliances with other companies to provide substantial additional funding for development and potential commercialization of our drug candidates. We may not be able to obtain funding on favorable terms from these alliances, and if we are not successful in doing so, we may not have sufficient funds to develop particular drug candidates internally, or to bring drug candidates to market. Failure or delays in bringing our drug candidates to market will reduce their competitiveness and prevent us from generating sales revenues, which may substantially harm our business.

Furthermore, in an effort to continually update and enhance our proprietary technology platform, we enter into agreements with other companies to develop, license, acquire and/or collaborate on various technologies. If we are unable to enter into the desired agreements, if the agreements do not yield the intended results or if the agreements terminate, we may need to find alternative approaches to such technology needs. If any of these occur, the development and commercialization of one or more drug candidates could be delayed, curtailed or terminated, any of which may adversely affect our business.

***We and our collaborative partners depend on third parties for the manufacture of products. If we encounter difficulties in our supply or manufacturing arrangements, our business may be materially adversely affected.***

We have a limited number of personnel with experience in, and we do not own facilities for, manufacturing products. In addition, we do not have, and do not intend to develop, the ability to manufacture material for our clinical trials or at commercial scale. To develop our drug candidates, apply for regulatory approvals and commercialize any products, we or our collaborative partners need to contract for or otherwise arrange for the necessary manufacturing facilities and capabilities. If these contract manufacturers are unable to manufacture sufficient quantities of product, comply with regulatory requirements, or breach or terminate their manufacturing arrangements with us, the development and commercialization of the affected products or drug candidates could be delayed, which could have a material adverse effect on our business. In addition, any change in these manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

We have relied upon third parties to produce material for preclinical and clinical studies and may continue to do so in the future. We cannot be certain that we will be able to obtain and/or maintain long-term supply and supply arrangements of those materials on acceptable terms, if at all. If we are unable to arrange for third-party manufacturing, or to do so on commercially reasonable terms, we may not be able to complete development of our products or market them.

In addition, the FDA and other regulatory authorities require that our products be manufactured according to current good manufacturing procedures, or cGMP, regulations and that proper procedures are implemented to assure the quality of our sourcing of raw materials and the manufacture of our products. Any failure by us, our collaborative partners or our third-party manufacturers to comply with cGMP, and/or our failure to scale-up our manufacturing processes could lead to a delay in, or failure to

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obtain, regulatory approval. In addition, such failure could be the basis for action by the FDA to withdraw approvals for drug candidates previously granted to us and for other regulatory action. To the extent we rely on a third-party manufacturer, the risk of non-compliance with cGMPs may be greater and the ability to effect corrective actions for any such noncompliance may be compromised or delayed.

***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate product revenues.***

We do not have a sales organization and have no experience as a company in the sale, marketing or distribution of pharmaceutical products. There are risks involved with establishing our own sales and marketing capabilities, as well as entering into arrangements with third parties to perform these services. For example, developing a sales force is expensive and time consuming and could delay any product launch. In addition, to the extent that we enter into arrangements with third parties to perform sales, marketing or distribution services, we will have less control over sales of our products and our future revenues would depend heavily on the success of the efforts of these third parties.

### **General Company Related Risks**

***Our directors, executive officers and major stockholders have substantial influence or control over matters submitted to stockholders for approval that could delay or prevent a change in corporate control.***

Our directors, executive officers and principal stockholders, together with their affiliates and related persons, beneficially owned, in the aggregate, approximately 21.3% of our outstanding common stock as of June 30, 2009. As a result, these stockholders, if acting together, may have the ability to significantly influence matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these persons, acting together, may have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

delaying, deferring or preventing a change in control of our company;

entrenching our management and/or board of directors;

impeding a merger, consolidation, takeover or other business combination involving our company; or

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

***Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our certificate of incorporation and our by-laws may delay or prevent an acquisition of us or a change in our management. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

a classified board of directors;

a prohibition on actions by our stockholders by written consent; and

limitations on the removal of directors.

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Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Finally, these provisions establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings. These provisions would apply even if the offer may be considered beneficial by some stockholders.

***Our stock price may be volatile, and purchasers of our common stock could incur substantial losses.***

The stock market in general and the market prices for securities of biotechnology companies in particular have experienced extreme volatility that often has been unrelated or disproportionate to the operating performance of these companies. The trading price of our common stock has been, and is likely to continue to be, volatile. Furthermore, our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

failure to obtain FDA approval for the M-Enoxaparin or M356 ANDA;

other adverse FDA decisions relating to the M-Enoxaparin or M356 ANDA, including an FDA decision to require additional data, including requiring clinical trials as a condition to M-Enoxaparin or M356 ANDA approval;

FDA approval of other companies' ANDAs for generic versions of Lovenox or Copaxone;

litigation involving our company or our general industry or both;

a decision in favor of or against Teva in the current patent litigation matter, or a settlement related to that case;

failure of our other product applications to meet the requirements for regulatory review and/or approval;

results or delays in our or our competitors' clinical trials or regulatory filings;

failure to demonstrate therapeutic equivalence with respect to our technology-enabled generic product candidates;

demonstration of or failure to demonstrate the safety and efficacy for our novel development product candidates;

our inability to manufacture any products in conformance with cGMP or in commercial quantities;

failure of any of our product candidates, if approved, to achieve commercial success;

developments or disputes concerning our patents or other proprietary rights;

changes in estimates of our financial results or recommendations by securities analysts;



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termination of any of our strategic partnerships;

significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

investors' general perception of our company, our products, the economy and general market conditions; and

significant fluctuations in the price of securities generally or biotech company securities specifically.

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If any of these factors causes an adverse effect on our business, results of operations or financial condition, the price of our common stock could fall and investors may not be able to sell their common stock at or above their respective purchase prices.

*We could be subject to class action litigation due to stock price volatility, which, if it occurs, will distract our management and could result in substantial costs or large judgments against us.*

The stock market in general has recently experienced extreme price and volume fluctuations. In addition, the market prices of securities of companies in the biotechnology industry have been extremely volatile and have experienced fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. These fluctuations could adversely affect the market price of our common stock. In the past, securities class action litigation has often been brought against companies following periods of volatility in the market prices of their securities. We may be the target of similar litigation in the future. Securities litigation could result in substantial costs and divert our management's attention and resources, which could cause serious harm to our business, operating results and financial condition.

**SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION**

This prospectus includes and incorporates forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements, other than statements of historical facts, included or incorporated in this prospectus regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will 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 or incorporated in this prospectus, particularly under the heading "Risk Factors," that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. Any such forward-looking statements represent management's views as of the date of the document in which such forward-looking statement is contained. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

**USE OF PROCEEDS**

We will not receive any proceeds from the sale of shares by the selling stockholder.

The selling stockholder will pay any underwriting discounts and commissions and expenses incurred by the selling stockholder for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholder in disposing of the shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees, Nasdaq Global Market listing fees and fees and expenses of our counsel and our accountants.

Table of Contents**SELLING STOCKHOLDER**

We issued the shares of common stock covered by this prospectus in a private placement in connection with the completion of certain milestones related to our acquisition of certain assets of the selling stockholder. The following table sets forth, to our knowledge, certain information about the selling stockholder as of August 9, 2009.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission, or SEC, and includes voting or investment power with respect to shares. Unless otherwise indicated below, to our knowledge, the selling stockholder named in the table has sole voting and investment power with respect to its shares of common stock. The inclusion of any shares in this table does not constitute an admission of beneficial ownership for the selling stockholder named below.

Name of Selling Stockholder	Shares of Common Stock Beneficially Owned Prior to Offering(1)		Number of Shares of Common Stock Being Offered	Shares of Common Stock to be Beneficially Owned After Offering(1)	
	Number	Percentage		Number	Percentage
Parivid, LLC	91,576	*	91,576	0	

\*

Less than one percent.

(1)

We do not know when or in what amounts the selling stockholder may offer shares for sale. The selling stockholder might not sell any or all of the shares offered by this prospectus. Because the selling stockholder may offer all or some of the shares pursuant to this offering, and because there are currently no agreements, arrangements or understandings with respect to the sale of any of the shares, we cannot estimate the number of the shares that will be held by the selling stockholder after completion of the offering. However, for purposes of this table, we have assumed that, after completion of the offering, none of the shares covered by this prospectus will be held by the selling stockholder.

On April 20, 2007, we entered into an Asset Purchase Agreement (the "Purchase Agreement"), with the selling stockholder, Parivid, LLC ("Parivid"), a data integration and analysis services provider to us, and S. Raguram, pursuant to which we acquired certain of the assets and assumed certain of the liabilities of Parivid related to the acquired assets, for \$2,500,000 in cash paid at closing and up to \$11,000,000 in contingent milestone payments in a combination of cash and/or stock in the manner and on the terms and conditions set forth in the Purchase Agreement.

The contingent milestone payments are structured to include (i) potential payments of no more than \$2,000,000 in cash if certain milestones were achieved within two years from the date of the Purchase Agreement (the "Initial Milestones") and (ii) the issuance of up to \$9,000,000 of our common stock to Parivid if certain other milestones are achieved within fifteen years of the date of the Purchase Agreement. In addition, upon the completion and satisfaction of those milestones that trigger the issuance of shares of our Common Stock, we granted Parivid certain registration rights under the Securities Act of 1933, as amended, with respect to such shares. We also entered into an employment agreement with S. Raguram pursuant to the terms of the Purchase Agreement.

On August 4, 2009, we entered into an Amendment to the Purchase Agreement pursuant to which we agreed to extend the time period for completion of the Initial Milestones to June 30, 2009, confirmed that certain of the Initial Milestones were achieved as of June 30, 2009 and further agreed to pay Parivid \$500,000 cash and to issue 91,576 shares of our common stock upon the completion and satisfaction of the Initial Milestones. In addition, in the event the net proceeds from any sale of the shares issued in connection with the Initial Milestones during certain time periods are less than the sum of the shares times the last reported sale price per share of the common stock on the effective date of the Amendment, we agreed to make a cash payment to Parivid in an amount equal to such difference.

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**DESCRIPTION OF CAPITAL STOCK**

Under our certificate of incorporation, we are authorized to issue 100,000,000 shares of common stock, par value \$0.0001 per share, and 5,000,000 shares of preferred stock, par value \$0.01 per share, of which 100,000 shares are designated Series A Junior Participating Preferred Stock, \$0.01 par value per share, or Series A preferred stock, as set forth in the Certificate of Designations of Series A Junior Participating Preferred Stock filed with the Secretary of State of the State of Delaware on November 8, 2005. As of July 31, 2009, there were 39,895,637 shares of common stock issued and outstanding and no shares of preferred stock issued and outstanding.

The material terms and provisions of our common stock, our preferred stock, our preferred stock purchase rights and each other class of our securities that qualifies or limits our common stock, are described in our Registration Statement on Form 8-A, as amended, which is incorporated by reference in this prospectus. For the complete terms of our common stock, preferred stock and preferred stock purchase rights, please refer to our certificate of incorporation, by-laws and stockholder rights plan that we have filed with the SEC. The terms of these securities may also be affected by the General Corporation Law Statute of the State of Delaware.

**PLAN OF DISTRIBUTION**

The shares covered by this prospectus may be offered and sold from time to time by the selling stockholder. The term "selling stockholder" includes donees, pledgees, transferees or other successors-in-interest selling shares received after the date of this prospectus from the selling stockholder as a gift, pledge, partnership distribution or other non-sale related transfer. The selling stockholder will act independently of us in making decisions with respect to the timing, manner and size of each sale. Such sales may be made on one or more exchanges or in the over-the-counter market or otherwise, at prices and under terms then prevailing or at prices related to the then current market price or in negotiated transactions. The selling stockholder may sell its shares by one or more of, or a combination of, the following methods:

purchases by a broker-dealer as principal and resale by such broker-dealer for its own account pursuant to this prospectus;

ordinary brokerage transactions and transactions in which the broker solicits purchasers;

block trades in which the broker-dealer so engaged will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

an over-the-counter distribution in accordance with the rules of the Nasdaq Global Market;

in privately negotiated transactions; and

in options transactions.

In addition, any shares that qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to this prospectus.

To the extent required, this prospectus may be amended or supplemented from time to time to describe a specific plan of distribution. In connection with distributions of the shares or otherwise, the selling stockholder may enter into hedging transactions with broker-dealers or other financial institutions. In connection with such transactions, broker-dealers or other financial institutions may engage in short sales of the common stock in the course of hedging the positions they assume with the selling stockholder. The selling stockholder may also sell the common stock short and redeliver the shares to close out such short positions. The selling stockholder may also enter into option or other transactions with broker-dealers or other financial institutions which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or



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amended to reflect such transaction). The selling stockholder may also pledge shares to a broker-dealer or other financial institution, and, upon a default, such broker-dealer or other financial institution, may effect sales of the pledged shares pursuant to this prospectus (as supplemented or amended to reflect such transaction).

In effecting sales, broker-dealers or agents engaged by the selling stockholder may arrange for other broker-dealers to participate. Broker-dealers or agents may receive commissions, discounts or concessions from the selling stockholder in amounts to be negotiated immediately prior to the sale.

In offering the shares covered by this prospectus, the selling stockholder and any broker dealers who execute sales for the selling stockholder may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. Any profits realized by the selling stockholder and the compensation of any broker-dealer may be deemed to be underwriting discounts and commissions.

In order to comply with the securities laws of certain states, if applicable, the shares must be sold in such jurisdictions only through registered or licensed brokers or dealers. In addition, in certain states the shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

We have advised the selling stockholder that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholder and its affiliates. In addition, we will make copies of this prospectus available to the selling stockholder for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholder may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

At the time a particular offer of shares is made, if required, a prospectus supplement will be distributed that will set forth the number of shares being offered and the terms of the offering, including the name of any underwriter, dealer or agent, the purchase price paid by any underwriter, any discount, commission and other item constituting compensation, any discount, commission or concession allowed or reallocated or paid to any dealer, and the proposed selling price to the public.

We have agreed to indemnify the selling stockholder against certain liabilities, including certain liabilities under the Securities Act.

We have agreed with the selling stockholder to keep the Registration Statement of which this prospectus constitutes a part effective until the earlier of (i) such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with the Registration Statement or (ii) one year from the effective date of this Registration Statement.

## LEGAL MATTERS

The validity of the shares offered by this prospectus has been passed upon by WilmerHale.

## EXPERTS

The consolidated financial statements of Momenta Pharmaceuticals, Inc. appearing in Momenta Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2008, and the effectiveness of Momenta Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2008, have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their reports thereon, included therein, and incorporated herein by reference in reliance upon such reports given on the authority of such firm as experts in accounting and auditing.

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**WHERE YOU CAN FIND MORE INFORMATION**

We file reports, proxy statements and other documents with the SEC. You may read and copy any document we file at the SEC's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You should call 1-800-SEC-0330 for more information on the public reference room. Our SEC filings are also available to you on the SEC's Internet site at [www.sec.gov](http://www.sec.gov).

This prospectus is part of a registration statement that we filed with the SEC. The registration statement contains more information than this prospectus regarding us and our common stock, including certain exhibits and schedules. You can obtain a copy of the registration statement from the SEC at the address listed above or from the SEC's Internet site.

**INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE**

The SEC requires us to "incorporate" into this prospectus information that we file with the SEC in other documents. This means that we can disclose important information to you by referring to other documents that contain that information. The information incorporated by reference is considered to be part of this prospectus. Information contained in this prospectus and information that we file with the SEC in the future and incorporate by reference in this prospectus automatically updates and supersedes previously filed information. We incorporate by reference the documents listed below and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus and prior to the sale of all the shares covered by this prospectus.

- (1) Our Annual Report on Form 10-K for the year ended December 31, 2008, as filed with the SEC on March 13, 2009;
- (2) Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2009, as filed with the SEC on May 7, 2009;
- (3) Our Quarterly Report on Form 10 Q for the quarter ended June 30, 2009, as filed with the SEC on August 6, 2009;
- (4) Our Current Report on Form 8 K, as filed with the SEC on February 2, 2009;
- (5) Our Current Report on Form 8 K, as filed with the SEC on June 11, 2009;
- (6) Any other filings we make pursuant to the Exchange Act after the date of filing the initial registration statement and prior to effectiveness of the registration statement; and
- (7) The description of our common stock contained in our Registration Statement on Form 8-A filed, pursuant to Section 12(b) of the Exchange Act, on June 14, 2004, as amended on November 8, 2005 and August 7, 2009, including any subsequent amendments or reports filed for purposes of updating the description of capital stock.

A statement contained in a document incorporated by reference into this prospectus shall be deemed to be modified or superceded for purposes of this prospectus to the extent that a statement contained in this prospectus, any prospectus supplement or in any other subsequently filed document which is also incorporated in this prospectus modifies or replaces such statement. Any statements so modified or superceded shall not be deemed, except as so modified or superceded, to constitute a part of this prospectus.

You may request a copy of these documents, which will be provided to you at no cost, by writing or telephoning us using the following contact information:

Momenta Pharmaceuticals, Inc.  
675 West Kendall Street  
Cambridge, MA 02142  
Attention: Bruce A. Leicher, Secretary  
Telephone: 617-491-9700





Table of Contents**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution.**

The following table sets forth the various expenses to be incurred in connection with the sale and distribution of the securities being registered hereby, all of which will be borne by Momenta Pharmaceuticals, Inc. (except any underwriting discounts and commissions and expenses incurred by the selling stockholder for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholder in disposing of the shares). All amounts shown are estimates except the SEC registration fee.

SEC registration fee	\$ 50
Legal fees and expenses	\$ 15,000*
Accounting fees and expenses	\$ 10,000*
Miscellaneous expenses	\$ 5,000*
<b>Total expenses</b>	<b>\$ 30,050</b>

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\*

Estimated

**Item 15. Indemnification of Directors and Officers.**

Section 102 of the General Corporation Law of the State of Delaware permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our certificate of incorporation provides that no director of the registrant shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the General Corporation Law of the State of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the General Corporation Law of the State of Delaware provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Our certificate of incorporation provides that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding

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(other than an action by or in the right of the corporation) by reason of the fact that he or she is or was, or has agreed to become, a director or officer of the registrant, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the corporation's best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our certificate of incorporation provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the Indemnitee is or was, or has agreed to become, a director or officer of Momenta, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnitee under certain circumstances.

The indemnification provisions contained in our certificate of incorporation are not exclusive of any other rights to which a person may be entitled by law, agreement, vote of stockholders or disinterested directors or otherwise.

In addition, we maintain insurance on behalf of its directors and executive officers insuring them against certain liability asserted against them in their capacities as directors or officers or arising out of such status.

### **Item 16. Exhibits**

Exhibit Number	Description	Filed With This Form S-3	Incorporated by Reference		
			Form	Filing Date With SEC	Exhibit Number
3.1	Third Amended and Restated Certificate of Incorporation.		S-1	March 11, 2004	3.3
3.2	Certificate of Designations of Series A Junior Participating Preferred Stock, as filed with the Secretary of State of the State of Delaware on November 8, 2005.		8-K	November 8, 2005	3.1
3.3	Amended and Restated By-laws.		S-1	March 11, 2004	3.2
4.1	Investor Rights Agreement, dated as of July 25, 2006, by and between Novartis Pharma AG and the Registrant		10-Q	November 8, 2006	10.2

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Exhibit Number	Description	Filed With This Form S-3	Incorporated by Reference		Exhibit Number
			Form	Filing Date With SEC	
4.2	Asset Purchase Agreement dated as of April 20, 2007 by and among Parivid, LLC, S. Raguram and the Registrant		10-Q	May 10, 2007	10.3
4.3	Amendment No. 1 to the Asset Purchase Agreement between Parivid LLC, S. Raguram and the Registrant dated August 4, 2009		10-Q	August 6, 2009	10.2
5.1	Opinion of Wilmer Cutler Pickering Hale and Dorr LLP.	X			
23.1	Consent of Independent Registered Public Accounting Firm.	X			
23.2	Consent of Wilmer Cutler Pickering Hale and Dorr LLP (included in Exhibit 5.1).	X			
24.1	Power of Attorney (included on page II-5 of this registration statement).	X			

### **Item 17. Undertakings.**

*Item 512(a) of Regulation S-K.* The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933, as amended (the "Securities Act");

(ii) To reflect in the prospectus any facts or events arising after the effective date of this Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in this Registration Statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective Registration Statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in this Registration Statement or any material change to such information in this Registration Statement;

*provided, however,* that paragraphs (1)(i) and (1)(ii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the Registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are incorporated by reference in this Registration Statement.

(2) That, for the purposes of determining any liability under the Securities Act, each post-effective amendment shall be deemed to be a new registration statement relating to the securities offered

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therein, and the offering of such securities at the time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

*Item 512(b) of Regulation S-K.* The Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the Registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in this Registration Statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

*Item 512(h) of Regulation S-K.* Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the indemnification provisions described herein, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.





Table of Contents**EXHIBIT INDEX**

Exhibit Number	Description	Filed With This Form S-3	Incorporated by Reference		Exhibit Number
			Form	Filing Date With SEC	
3.1	Third Amended and Restated Certificate of Incorporation.		S-1	March 11, 2004	3.3
3.2	Certificate of Designations of Series A Junior Participating Preferred Stock, as filed with the Secretary of State of the State of Delaware on November 8, 2005.		8-K	November 8, 2005	3.1
3.3	Amended and Restated By-laws.		S-1	March 11, 2004	3.2
4.1	Investor Rights Agreement, dated as of July 25, 2006, by and between Novartis Pharma AG and the Registrant		10-Q	November 8, 2006	10.2
4.2	Asset Purchase Agreement dated as of April 20, 2007 by and among Parivid, LLC, S. Raguram and the Registrant		10-Q	May 10, 2007	10.3
4.3	Amendment No. 1 to the Asset Purchase Agreement between Parivid LLC, S. Raguram and the Registrant dated August 4, 2009		10-Q	August 6, 2009	10.2
5.1	Opinion of Wilmer Cutler Pickering Hale and Dorr LLP.	X			
23.1	Consent of Independent Registered Public Accounting Firm.	X			
23.2	Consent of Wilmer Cutler Pickering Hale and Dorr LLP (included in Exhibit 5.1).	X			
24.1	Power of Attorney (included on page II-5 of this registration statement).	X			

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